IMMULITE® 2000
IMMULITE® 2000 XPi
IMMULITE® 2500
Immunoassay Systems

IMMULITE 2000 Systems
IMMULITE 2500 System Immunoassay System

# Operator's Guide

601005-0004 Rev. A, 2010-10

CE

SIEMENS

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The information in this operator's guide was correct at the time of printing. However, Siemens continues to improve products and reserves the right to change specifications, equipment, and maintenance procedures at any time without notice.

If the system is used in a manner differently than specified by Siemens, the protection provided by the equipment may be impaired. Refer to caution, warning, and import statements.

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# Using This Guide

This system is intended for professional use in a laboratory environment only. Tests performed using this system are intended for *in vitro* diagnostic use. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

The guide provides information for the following clinical laboratory professionals who use the IMMULITE® 2000 systems and IMMULITE 2500 system:

- System operators who perform daily operating tasks such as preparing the system, processing samples, reviewing results, and performing maintenance.
- System key operators who perform daily and other tasks such as reviewing control data, managing data files, and modifying system parameters.

## Organization

The following table describes how this operator's guide is organized:

| If you want to... | Then refer to... |
|---|---|
| learn about system features such as no-pause sample reloading,<br>learn about user interface components, how to use online information, review the hardware and the operating sequence, | Section 1:<br>*System Features*<br>*Hardware Overview,*<br>*Software Overview,*<br>*Technology.* |
| process samples, monitor status, or manage sample results, | Section 2:<br>*Operating the System.* |
| review Master Curve and 2-point adjustor principles, process adjustors, | Section 3:<br>*Adjusting the System.* |
| learn about accessing QC, Scheduled QC defining quality control materials, | Section 4:<br>*Quality Control.* |
| perform scheduled maintenance activities,<br>record maintenance activities, | Section 5:<br>*Maintenance.* |
| investigate and correct system problems, | Section 6: *Troubleshooting.* |
| learn about saving results data files to an archive,<br>learn about backing up your system configuration files, | Section 7:<br>*Data Management.* |
| modify test definition parameters,<br>modify system parameters,<br>set up LIS and LAS parameters, | Section 8:<br>*System Configuration.* |
| review biohazard precautions,<br>review laser precautions, | Appendix A:<br>*Safety.* |

| If you want to... | Then refer to... |
|---|---|
| view warranty, legal, and support information, view contact information, | Appendix B: *Warranty and Support Information.* |
| view information about primary reagents, ancillary reagents, and system fluids, | Appendix C: *Reagents and System Fluids.* |
| view information about ordering supplies, | Appendix D: *Supplies.* |
| view system specifications, | Appendix E: *Specifications.* |
| view system symbols, | Appendix F: *Symbols.* |
| view the glossary, | Appendix G: *Glossary.* |
| view error messages and possible solutions, | Appendix H: *Error Messages.* |
| learn about hepatitis confirmatory testing, | Appendix I: *Hepatitis Confirmatory Testing.* |

## Conventions

The *IMMULITE 2000 systems and IMMULITE 2500 system Operator's Guide* uses the following text and symbol conventions:

| Convention | Description |
|---|---|
| IMMULITE 2000 systems and IMMULITE 2500 system | Refers to instructions for the IMMULITE 2000 system, IMMULITE 2500 system, and IMMULITE 2000 XPi system. |
| IMMULITE 2000 systems only | Refers to instructions for both the IMMULITE 2000 system and the IMMULITE 2000 XPi systems. |
| IMMULITE 2500 system only | Refers to instructions for the IMMULITE 2500 system. |
| IMMULITE 2000 XPi system only | Refers to instructions for the IMMULITE 2000 XPi system only. |
|  **BIOHAZARD** | Biohazard statements alert you to potentially biohazardous conditions. |
|  **LASER WARNING** | Laser Warning statements alert you to the risk of exposure to lasers. |
|  **WARNING** | Warning statements alert you to conditions that may cause personal injury. |

| Convention | Description |
|---|---|
|  **CAUTION** | Caution statements alert you to conditions that may cause product damage or loss of data.<br>On the system, this symbol indicates that you should refer to the operator's guide for more information. |
| **NOTE**: | Note statements alert you to important information that requires your attention. |
| **Bold** | Bold type indicates commands on the user interface, keys, or the exact text that an operator needs to type.<br>For example, if the word save displays as **Save**, it refers to the selecting the Save button on the user interface.<br>Another example is typing a specific entry into a text box. If the word welcome displays as **welcome**, it means that you should type that word into the specified field. |
| *Italic* | Italic type refers to the title of a document or a section title in this operator's guide. For example, *Operating the System,* in Section 2 refers to Section 2 of this operator's guide.<br>Italics are also used for latin words and phrases. |

# *Terminology*

The following table explains some of the special terminology used in this operator's guide and the specific actions that you need to take when you see the terminology:

| Term | Description |
|---|---|
| Select | To select an item, use your finger to touch the item on the touchscreen monitor or select the item with the system pointing device. |
| Enter | Type the specified information using the keyboard and then press the Enter key. |
| Scan | Move the handheld barcode scanner over the specified barcode to enter the information. |

# Contents



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## Appendix I: Hepatitis Confirmatory Test

# 1 System Overview

# System Overview

## IMMULITE 2000 Systems and IMMULITE 2500 System

The *IMMULITE® 2000 Systems and IMMULITE 2500 System Operator's Guide* describes the operation of the IMMULITE 2000 systems and IMMULITE 2500 system. This guide includes overviews of the systems, configuration instructions, and operating, maintenance, and troubleshooting procedures.

### Control Naming Conventions

To ensure control data is grouped appropriately for peer group reports and QC alerts, the following naming conventions are used.

For Bio-Rad controls, use the control name `BIOR`, followed by the first two digits of the lot number. The last three digits of the lot number are entered in the lot number field. For example, Bio-Rad lot 40130 becomes `BIOR40 lot 130`. The control level is 1, 2, or 3.

For Siemens Healthcare Diagnostics controls, use the control name and three-digit lot number (preceded by a zero as necessary). For example, LRBC lot 0110 becomes `LRBC lot 110`. The control level is 1, 2, or 3. Likewise, CON6 lot XX becomes `CON6 lot 0XX`. The control level is 4, 5, or 6.

For other controls, use the same ordering convention.

### Product Descriptions

The IMMULITE 2000 systems are continuous random-access instrument that perform chemiluminescent immunoassays.

The IMMULITE 2500 system performs chemiluminescent immunoassay testing using logic driven incubation to provide dynamic resource allocation that optimizes the use of the incubators, wash stations, and pipettors.

These instruments use serum, plasma, or urine samples for *in vitro* diagnostic testing and work seamlessly with RealTime Solutions℠ and a VersaCell® systems.

The instruments automate the entire testing procedure and accommodate high volume testing, generating up to 200 test results per hour.

Primary, secondary, and microsample tubes may be loaded directly on the instrument. The IMMULITE 2000 XPi also allows for loading tube top samples on to a conductive rack. An LIS (Laboratory Information System) interface is optional.

## Principles of Operation

The instrument uses assay-specific antibody or antigen-coated polystyrene beads as the solid phase.

A bead is dispensed into a specially designed reaction tube, which serves as the vessel for the incubation, wash, and signal development processes.

After the sample is incubated with an alkaline phosphatase-labeled reagent, the reaction mixture is separated from the bead by spinning the reaction tube at high speed along its vertical axis. The fluid is transferred to a coaxial sump chamber, which is integral to the bead/tube wash station. Four discrete washes occur within seconds, allowing the reaction tubes to be processed sequentially with uniform timing. The bead remains in the reaction tube with no residual unbound label.

The bound label is then quantified using the dioxetane substrate to produce light. Light is emitted when the chemiluminescent substrate reacts with the alkaline phosphatase label bound to the bead. The amount of light emitted is proportional to the amount of analyte originally present in the sample. This light emission is detected by the photomultiplier tube (PMT) and results are calculated for each sample.

## Output Specifications

The table below displays the output specifications for the IMMULITE 2000 systems and IMMULITE 2500. For a list of all system specifications, refer to *System Specifications*, page E-1.

| Output Specification | Quantity |
|---|---|
| Throughput | Up to 200 tests per hour |
| Time to first result | IMMULITE 2000 and XPi: 35 minutes<br>IMMULITE 2500: 15 minutes |
| Tests per sample | Unlimited |

# Hardware Overview

## Pipetting Sequence

Sample tubes are processed in the following order, based on priorities built into the software.

1. Adjustors
2. Controls
3. STAT samples
4. Labile, for example, intact PTH
5. Patients
6. Verifiers

## System Components

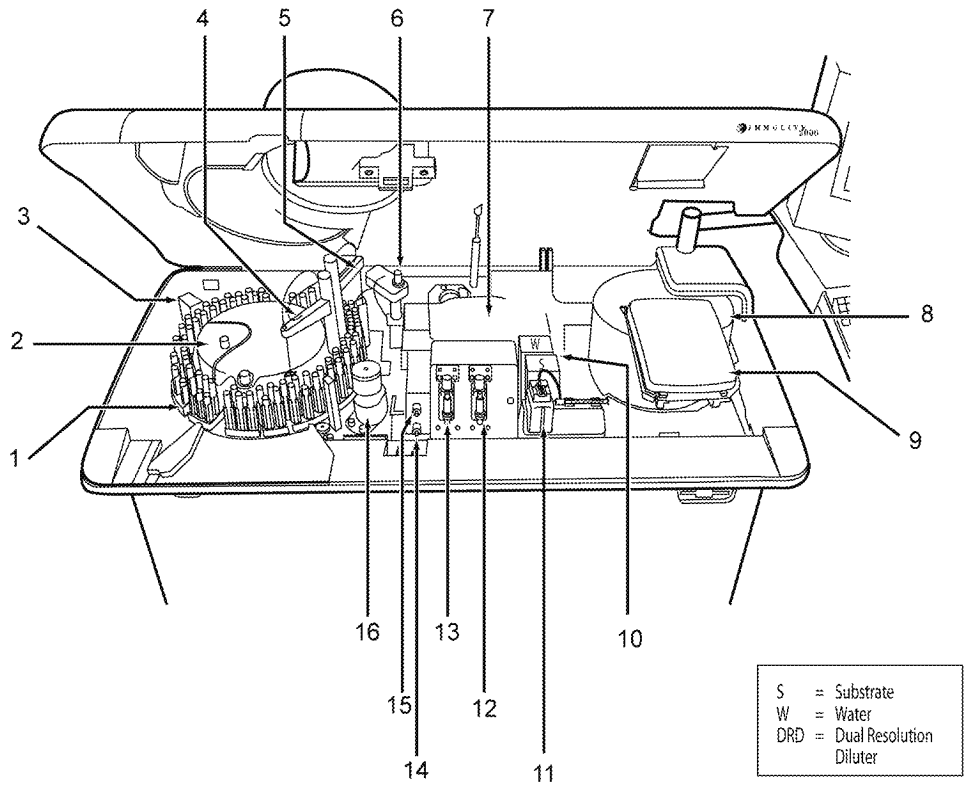
The system components are described in this table:

| Part | Description |
|---|---|
| Bead carousel | A rotating, dehumidified carousel that holds 24 bead packs.<br>The beads are dispensed individually from these test-specific packs. |
| Bead pack barcode reader | Reads barcodes on the bead packs in the bead carousel.<br>**NOTE:** The bead pack barcode reader is not visible in the figures. |
| Bead/tube wash station | Washes and spins the bead after the immune reaction (to remove any residual unbound reagent and sample) and adds the luminogenic substrate. |
| Imaging scanner or hand-held 2D scanner | Reads kit barcodes.<br>Users of allergy kits must have the imaging scanner so allergen wedges that are loaded with allergen vials can be scanned.<br>**NOTE:** The scanner is not visible in the figures. |
| Photomultiplier tube (PMT) | Measures the photon counts.<br>**NOTE:** The PMT is not visible in the figures. |
| Reaction tube hopper gear driven reaction tube hopper | Holds the empty reaction tubes. |
| Reagent and sample valves | Mechanism that redirects the flow of liquid used by the sample Dual Resolution Dilutor (DRD) and the reagent DRD. |

| Part | Description |
|---|---|
| Reagent carousel | A rotating carousel that holds 24 reagent wedges or allergen wedges.<br>**NOTE:** To run allergy tests, the allergen wedge for the allergy kit must be on the reagent carousel, which leaves 23 positions for additional wedges.<br>Reagent wedges are divided into two or three compartments, holding up to three reagents. Wedges are identified by barcodes, which are read by the sample/reagent barcode reader.<br>Allergen wedges are the wedge-shaped frames that hold the allergen vials used in allergy testing. An allergen wedge can hold up to six allergen vials. Information about an allergen wedge is entered into the database by scanning the barcodes on the side of the wedge using the imaging scanner. Allergen wedges also have a barcode on the edge, similar to a reagent wedge, so the sample/reagent barcode reader can identify their position on the reagent carousel.<br>Because the reagent carousel is refrigerated between 2° to 8°C (35.6° to 46.4 °F), reagent wedges can be stored on the instrument. While it is possible to store allergen vials on the instrument, it is recommend that they be sealed with a standard cap and stored off the instrument if they will not be used for an extended period of time. |
| Reagent DRD (Dual Resolution Dilutor) | Extracts reagent and water and moves the liquid to the reagent pipettor. |
| Reagent pipettor | Pipettes reagent onto the bead in the reaction tube. |
| Sample carousel | A rotating carousel that holds six removable racks. Each rack holds up to 15 specimen or diluent tubes of varying sizes. The barcodes on the tubes are read as the carousel rotates. |
| Sample dilution well | Mixes specified quantities of specimen, diluent, and water to form a homogenous mixture.<br>The sample probe dispenses the materials into the well for mixing. After the diluted sample is pipetted into the reaction tube, the dilution well insert is spun at a high speed, discarding the unused portion of the diluted sample. |
| Sample DRD | Extracts sample from the sample tube and moves it to the sample pipettor. |
| Sample pipettor | Pipettes sample onto the bead in the reaction tube. |

| Part | Description |
|---|---|
| sample/reagent barcode scanner | Reads barcodes on the tubes in the sample carousel and on the reagent and allergen wedges in the reagent carousel. |
| substrate pump | Dispenses 200 µL of substrate from the substrate reservoir into a reaction tube. |
| tube processor incubators | Device where the immune and luminogenic reactions are incubated.<br>Reaction tubes are continually agitated at 37°C (98.6°F) during these processes. |
| water pump | Accurately dispenses water into a reaction tube at the bead/tube wash station. |

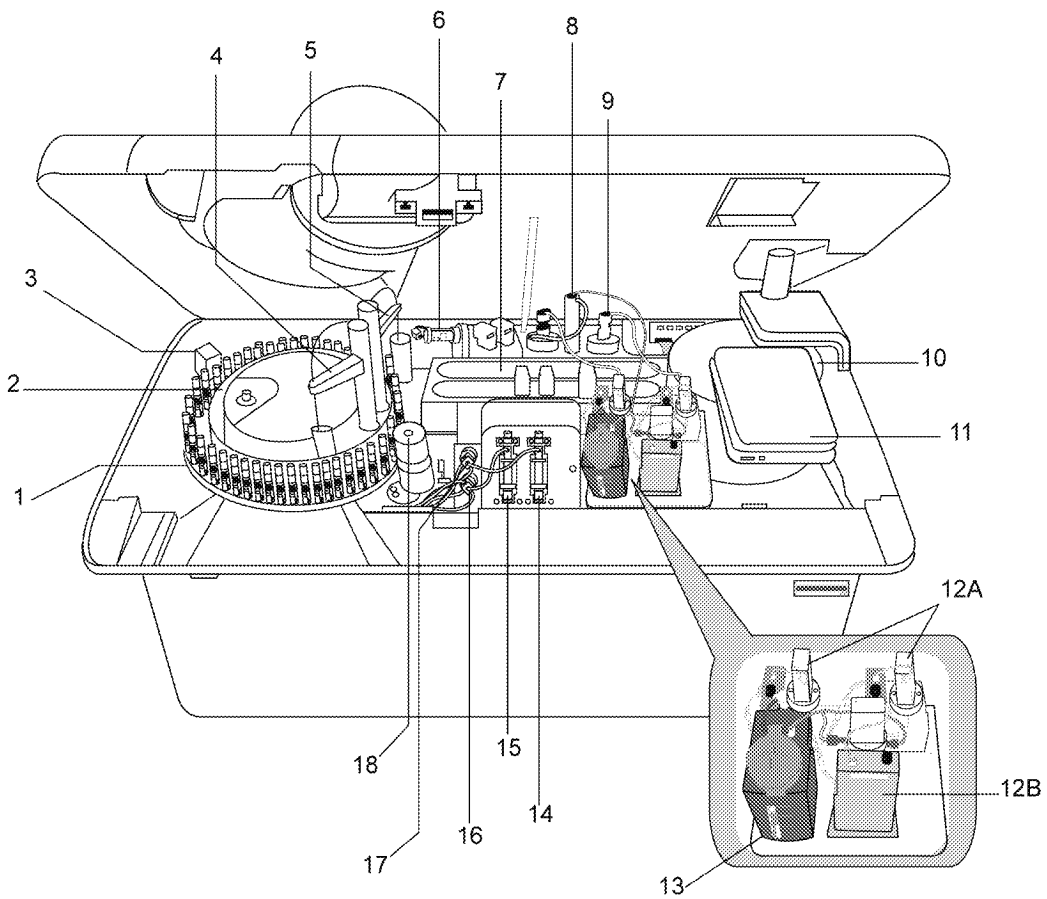
The following image displays the location of the various IMMULITE 2000 instrument components.




| | | | |
|---|---|---|---|
| **1** | Sample carousel | **9** | Bead carousel cover |
| **2** | Reagent carousel (covered) | **10** | Substrate and water pumps) |
| **3** | Sample reagent barcode scanner | **11** | Substrate reservoir |
| **4** | Sample pipettor | **12** | Reagent DRD |
| **5** | Reagent pipettor | **13** | Sample DRD |
| **6** | Bead/tube wash station | **14** | Sample valve |
| **7** | Tube processor | **15** | Reagent valve |
| **8** | Bead carousel | **16** | Sample dilution well |

**Figure 1-1 IMMULITE 2000 System (Overhead View)**

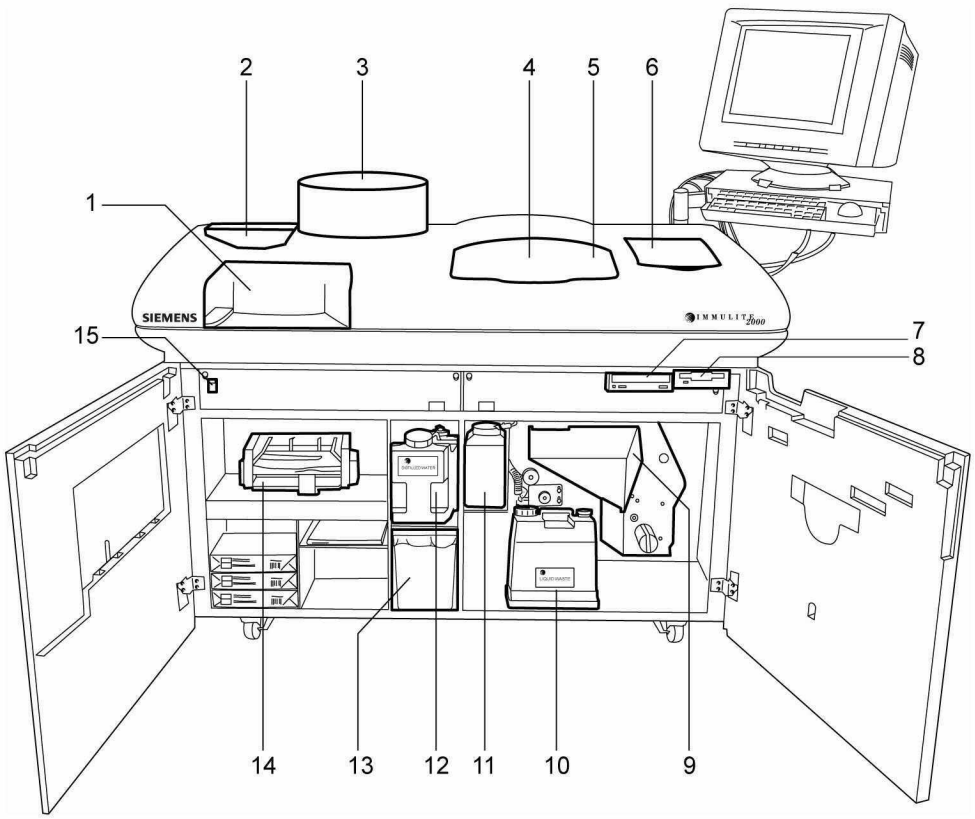
The following image displays the location of the various IMMULITE 2500 instrument components.




| | | | |
|---|---|---|---|
| **1** | Sample Carousel | **10** | Bead Carousel |
| **2** | Reagent Carousel (Covered) | **11** | Bead Carousel Cover |
| **3** | Sample Reagent Barcode Scanner | **12** | A. Water Pumps<br>B. Substrate Pump |
| **4** | Sample Pipettor | **13** | Substrate Reservoir |
| **5** | Reagent Pipettor | **14** | Reagent DRD |
| **6** | PMT | **15** | Sample DRD |
| **7** | Incubator | **16** | Sample Valve |
| **8** | Substrate Probe | **17** | Reagent Valve |
| **9** | Water Probe | **18** | Sample Dilution Well |

**Figure 1-2 IMMULITE 2500 (Overhead View)**

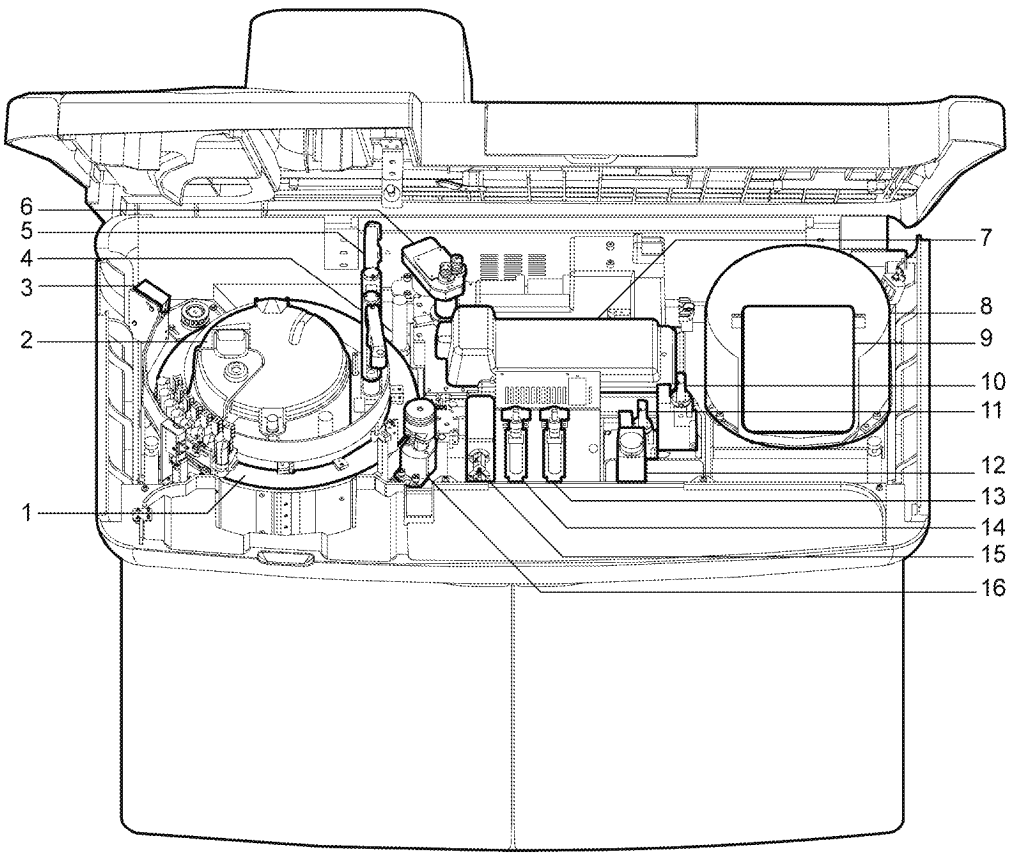
The following image displays the front view and locations of the IMMULITE 2000 systems and IMMULITE 2500 system components, and the items on the shelves underneath the instrument.




| | | | |
|---|---|---|---|
| **1** | Rack loader door | **9** | Reaction tube hopper |
| **2** | Reagent carousel (covered) | **10** | Liquid waste |
| **3** | Pipettors | **11** | Probe wash |
| **4** | DRD priming accessories | **12** | Distilled water |
| **5** | Substrate reservoir | **13** | Solid waste |
| **6** | Bead carousel | **14** | Printer |
| **7** | CD/DVD drive | **15** | Power switch |
| **8** | Floppy drive | | |

**Figure 1-3 IMMULITE 2000 Systems and IMMULITE 2500 System (Front View)**

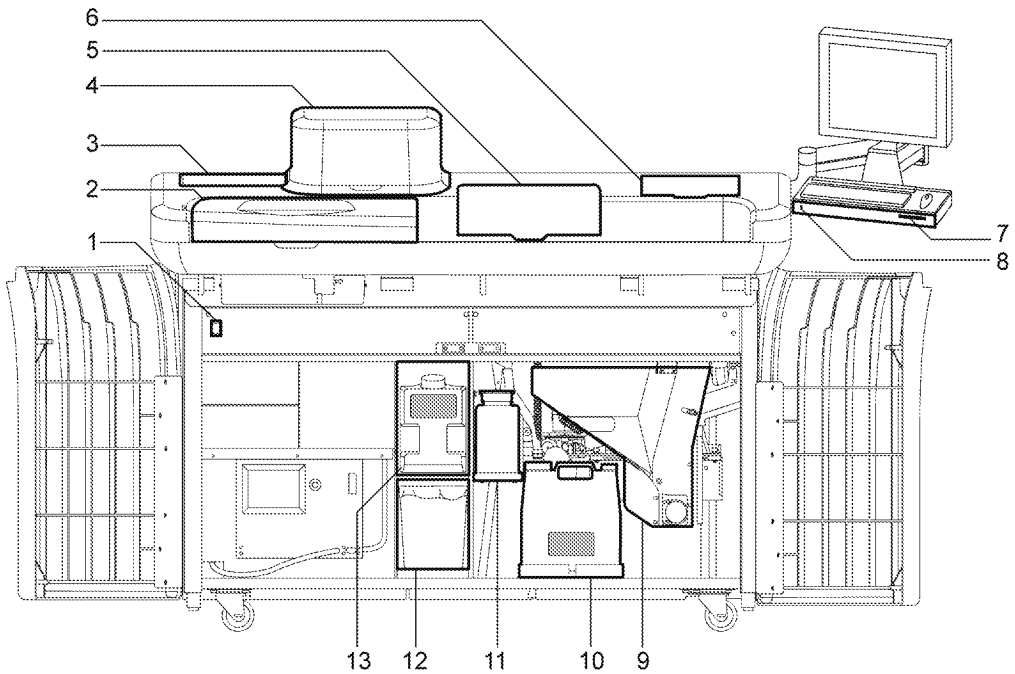
The following image displays the location of the various IMMULITE 2000 XPi instrument components.




| | | | |
|---|---|---|---|
| **1** | Sample Carousel | **9** | Bead Carousel Cover |
| **2** | Reagent Carousel (Covered) | **10** | Water Pump |
| **3** | Sample Reagent Barcode Scanner | **11** | Substrate Pump |
| **4** | Sample Pipettor | **12** | Substrate Reservoir |
| **5** | Reagent Pipettor | **13** | Reagent DRD |
| **6** | Bead/Tube Wash Station | **14** | Sample DRD |
| **7** | Tube Processor | **15** | Reagent Valve/Sample Valve |
| **8** | Bead Carousel | **16** | Sample Dilution Well |

**Figure 1-4 IMMULITE 2000 XPi System (Overhead View)**

The following image displays the front view and locations of the IMMULITE 2000 XPi instrument components, and items held on the shelves underneath the instrument.




| | | | |
|---|---|---|---|
| **1** | Power switch | **8** | USB |
| **2** | Rack loader for sample carousel | **9** | Reaction tube hopper |
| **3** | Reagent carousel (covered) | **10** | Liquid waste |
| **4** | Sample pipettor door | **11** | Probe wash |
| **5** | DRD priming / substrate reservoir | **12** | Solid waste |
| **6** | Bead carousel | **13** | Distilled water |
| **7** | CD/DVD drive | | |

**Figure 1-5 IMMULITE 2000 XPi System (Front View)**

## Kit Components

Test kits include the materials needed to run assays. The components in a kit are listed and described below:

- Adjustor antibody (for allergy kits only)
- Adjustors
- Barcode labels for adjustor tubes
- Bead packs
- Control antibody (for allergy kits only)
- Controls (for certain kits, including allergy kits)
- Diluents (for assays requiring a pre-dilution)
- Kit barcode
- Package insert
- Reagent wedges
- Important notices

### Reagent Wedge

A barcoded reagent wedge contains an assay-specific enzyme conjugate. The reagent is pipetted into the reaction tube. The reagent wedges in allergy kits contain an anti-immunoglobulin reagent used for allergy tests with all allergens. In the software and documentation, this reagent is referred to as universal reagent, such as IgE or SPE. Figure 1-6 displays the reagent wedge label.

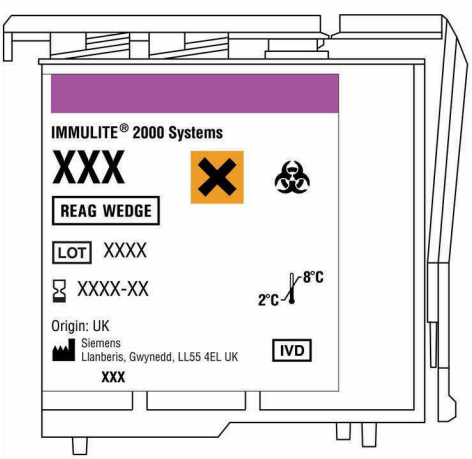



**Figure 1-6 Reagent Wedge Label**

Figure 1-7 displays the reagent wedge compartments.

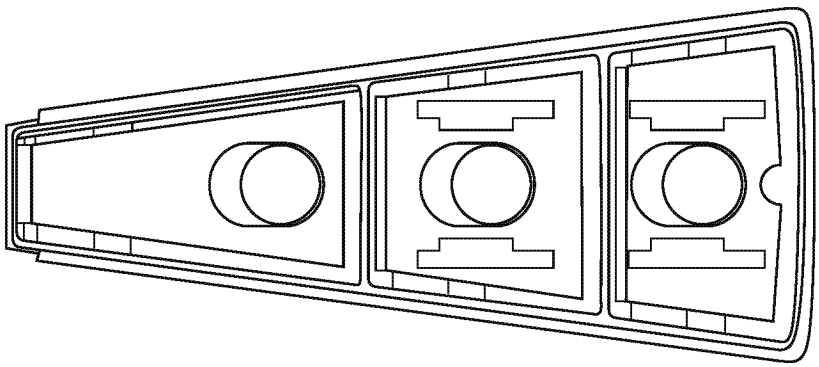


**Figure 1-7 Reagent Wedge Compartments**

## Bead Packs

A bead pack contains the assay-specific beads. A single bead is dropped into a reaction tube. Figure 1-8 displays the bead pack label.

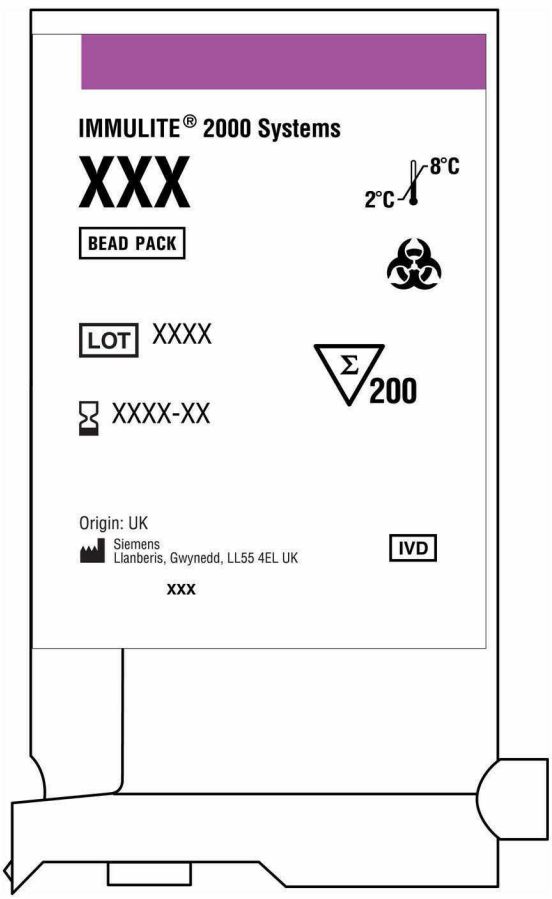



**Figure 1-8 Bead Pack Label**

## Adjustors

Each kit contains one or two Adjustors. Kits with two adjustors have a LOW and a HIGH adjustor, which contain different concentrations of analyte. The adjustor can be in either liquid or lyophilized form.

For more information regarding the adjustors, refer to the package insert.

## Adjustor Barcode Labels

Each kit contains adjustor barcode labels to be placed on test tubes. The label identifies the tube as an adjustor for that particular test.

## Controls (QC)

Controls are run to determine if adjustments are valid. They can also be used to verify if the reagent and beads are viable. Some kits, such as infectious disease or allergy kits, require specialized controls that are included in those kits. Controls are available separately for other assays.

## Adjustor Antibody

Allergy kits include an adjustor antibody. The adjustor antibody must be loaded in an allergen wedge and placed on the instrument when the adjustors for an allergy kit are run. An adjustor antibody vial contains 40 tests. Each adjustor antibody vial has a corresponding 2D barcode that contains lot-specific information about the adjustor antibody. The 2D barcode must be scanned before the adjustor antibody vial is loaded into an allergen wedge.

## Control Antibody

Allergy kits include a control antibody. The control antibody must be loaded in an allergen wedge and placed on the instrument when running controls on allergy tests. A control antibody vial contains 40 tests. Each control antibody vial has a corresponding 2D barcode that contains lot-specific information about the control antibody. The 2D barcode must be scanned before the control antibody vial is loaded into an allergen wedge.

## Kit Barcode

The 2D kit barcode (displayed below) is located on the box flap inside the kit. Information specific to the kit lot is included in the barcode and must be entered the first time a kit lot is used.

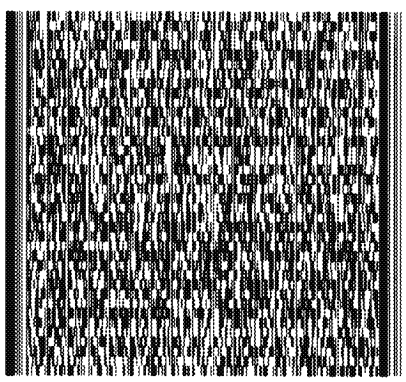


**Figure 1-9 2D Kit Barcode**

### Package Insert

The package insert contains specific information regarding the assay. Be sure to read the package insert before using a new kit.

### Important Notices

Important Notices contain information regarding usage of the assay kit components. A sticker on the outside of the kit package alerts the user that an important notice is enclosed.

## *Other Test Supplies*

**NOTE:** These supplies are not included in the kit.

Other test supplies needed to run the instrument include:

- chemiluminescent substrate
- probe wash
- diluents
- allergens (for allergy tests only)
- allergen wedge (for allergy tests only)

### Chemiluminescent Substrate Module

**WARNING**

Do not add fill the substrate reservoir beyond the maximum capacity of 1000 tests. Filling the substrate reservoir beyond the maximum capacity may cause substrate to enter the $CO_2$ scrubber and cause a blockage. This can result in damage to the instrument and possible misreporting of results. Each bottle of chemiluinescent substrate contains enough material for 1000 tests.

The chemiluminescent substrate module includes two bottles of chemiluminescent substrate. Store the substrate between 2° and 8°C (35.6° and 46.4°F). Each bottle of chemiluminescent substrate contains enough material for 1000 tests.

**CAUTION**

Do not leave substrate spills on the load scale. Spilled substrate may cause the load scale to stick and the substrate status indicator to appear full when the substrate reservoir is empty. This could affect results. Immediately clean up any substrate spills using moistened tissues.

### Probe Wash Module

The probe wash module contains two bottles of probe wash concentrate, which should be stored at room temperature. Each 200 mL bottle must be diluted with 1800 mL of distilled/de-ionized water before it is used.

### Diluent Module

Diluent tubes may be barcoded for instrument identification and used for the onboard dilution of patient samples with analyte concentrations above the calibration range. The diluent is packaged in bulk bottles, along with barcoded labels that are used with 16 x 100 tubes.

### Allergens

To test patient samples for an allergy, a vial containing the appropriate allergen must be placed in an allergen wedge on the reagent carousel. Vials that contain several allergens are used to test samples for a broader range of allergic reactions. Allergen vials contain 20 or 40 tests, based on the allergen type. Each allergen Vial has a 2D barcode that must be scanned like the 2D barcodes from an assay kit.

### Allergen Wedges

Allergen wedges are the wedge-shaped frames that hold the allergen vials used in allergy testing. An allergen wedge can hold up to six allergen vials. Information about the contents of an allergen wedge is entered into the database when the wedge and vial barcodes are scanned with the imaging scanner. Allergen wedges also have a barcode on the edge, like a reagent wedge, so their position on the reagent carousel can be identified by the sample/reagent barcode reader.

## *Using the Consumables Report*

Follow these steps to review the consumables report:

1. If the button on the Worklist screen is red, select **Consumables**.
2. Load any kit components that are low or missing.

   **NOTE:** The next time the Consumables button is selected or the next time the barcodes are read, the button returns to the original color.
3. Select **CLOSE** to remove the consumables report from the screen.

   The assays begin processing.

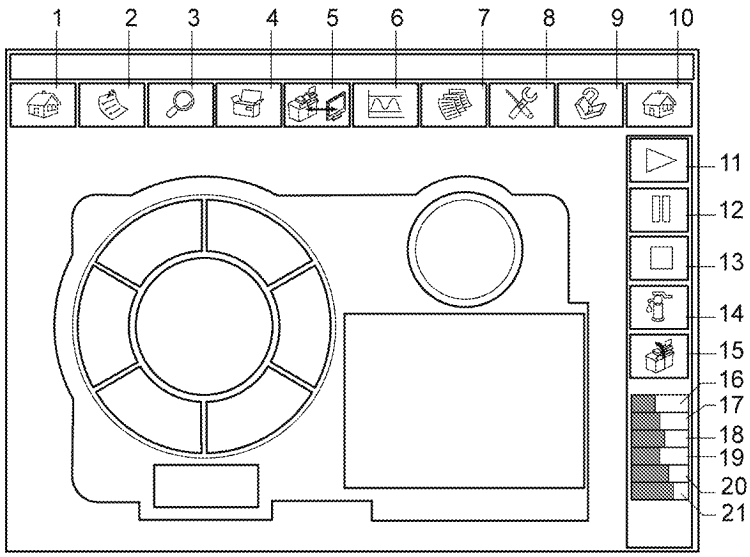
# *Software Overview*

The software provides tools to direct instrument operations and manage data. The software also informs the operator of system conditions and provides answers to operator questions.

**NOTE:** The computer supplied with the instrument is designed to run the included software. The installation of third-party software applications may adversely affect the proper operation of the instrument software and/or system.

Certain screens display automatically at the appropriate time, while others can be accessed from the toolbar. The following image displays both the horizontal and vertical toolbar, the buttons along the top and right side.

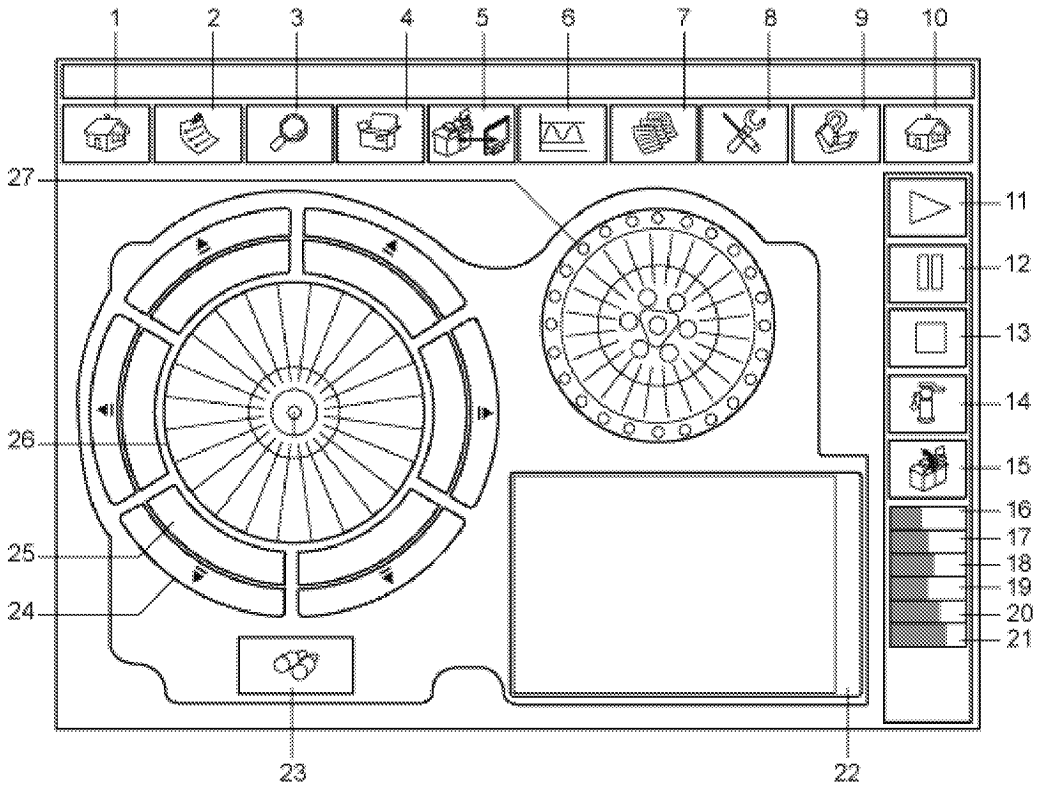
The following image displays the updated IMMULITE 2000 system and the IMMULITE 2500 system Home screen.




| | | | |
|---|---|---|---|
| **1** | HOME | **12** | PAUSE |
| **2** | WORKLIST | **13** | STOP |
| **3** | REVIEW | **14** | PRIME |
| **4** | KITS | **15** | COVER |
| **5** | LIS | **16** | WATER |
| **6** | QC | **17** | WASH |
| **7** | REPORTS | **18** | SUBSTRATE |
| **8** | MENU | **19** | SOLID WASTE |
| **9** | HELP | **20** | LIQUID WASTE |
| **10** | LOGOFF | **21** | TUBES |
| **11** | RUN | | |

**Figure 1-10 Home Screen for the IMMULITE 2000 System and the IMMULITE 2500 system**

The following image displays the IMMULITE 2000 XPi Home screen.




| | | | |
|---|---|---|---|
| **1** | HOME | **15** | COVER |
| **2** | WORKLIST | **16** | WATER |
| **3** | REVIEW | **17** | WASH |
| **4** | KITS | **18** | SUBSTRATE |
| **5** | LIS | **19** | SOLID WASTE |
| **6** | QC | **20** | LIQUID WASTE |
| **7** | REPORTS | **21** | TUBES |
| **8** | MENU | **22** | INSTRUMENT |
| **9** | HELP | **23** | FIND |
| **10** | LOGOFF | **24** | EJECT |
| **11** | RUN | **25** | SAMPLE RACK |
| **12** | PAUSE | **26** | REAGENT CAROUSEL |
| **13** | STOP | **27** | BEAD CAROUSEL |
| **14** | PRIME | | |

**Figure 1-11 IMMULITE 2000 XPi Home Screen**

## IMMULITE 2000 XPi Home Screen

The IMMULITE 2000 XPi Home screen displays a graphical representation of the sample, reagent, and bead carousels, and is touch sensitive.

At the Home screen, you can:

- Manually release a sample rack by selecting the eject symbol.

  **NOTE:** The rack identifiers may display in uppercase or lowercase alpha or numeric if there is a bad barcode.
- Access a sample rack by selecting the rack identifier.
- Access the reagent or bead carousel screen by selecting the reagent or bead pack.

### Wedge Status Indicators

The colors displayed on the reagent and bead wedge indicate the status:

| Color | Status |
|---|---|
| Red | Error |
| Yellow | Warning |
| White | Ok to Run |

### Sample Rack Status Indicator

The colors displayed on the sample rack indicate the status:

| Color | Status |
|---|---|
| Red | Error |
| Gray with identifier | Sample rack in position without errors. |
| Gray without identifier | No rack present |

### Find Button

| Command | Function |
|---|---|
| FIND | Offers sample search capabilities. |

## Toolbar

The IMMULITE 2000 systems and IMMULITE 2500 system toolbar provides quick access to commands or screens used in routine instrument operation.

The command buttons on the horizontal toolbar provide tools for data management.

The buttons on the vertical toolbar directly affect instrument operations. The status indicators under the horizontal toolbar display the instrument fill-levels for water, probe wash, substrate, the tube hopper, and liquid and solid waste.

Use the trackball or your finger to select a button on the toolbar.

**NOTE:** The operator may touch the screen with a bare or gloved hand or with an eraser. Do not use your fingernails or any hard implement such as a pen.

## Horizontal Toolbar

The table below provides description of the horizontal toolbar buttons:

| Command | Function |
|---|---|
| HOME | Returns to the Home screen.<br>• Select reagents or beads to view the information.<br>• The IMMULITE 2000 XPi Home screen displays the status of reagent, beads, and samples currently onboard the instrument.<br>Refer to *Home Screen for the IMMULITE 2000 System and the IMMULITE 2500 system*, page 1-18 or *IMMULITE 2000 XPi Home Screen*, page 1-19. |
| WORKLIST | Accesses the Worklist screen, allowing the operator to create or modify a worklist. The worklist directs the instrument regarding the test orders to perform for each patient, adjustor, control, or calibration verifier sample. |
| REVIEW | Used to review test results. |
| KITS | Used to review kit information. |
| LIS | Used to review data received from (or being sent to) the Laboratory Information System (LIS).<br>When the system is configured to send data manually to the LIS, results are tagged (for sending) from this screen. |
| QC | Used to enter control identification information, to specify whether to use the control results for quality control tracking, and to view control results in graphical format |
| REPORTS | Used to print or configure reports. |
| MENU | Used to access tool and configuration selections. |
| HELP | Used to access online help. |
| LOG OFF | Initiates a system back-up and ends the working session. |

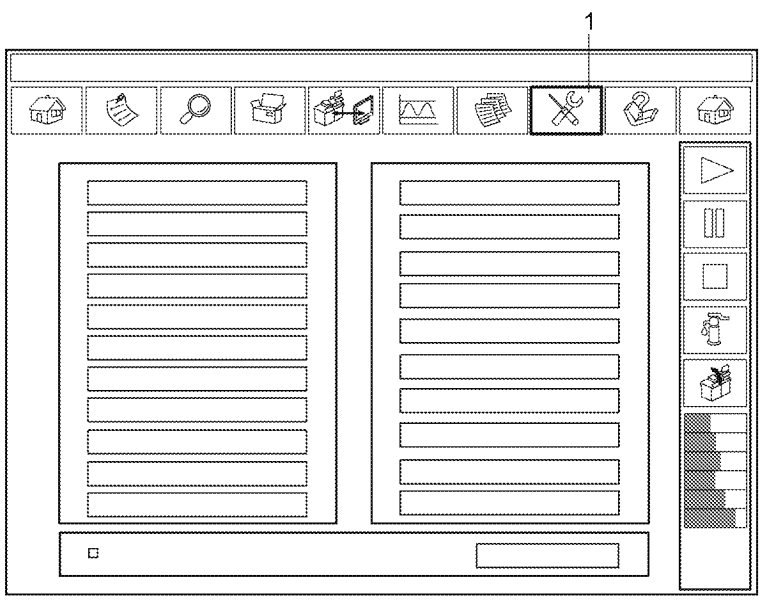
## Vertical Toolbar

The table below provides a brief description of the vertical toolbar buttons:

| Command | Function |
|---|---|
| RUN | Starts the instrument processing. |
| PAUSE | Stops the pipettors from processing any new tests, but allows it to continue to process tests which are already on the instrument. |
| STOP | Stops the instrument from processing.<br>All mechanical movements are stopped, completed tests are saved, and tests in progress are terminated. |
| PRIME | Primes the pipettors to remove air from the fluidic lines. |
| COVER | Releases the lock on the main cover so it can be opened. |

## IMMULITE 2000 / 2500 Menu Screen

The Menu screen enables you to access tools and configuration settings. Select **MENU** from the horizontal toolbar.




1 MENU button

**Figure 1-12 New IMMULITE 2000 / 2500 Menu Screen**

### *Menu Screen Tools Panel*

| Tools | Description |
|---|---|
| Formfeed | Causes the system to print all the data in the print buffer.<br>The system waits to print patient results until it has enough data for a full page. A partial page of patient results will print if no results are posted after 30 minutes.<br>When Formfeed displays in black, results are available for printing. Select **Formfeed** to print these results. |
| Export Data | Displays the Export Data screen, which is used to export data to a file, the screen, or the printer. |
| Sample Tubes in Racks | Displays a screen that displays color-coded tubes on the sample carousel. |
| Temperatures | Displays the Temperature screen, which is used to view the instrument temperature and humidity levels. |
| Day Error Log | Displays the Daily Error Log. |
| Debug Form | For use by Siemens personnel only. |
| Beads and Reagents Onboard | Displays details regarding the beads and reagents onboard the instrument. |
| Allergens Onboard | Use this command to open the Allergens Onboard window to view information about allergens onboard the instrument. |
| Adjustment Log | Displays an Adjustment Log displaying the adjustment history. |
| Find Last Tube Location | Displays the user to determine the rack and position where a specified tube was last located.<br>This feature is available for bar-coded patient samples only. |

### *Menu Screen Configurations Panel*

| Configurations | Description |
|---|---|
| Configure | Displaysscreens used to configure instrument settings including Display Options, Automatic Dilutions, Instrument Identification, LIS and Configuration Settings screens. |
| Test Ranges | Specifies reference ranges. |
| Allergen Ranges | Displays the ranges of immunoglobulin concentrations for allergic reactions. |
| Reflexive Tests | Specifies the test to perform when a result is outside a specified range. |
| Panels | Used to create or change a panel. |
| Units | Used to change the default units for a specific test. |
| Auto Rack | Used to view the contents of an automation rack when the instrument is connected to a VersaCell system. |

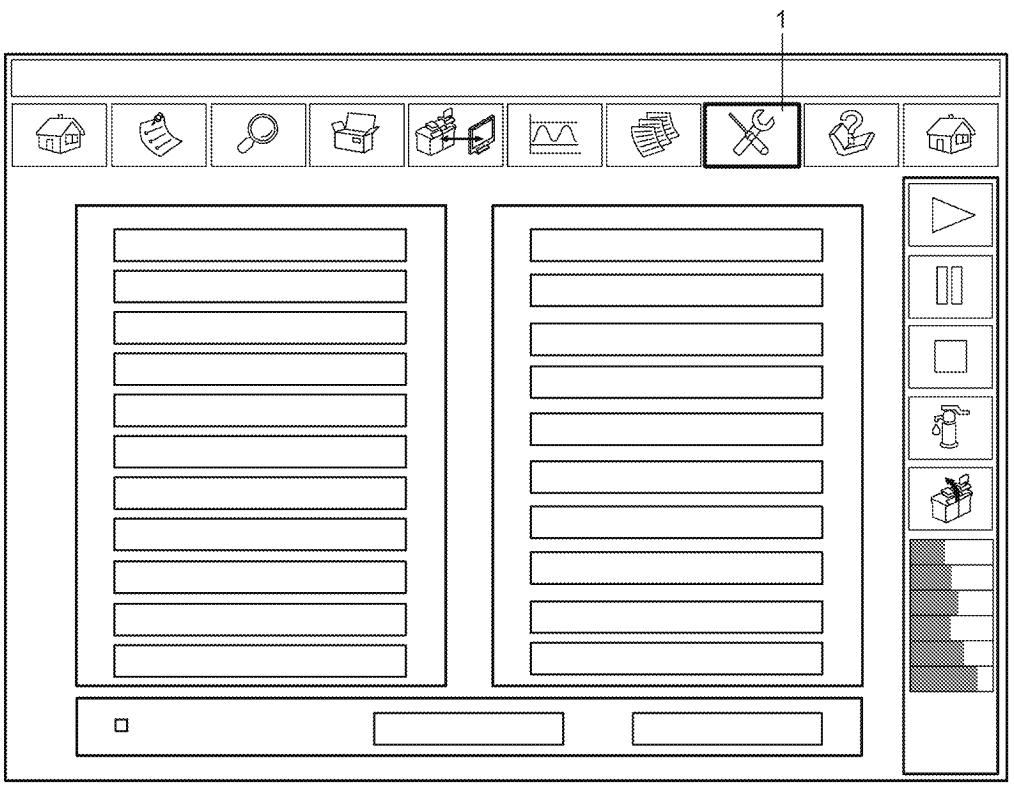
| Configurations | Description |
|---|---|
| Confirm HBS | Used to order HBS confirmatory tests and printed results. |

***Menu Screen Task Bar***

| Options | Description |
|---|---|
| Hide Names | Used to hide patient names on the following screens:<br>• Export data (Onscreen, printed, and text)<br>• Review<br>• LIS<br>• Worklist |
| About | Displays the software version, a general statement regarding the instrument software, and the EMERGENCY SHUTDOWN button. |

## IMMULITE 2000 XPi Menu Screen

The Menu screen enables you to access tools and configuration settings. Select **MENU** from the horizontal toolbar.




**1** MENU button

**Figure 1-13 IMMULITE 2000 XPi Menu Screen**

### *Menu Screen Tools Panel*

| Tools | Description |
|---|---|
| Formfeed | Causes the system to print all the data in the print buffer.<br>The system waits to print patient results until it has enough data for a full page. A partial page of patient results will print if no results are posted after 30 minutes.<br>When Formfeed displays in black, results are available for printing. Select **Formfeed** to print these results. |
| Export Data | Displays the Export Data screen, which is used to export data to a file, the screen, or the printer.<br>Refer to *Exporting Data*, page 7-1. |
| Sample Tubes in Racks | Displays a screen that displays color-coded tubes on the sample carousel.<br>Refer to *IMMULITE 2000 XPi Home Screen*, page 1-20. |

| Tools | Description |
|---|---|
| Temperatures | Displays the Temperature screen, which is used to view the instrument temperature and humidity levels. |
| Day Error Log | Displays the Daily Error Log. |
| Debug Form | For use by Siemens personnel only. |
| Beads Reagents Onboard | Displays details regarding the beads and reagents onboard the instrument. |
| Allergens Onboard | Use this command to open the Allergens On Board window to view information about allergens onboard the instrument. |
| Adjustment Log | Displays an Adjustment Log displaying the adjustment history. |
| Find Last Tube Location | Displays the user to determine the rack and position where a specified tube was last located.<br>This feature is available for bar-coded patient samples only. |
| Scheduled QC | Allows the user to define a schedule for performing quality control assays during AutoStart. |

***Menu Screen Configurations Panel***

| Configurations | Description |
|---|---|
| Configure | Displays screens used to configure instrument settings including Display Options, Automatic Dilutions, Instrument Identification, LIS and Configuration Settings screens. |
| Test Ranges | Specifies reference ranges. |
| Allergen Ranges | Displays the ranges of immunoglobulin concentrations for allergic reactions. |
| Reflexive Tests | Specifies the test to perform when a result is outside a specified range. |
| Panels | Used to create or change a panel. |
| Units | Used to change the default units for a specific test. |
| Auto Rack | Used to view the contents of an automation rack when the instrument is connected to a VersaCell system. |
| Confirm HBS | Used to order HBs confirmatory tests and printed results. |
| Communication | Used to configure the instrument to communicate via informatics applications such as RealTime Solutions. |
| AutoStart Configuration | Used to configure the instrument to automatically or manually process routine maintenance tasks. |

***Menu Screen Task Bar***

| Options | Description |
|---|---|
| Hide Names | Used to hide patient names on the following screens:<br>• Export data (Onscreen, printed, and text)<br>• Review<br>• LIS<br>• Worklist |
| Run AutoStart | Starts the maintenance tasks automatically.<br>Refer to *AutoStart Maintenance (IMMULITE 2000 XPi System)*, page 5-35.<br>The instrument must be in STOP mode or logged off for processing to begin. |
| About | Displays the software version, a general statement regarding the instrument software, and the EMERGENCY SHUTDOWN button. |

## *Online Help*

Select **HELP** on the toolbar for information about the operation of the instrument and its software. The online help is context-sensitive software including complete operating, maintenance, and troubleshooting procedures about the currently displayed screen.

1. At the instrument window, select **HELP**.
2. At the Help window, select **Help Topics** to display a list of help topics.

### Navigating Online Help

Help is organized much like books in a library. A book icon represents each help topic with sub-topics displayed as chapters within the topic. The toolbar buttons can be used to display all online help topics and allow navigation within the topics.

1. Select **Help** on the horizontal toolbar to display all help topics.
2. The help screen displays help topics in the left pane and information about a highlighted topic in the right pane.
3. To move from topic to topic, select the plus symbol (+) next to the book icon.
4. Select **Back** to move to the previously viewed topic.
5. Select the << or >> buttons to move forward or backward through sub-topics.

## Menu Options

The operator can access different views and display options within the Help using the menu options.

| Menu Option | Function |
|---|---|
| File | • Open<br>Allows the user to open a Help file.<br>• Print Topic<br>Allows the user to print a Help topic.<br>• Exit<br>Allows the user to exit the Help file. |
| Edit | • Copy<br>Copy text from the help file to the clipboard.<br>• Annotate<br>Associate additional information with a specific topic. When a topic is annotated, a paper clip icon displays next to the topic. Select the paper clip icon to display the annotation text. |
| Bookmark | Define<br>Allows the user to define an electronic placeholder to allow the user to return to a specific Help topic. |
| Options | • Keep Help on Top<br>Options that determine the visual position of the Help window when other applications are open simultaneously.<br>- Default – Sets the Help file as always open and visibly in front of all open applications.<br>- On Top – Sets the Help file as always open and visibly in front of all open applications but inactive. The title bar at the top of the Help file window becomes gray when another application is opened.<br>- Not on Top – Sets the Help file to open upon user initiation. The Help file minimizes when another application is opened.<br>• Display History Window<br>Opens a window that displays the history of the help topics previously viewed. Double-clicking a topic in this window opens that Help topic.<br>• Font<br>Changes the size of the font for Help topics.<br>• Use System Colors<br>Sets colors used in the Help file to match those that are used for the PC. |
| Help | • Version<br>Displays current version and copyright statement for Windows Help.<br>• About Windows 2000<br>Provides WinHelp product description. |

## Locating Routine Procedures

Instrument operating procedures that are common within normal day-to-day operation are listed in the Help window. You can locate maintenance procedures, solutions for error messages, and checklists for secondary operator training.

To locate instructions on operating procedures, perform the following steps:

1. Select **HELP**.
2. In the Help window, select **Help Topics** to display a list of help topics.
3. Select the help topic by selecting the addition symbol to the front of the book icon to the left of the topic.

   The sub-topics within that topic display.
4. Select the sub-topic of interest.

   The information on that sub-topic displays in the right panel of the Help screen.

## Using the Index Feature

Help is indexed to enable the operator to locate pertinent information alphabetically.

To access the index, perform the following:

1. Select **HELP** from the Horizontal Toolbar.
2. Select **Index** from the Help screen to display a list of Index contents.
3. Select the index topic by clicking the topic.

   The sub-topics (if applicable) within that topic display.
4. Select the index topic of interest. The information on that topic displays in the right pane of the Help screen.

## Using the Search Feature

The search feature allows the operator to search for specific words or phrases in the Help software. Prior to initial use, a database must be created that lists every word in the Help software.

### *Initializing the Search Feature*

To initialize the search feature the first time, perform the following:

1. Select **HELP** from the Horizontal Toolbar.
2. Select **Search** on the Help screen.
3. Leave the default selection to minimize database size, and then select **Next** to proceed.

4. Select **Finish** to complete the setup wizard.

   The Search database is now ready for use.

#### *Searching the Help Database*

To conduct a search of the Help database, perform the following:

1. Select **HELP**.
2. Select **Search**.
3. In the search window, type a word or phrase, such as **load**.

   The second window displays with matching words.
4. Select a word or phrase to narrow the search.
5. The results window displays with all topic entries that contain the word or phrase.
6. Select the topic to display.

   The topic displays in the right pane of the screen with the search results highlighted.

# *Technology*

## *Data Reduction and the Chemiluminescent Reaction Internal Calculations*

This section provides a step-by-step description of the internal calculations performed by the system when determining test results.

1. Because the instrument's ultra-sensitive assays can produce up to several hundred million counts per second (CPS), the instrument uses an attenuator disk in front of the photomultiplier tube (PMT) to provide accurate readings over a very broad range of light signals. This attenuator disk has three positions:
   - Closed - completely blocks the PMT
   - Attenuated - positions a neutral density filter in front of the PMT
   - Open - an open, unfiltered position

   The instrument's attenuation filter restricts the amount of light striking the PMT, ensuring an accurate count, even if the actual light output from the tube exceeds the linear range of the PMT.
2. For each sample, the instrument takes two one-second readings (dark count in the closed position and a decision count reading in the attenuated position).
3. If the decision count reading indicates the light level is within the working range of the PMT, the attenuator disk moves to the open position; otherwise, it remains in the attenuated position while the sample readings are taken.

4. The instrument takes five one-second readings.
5. The average of the last 10 dark count readings is subtracted from each of the five readings of the sample tube and the average of the five readings is then calculated.

   **NOTE:** A dark count reading is taken every 18 seconds when a Reaction Tube is in the read position.
6. If the counts were measured attenuated, the mean of the five individual readings is multiplied by the instrument-specific attenuation factor to estimate what the reading would have been if it could have been taken without the attenuator.
7. CPS (unattenuated)= CPS(attenuated) x attenuation factor
8. To determine analyte concentrations, the instrument uses the counts together with the adjustment data and the master curve.

## Chemiluminescent Reaction

This section provides a brief overview of the chemiluminescent reaction used in the instrument.

During the initial immune reaction between the reagent antibodies and the analyte in the sample, that component of the reagent labeled with alkaline phosphatase (known as the conjugate) is bound to the bead within the reaction tube. The amount of alkaline phosphatase bound is directly proportional (for a sandwich assay), or inversely proportional (for a competitive assay) to the concentration of the analyte in the patient sample.

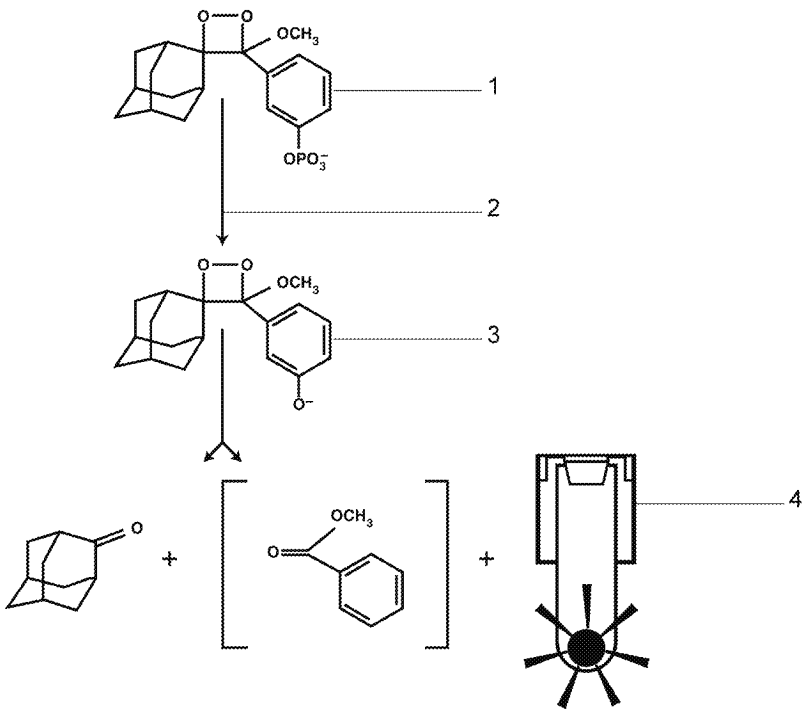
After the reaction tube is washed, a luminogenic substrate is added to the reaction tube.

Five minutes later, the reaction tube arrives in front of the photomultiplier tube (PMT), where the light generated by the luminogenic reaction is measured. The enzyme-amplified reaction in the system produces a prolonged output of light causing the tube to glow.

In the luminogenic reaction (illustrated in the next figure), the substrate (an adamantyl dioxetane phosphate) is dephosphorylated into an unstable intermediate by the alkaline phosphatase bound on the bead. The unstable intermediate rapidly and spontaneously breaks down, emitting a photon of light. The amount of light emitted is directly proportional to the amount of bound alkaline phosphatase.

Compared to other means of detection, chemiluminescence provides the highest degree of sensitivity available. In many cases, the sensitivity is orders of magnitude better than that attainable with radioimmunoassays.

LUMIGEN PPD:
4-methoxy-4-(3-phosphatephenyl)-spiro-(1,2-dioxetane-3,2′-adamantane).




**1** Dioxetane phosphate (stable
**2** Alkaline phosphatase label
**3** Dioxetane (unstable)
**4** Light (hv)

**Figure 1-14 Chemical Reaction of Instrument Substrate**

# 2 Operating the System

# Operating the System

This section provides information about operating the system.

## Operator Tasks

The procedures performed by the operator when running assays on the instrument are outlined below.

1. Perform the Daily Probe Cleaning procedure.

   Refer to *Cleaning the Sample and Reagent Probes*, page 5-5.

2. Select **RUN IMMULITE 2000** or **RUN IMMULITE 2500** on the startup screen.

3. Check the system status indicators and fill or empty the reservoirs.

   Refer to *Checking the Status Indicators*, page 5-6.

4. Prime the sample and reagent pipettors, the water probe, and the substrate probe.

   Refer to *Priming the Sample and Reagent Pipettors*, page 5-13.

5. Scan any allergen wedges on the reagent carousel using the imaging scanner.

   Refer to *Scanning a 2D Kit Barcode Using an Imaging Scanner*, page 2-26.

6. Load the patient samples, controls, adjustors, and diluents (as necessary) on the sample carousel.

   **NOTE:** The materials needed to operate the instrument are included in the IMMULITE 2000 and IMMULITE 2500 test kits. Diluents are only included for pre-diluted assays.

   Refer to *Managing Sample Racks*, page 2-2.

7. Check that a sufficient quantity of reagent wedges and matching bead packs are available to process the tests ordered.

   Refer to *Maintaining Reagent Wedges, Allergen Wedges and Bead Packs*, page 2-12.

8. If necessary, associate the accession numbers with the tests ordered via the Worklist screen.

   Refer to *Managing Worklist*, page 2-41.

9. Select **RUN** to begin the automated test process.

# Managing Sample Racks

### *Procedural Notes*

- Be sure to read the preliminary *Sample Volume and Tube Sizes*, page E-3 before beginning the first step.
- Use the following procedure to label and load sample tubes.

## Labeling and Loading Sample Tubes

**WARNING**

Do not load multiple sample tubes with the same accession number on the Sample Carousel at the same time. Only the sample in the lowest sample carousel positions are pipetted, if multiple sample tubes with the same accession number are onboard at the same time.

**NOTE:** The instrument only accepts barcodes containing the following valid characters: the numbers 0-9, the letters A-Z, the characters (+), (-), (.), (#), (\), (~), and a blank space ( ). Barcodes containing invalid characters will not be accepted.

The instrument recognizes five barcode symbologies:

- Code 39
- Code-A-Bar
- UPC
- Code 128
- I-2 of 5 (Interleaved)

I-2 of 5 includes different dialects; therefore, the system must be configured before running a sample with this barcode. For information about this configuration, contact your local technical service provider or distributor.

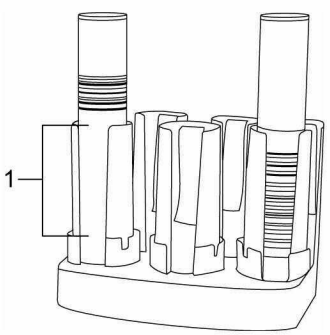
## Preparing Samples for Loading

**NOTE:** Before loading the controls, samples, and diluents, make sure all new kit barcodes have been scanned and check for bubbles or moisture at the top of the tubes.

**WARNING**

Handle samples carefully to avoid agitation that might introduce bubbles. Bubbles in the sample tube can potentially cause incorrect results. Prior to processing samples, carefully inspect the sample tubes to ensure all bubbles are eliminated.

1. Place the barcode labels on the sample tubes:
   a. Make sure the labels are visible in the tube guide reading screen or directly above the tube guide reading screen.




**1** Reading screen of the tube guide

**Figure 2-1 Section of a Sample Rack**

   b. Place the bottom edge of the label at least 0.5 in. (13mm) from the bottom of the tube.

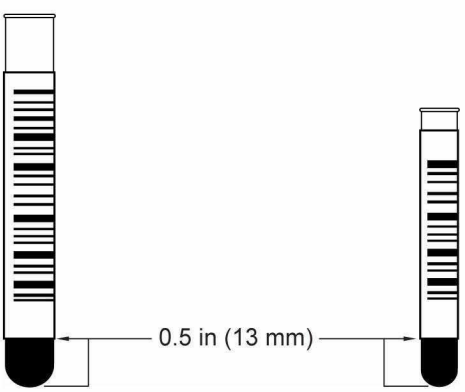



**Figure 2-2 Label Positioning**

### *Loading Samples on the IMMULITE 2000 System and the IMMULITE 2500 System*

1. At the instrument screen, select a sample rack to load by selecting the letter corresponding to the appropriate sample rack or an empty rack position.

   The sample carousel rack rotates so the rack is accessible.

2. To remove a current rack from the system, do the following:
   a. Lift the sample cover.
   b. Grasp the sample carousel rack using the finger indentations and pull the rack forward until it slides out.

**WARNING**

Use only the tube sizes listed in *Sample Volume and Tube Sizes*, page E-3 and ensure the tubes are firmly seated in the sample racks. If you use the wrong size tubes or do not seat the tubes as instructed, sampling problems or incorrect results may occur.

3. Load the controls, patient samples, and diluents in the sample rack, positioning the tubes so the barcodes face out.

   Ensure that the bottom of the barcode label is not obscured by the rack. The entire barcode label must be readable.

4. After samples are placed in the sample rack, slide it back into the carousel, making sure the rack snaps back into position.
5. Repeat steps 1 through 4 with the next sample carousel rack until all controls, samples, and diluents are loaded onto the instrument.
6. Close the sample carousel door.
7. Select **RUN** to interrogate the sample carousel.

## IMMULITE 2000 XPi Sample Loading

**WARNING**

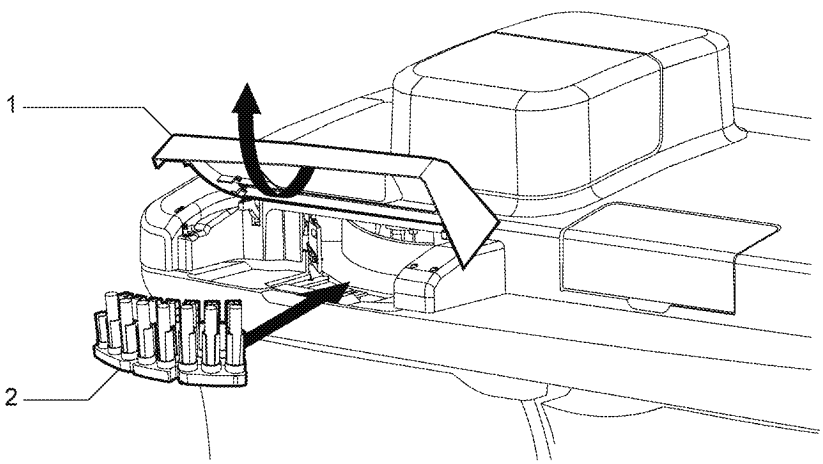
Use only the tube sizes listed in *Sample Volume and Tube Sizes*, page E-3 and ensure the tubes are firmly seated in the sample racks. If you use the wrong size tubes or do not seat the tubes as instructed, sampling problems or incorrect results may occur.

1. View the lights to the left of the rack loader door to determine if the instrument is ready for a new rack.
   - A solid red light on the rack loader indicates the instrument is not ready to accept a rack.

     The light remains red when the rack loader is full.

- A flashing red light on the rack loader indicates the instrument has an error loading or ejecting a rack.
- A solid green light on the rack indicates the instrument is ready to accept a rack.

2. Lift the rack loader door.
3. Set the sample rack into the sample tray.




**1** Rack loader door
**2** Sample rack

**Figure 2-3 Loading the Sample Carousel Rack (IMMULITE 2000 XPi System)**

4. Close the rack loader door.

   The instrument automatically loads the rack onto the system when the sample carousel has an empty rack position.

## *Loading Microsamples*

The instrument can perform assays using samples whose volumes are less than 250 µL. The minimum sample volume for an assay is indicated in the package insert for that assay, and with the microsampling feature, the instrument can operate properly using at least 50 µL of additional sample.

**CAUTION**

Ensure the tubes for microsample cups are inserted so that they touch the bottom of the rack. If they do not touch the bottom of the rack, it can create the risk of erroneous results. Always follow sample loading instructions completely.

Load the microsample on the instrument in a disposable 10 x 50 mm polystyrene sample tube (catalog number LSMT). Place each tube in a re-usable microsample tube holder (catalog number LMH15) that fits on the sample rack.

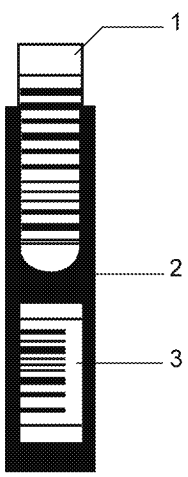
- Ensure that you insert microsample tube holders completely so that they touch the bottom of the rack.
- Verify that barcode labels are not scratched, marred, positioned incorrectly, or rendered unreadable by any marks or spills.

After you place the holders on the sample carousel and put the instrument into RUN mode, the samples are ordered the same as primary and secondary tubes.

**NOTE:** Pipette no more than five tests from a single microsample tube.

Microsample tube holders have permanently affixed barcodes. The 10 x 50 mm sample tubes can be barcoded to allow identification of the specimens.

For information about labeling patient sample tubes, refer to the next section




**1** 10 x 50 microsample tube with patient bar-code label
**2** Microsample tube holder
**3** Microsample holder bar code label (do not remove the label)

**Figure 2-4 Microsample Tube Holder**

If sample barcode labels are larger than the 10 x 50 mm tubes, assays may be run on microsamples without barcodes. To enter patient information manually on samples without barcodes, refer to *Damaged or Missing Barcodes*, page 2-44

# Tube Top Sample Cups (IMMULITE 2000 XPi System)

**NOTE:** Tube top sample cups are also known as nesting cups or small sample cups (SSC).

**WARNING**

Sample cups placed in the tops of primary collection tubes are not approved for use on the IMMULITE 2000 and IMMULITE 2500 systems. Placing sample or nesting cups in a primary tube may cause the system to use an inaccurate sample volume during testing. The principle risk is undetected short sampling from the cup, creating a risk of erroneous results.

Only the IMMULITE 2000 XPi instrument supports this type of testing on the tube top rack with the approved tube top sample cups / nesting cups.

The IMMULITE 2000 XPi instrument allows you to pipette a small sample into an approved tube top cup and place the cup back in the original sample tube and put it in a rack on the instrument. To use tube top sample cups, you must load them into a tube top rack designed for that purpose.

The tube top rack has a capacity of 15 tubes. However, you can only load 8 shorter tubes (75 mm) in the front row and 7 taller tubes (100 mm) in the back row. If you do not have that mix of tube sizes, your maximum capacity is less.

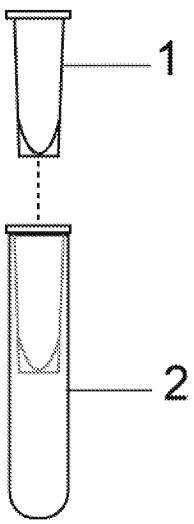
**NOTE:** Pipette no more than five tests from a single tube top cup.

Use an approved 1 mL or 2 mL tube top sample cup to pipette low volume samples with a dead volume of 50 to 100 µL.

| Approved Cup Sizes | Part Number | For use with this tube diameter... |
|---|---|---|
| 1 mL (tube top cup) | 905288 (REF 10374178) | 12 mm and 13 mm |
| 2 mL (tube top cup) | 905289 (REF 10374179) | 16 mm |

To use tube top sample cups, perform the following steps:

1. Pipette the sample from the barcoded primary tube into the tube top sample cup and place it inside the primary tube.




1 Tube top sample cup
2 Primary tube

**Figure 2-5 Tube Top Sample Cup and Primary Tube**

**CAUTION**

Do not use a regular sample rack for loading tube top cups. Using a regular sample rack could cause damage to the system or report incorrect results. Use only the racks dedicated for tube top cups. These racks use a lower-case alpha character on the rack barcode label.

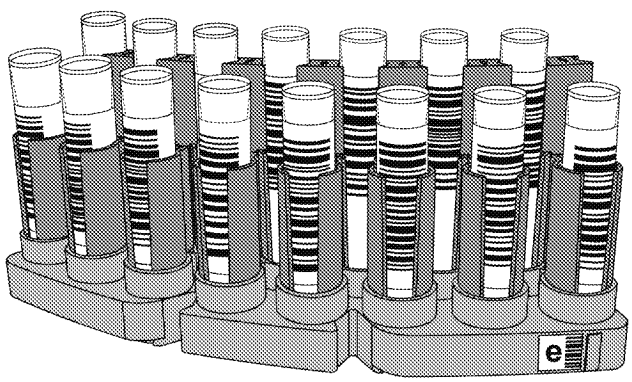
2. Ensure you are using a dedicated tube top sample rack.

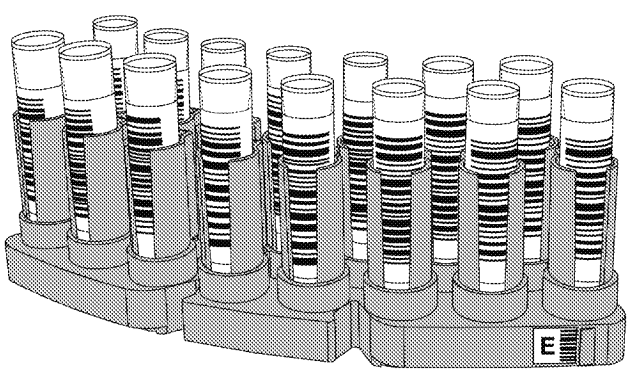
   Tube top sample racks have a conductive surface on the pylons between tubes. This allows the instrument to perform level sensing on the tube top cups.

   The figures below display the differences between the standard rack and the tube top rack:

   - Standard racks have no pylons between the tube holders.
   - Standard racks have an uppercase letter on the barcode.
   - Tube top racks have a lowercase letter on the barcode.

**Tube Top Rack**



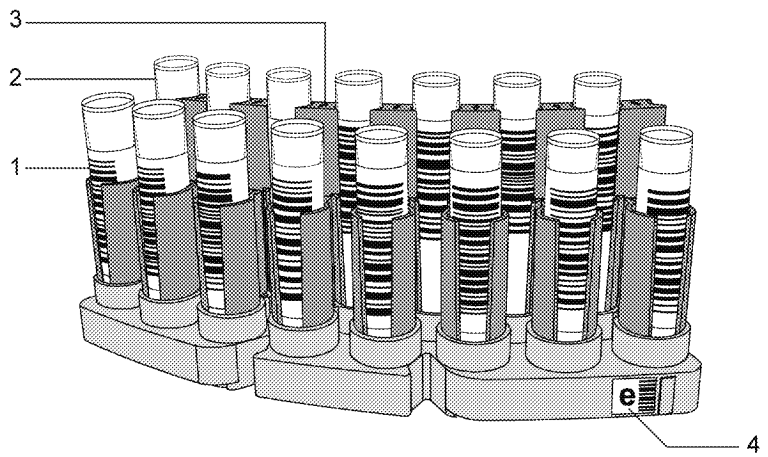

**Standard Rack**

Load the barcoded primary tube containing the tube top sample cup into the tube top rack on the instrument.

a. Load only 75 mm tubes in the front row of the rack.

b. Load only 100 mm tubes in the back row of the rack.

c. As with regular tubes, ensure the bar code is clear of any obstruction.




**1** Conductive pylons
**2** 100 mm tubes with tube top sample cups
**3** 75 mm tubes with tube top sample cups
**4** Tube top rack bar code displaying a lowercase letter

**Figure 2-6 IMMULITE 2000 XPi Tube Top Rack**

The instrument reads the barcode and detects that all samples in the tube top rack are tube top sample cups.

View the status and rack position on the Sample Tubes In Rack screen.

## *Automated Test Process*

After the operator selects **RUN**, the instrument processes the tests and generates the results. A step-by-step description of this process displays below:

1. A single assay-specific bead is dropped into a reaction tube.
2. Sample, assay-specific reagent, and water are pipetted onto the bead.
3. The reaction tube is moved into the incubation area, where the tube is agitated at 37°C (98.6°F).
4. The reaction tube is washed.
5. Substrate is added and the chemiluminescent reaction occurs, generating light.
6. The amount of light generated is measured by the photomultiplier tube (PMT) and the test results are calculated and printed.

## Operating Modes

The IMMULITE 2000 Systems and IMMULITE 2500 system have the following three operating modes:

- RUN
- PAUSE
- STOP

  The IMMULITE 2000 XPi instrument has the following operating mode in addition to those listed above:

- AutoStart

### RUN Mode

Assays are in progress and the instrument is operating.

### PAUSE Mode

Pipettors stop and the processing of any new tests is temporarily halted; however, tests already on the instrument continue processing. There are four different PAUSE modes:

**NOTE:** Enhanced Pause Message – All Pause, Reagent Pause, and Bead Pause mode each display messages when sequential or pretreatment assays are running. The messages display to let you know when it is safe to pause the instrument to prevent sequential and pretreatment tests from being lost.

- All Pause

  Stops all loading and pipetting operations, as well as bead and reagent dispensing. The assays in progress continue to process; however, no new samples are pipetted.

- Reagent Pause

  Stops the reagent carousel, reagent DRD, and reagent pipettor so no new reagent is dispensed. Other parts of the instrument continue processing assays.

- Bead Pause

  Stops the bead carousel so no new beads are dispensed. Other parts of the instrument continue processing assays.

  **NOTE:** You do not need to put the IMMULITE 2000 XPi instrument into PAUSE mode when loading samples.

- Sample Pause

  Pauses the sample carousel, sample DRD, and sample pipettor so no new sample is dispensed. Other parts of the instrument continue processing assays. Sample Pause may be delayed up to 36 seconds while the samples currently being processed finish processing.

### STOP Mode

All mechanical movements are stopped and no new tests are processed.

STOP mode is automatically initiated when no new samples have been processed in the last 20 minutes, as long as the instrument is not connected to an VersaCell.

### AutoStart Mode

***For the IMMULITE 2000 XPi Instrument Only***

Starts routine maintenance tasks automatically. For more information, refer to *AutoStart Maintenance (IMMULITE 2000 XPi System)*, page 5-35.

## Maintaining Reagent Wedges, Allergen Wedges and Bead Packs

Check the status of the reagent wedges, allergen wedges, and bead packs on board the instrument and replace the necessary wedges or packs.

### Checking the Status of Reagent Wedges and Allergen Wedges

Follow the instructions below to check the status of reagent wedges and allergen wedges:

1. If the Home screen is not displayed, select **HOME** to display it.
2. Select the **REAGENTS** circle.

   The Reagent Status screen displays.
3. Determine which wedges on the Reagent Carousel need to be replaced using the information in the Reagent Status screen.
4. If no wedges need to be replaced, proceed to *Checking the Status of Bead Packs*, page 2-19.

## Reagent Status Screen

The Reagent Status screen displays the status of all allergen wedges and reagent wedges on the reagent carousel. The information displayed in the Reagent Status screen includes:

- Reagent wedge test codes or allergen wedge IDs
- Allergen vial status for each allergen wedge
- Reagent wedge lot numbers
- Error messages
- Adjustment status
- Number of tests remaining in each compartment of a reagent wedge
- Wedge positions on the reagent carousel

Wedges are displayed alphanumerically by test code, not by their positions on the reagent carousel. Each wedge on the reagent carousel is represented by a square in the Reagent Status screen. On allergen wedge squares, allergen vial status is indicated in fields labeled 1 through 6, to represent the positions of allergen vials in the allergen wedges.

### Background color

The error status of a wedge is indicated by the color of its square in the Reagent Status screen. Allergen wedge squares have fields for each allergen vial that uses the same color scheme. The color of an allergen wedge square reflects that allergen wedge's highest priority error.

The following table contains a list of the background colors and the status associated with each color:

| Background Color | Status |
|---|---|
| White | No errors |
| Gray | Empty position on the Reagent Carousel or in an Allergen Wedge |
| Light brown | An error condition exists, but the wedge or allergen can still be used. Errors include:<br>• The reagent wedge has a few tests remaining.<br>• An allergen vial is expired.<br>• The adjustment is overdue for this kit.<br>• Kit is expired. |

| Background Color | Status |
|---|---|
| Red | An error condition exists which prohibits tests from being run. Error conditions include:<br>• The kit barcode was not entered on the instrument.<br>• The reagent wedge is empty.<br>• An allergen vial is empty.<br>• An allergen wedge was not entered on the instrument.<br>• The reagent wedge barcode could not be read.<br>• A matching bead pack is not onboard the instrument.<br>• The kit was never adjusted, but will run. |

## Error messages

If an error occurs for a reagent or allergen wedge, it displays in the square for the wedge in the Reagent Status screen.

- A plus (+) sign at the right of the error message indicates that a second error is associated with that wedge.
- Two plus (++) signs indicate that two or more additional errors exist for that wedge.

  Details about a wedge can be viewed in the Reagent Detail and Allergen Wedge Detail screens. These screens include a list of all errors that have occurred for the wedge. Refer to the next section for information about viewing wedge detail.

The table below contains some examples of errors and how they display in the Reagent Status screen:

| Error Message | Examples |
|---|---|
| Kit Expired + | The kit is expired and either the reagent wedge or bead pack has expired or an adjustment is due. |
| Kit Expired + + | The kit has expired and both the reagent wedge and bead pack have expired. |
| Adjustment Due + | An adjustment is due and the number of tests remaining is low. |
| Expired Beads + or Expired Matching Beads + | The bead pack has expired and an adjustment is due. |
| Expired Reagent + or Expired Matching Reagent + | The reagent wedge has expired and an adjustment is due. |

### *Viewing Wedge Detail*

All details for a wedge can be viewed using the Reagent Detail screen or Allergen Wedge Detail screen. The information in this screen includes a list of errors that have occurred for the wedge.

To display the Detail screen for a wedge while the instrument is in RUN mode, select the square for the wedge in the Reagent Status screen.

If the instrument is in PAUSE or STOP mode, follow these instructions to open the Reagent Detail or Allergen Wedge Detail screen:

1. Select **HOME**.
2. Select the **REAGENTS** circle.

   The Reagent Status screen displays.
3. Select **ROTATE**.

   The button changes to the **REVIEW** button.
4. Select the square corresponding to the reagent wedge or allergen wedge to view.
   - If the square for a reagent wedge is selected, the Reagent Detail screen displays.
   - If the square for an allergen wedge is selected, the Allergen Wedge Detail screen displays.
5. Select the **Close** button to close the screen.

## Replacing Reagent Wedges and Allergen Wedges

**WARNING**

Handle reagent and allergen wedges carefully to avoid agitation that might introduce bubbles. Bubbles in the reagent and allergen wedges can potentially cause incorrect results. Prior to processing samples, carefully inspect the wedges to ensure all bubbles are eliminated. Removal of the reagent carousel must be handled with care. Improper handling of the reagent carousel can introduce bubbles in the reagent wedge.

Follow these instructions to replace a reagent wedge or an allergen wedge.

**NOTE:** When loading a reagent or allergen wedge, handle carefully to avoid agitation that might introduce bubbles.

1. Open the small reagent carousel lid.

   The instrument enters Reagent PAUSE Mode. The Reagent Status screen displays.

2. If assays are running, a warning message displays requiring all doors to be closed and to select **RUN**.

   Depending on the type of assay running and if PAUSE MODE is intentionally enabled, one of the following messages displays:

   ```
   Sample pre-treatment assay detected on board. If you
   put the instrument in pause mode you will need to
   close all doors and press RUN in x minutes and xx
   seconds. Would you like to put the instrument in
   pause now?
   [Yes]   [No]
   ```

   ```
   Sequential assay detected on board. If you put the
   instrument in pause mode you will need to close all
   doors and press RUN in x minutes and xx seconds.
   Would you like to put the instrument in pause now?
   [Yes]   [No]
   ```

3. Select the square for the reagent wedge or allergen wedge to replace.

   The reagent carousel rotates so that the selected wedge is in front of the silver arrow.

**CAUTION**

Do not remove the wedge to change the position of the allergen vials within an allergen wedge until you perform the following procedure.

a. Open the small reagent carousel lid.

b. Be sure that the instrument has entered Reagent PAUSE mode.

c. Select the wedge's position using the Reagent Status window.

After changing the positions of the allergen vials in the allergen wedge, re-scan the wedge before loading it on the reagent carousel.

4. Remove the wedge by lifting the narrow end of the wedge near the center of the carousel, tilting the wedge back on its opposite end.

5. Slide the wedge toward the center of the carousel until the slot clears the tab on the carousel.

   The wedge should lift out easily.

   **NOTE:** When adding an allergen wedge, load the wedge with allergen vials, scan it using the imaging scanner, and follow the steps below to add it to the reagent carousel. Refer to *Entering Allergens and Allergen Wedges*, page 2-28.

6. Inspect the new reagent and/or reagent allergen wedge for bubbles.

7. If bubbles are observed, remove the bubbles prior to placing the system into run.

8. Place the new wedge between the carousel dividers with the barcode facing *out*.

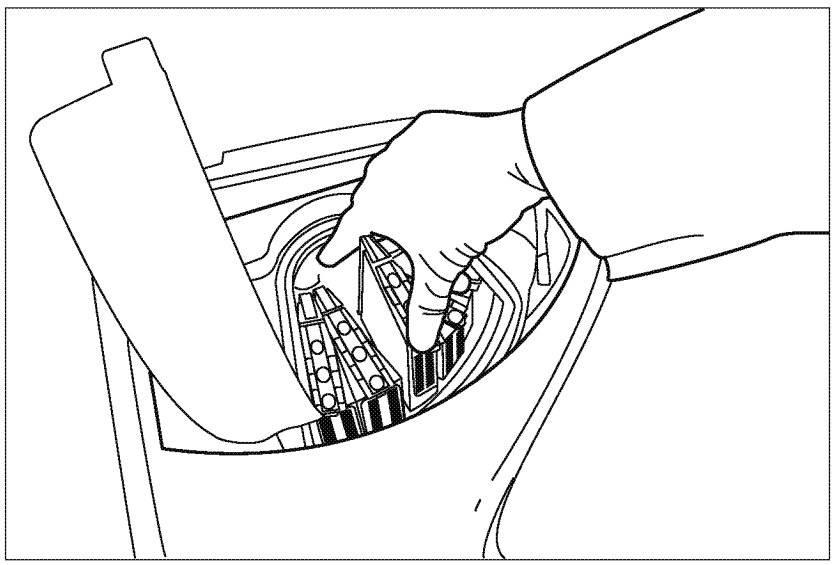
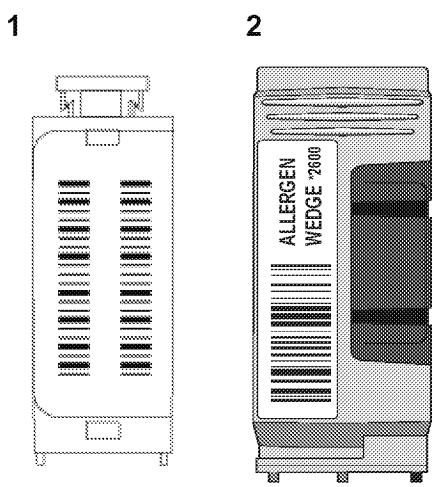


**Figure 2-7 Loading a Reagent Wedge**

9. Tilt the side of the wedge with the barcode label down so the tab on the reagent carousel locks into the wedge slot under the barcode label.




**1** Reagent wedge, side view
**2** Allergen wedge, side view

**Figure 2-8 IMMULITE System Wedges**

10. Press down on the narrow side of the wedge to lock it into place.

11. Push the glide of the wedge toward the center of the carousel to ensure that it moves freely.

### *Check for Bubbles or Moisture at the Top of the Wedge*

1. If bubbles are at the top of a reagent wedge:
   a. Remove the wedge.
   b. Carefully remove the glide.
   c. Dry the glide and the areas surrounding it where the probe enters the wedge.
   d. Replace the glide and re-load the wedge.
2. If there is moisture at the top of an allergen wedge:
   a. Remove the allergen wedge.
   b. Open the allergen wedge.
   c. Dry or replace the septum caps on the allergen vials and dry any liquid on top of the allergen wedge.
   d. Close the wedge and re-load it on the reagent carousel.

### *Procedural Notes*

**NOTE:** Kit components can remain on the instrument until they are empty or expired. Bead packs and reagent wedges expire 90 days after being loaded on the instrument. Kit components should not be used after the expiration date printed on the kit label.

**NOTE:** Allergen vials left on board the instrument expire 90 days after opening, due to evaporation. Allergens can evaporate up to 5 µL per day when left on the instrument.

To extend the life of infrequently used allergens, remove the vials from the instrument after each use, cap them with a standard cap, and refrigerate to minimize evaporation.

Alternatively, wrap the entire allergen wedge in parafilm, leaving the vials with the septum caps in place and refrigerate.

Allergens stored under these conditions (refrigerated and protected from air exposure) may be used until the expiration date printed on the vial label.

### *Completing the Procedure*

1. Close the reagent carousel lid.
2. Apply pressure until it clicks into place.
3. Select **RUN** to update the reagent status screen.

**NOTE:** An error message displays in the reagent status screen if the kit barcode for a loaded reagent wedge was not entered. If a loaded allergen wedge has not been scanned, a message displays.

4. Select the **CLOSE** button to close the Reagent Status screen and return to the Home screen.

### Checking the Status of Bead Packs

Follow the instructions below to check the status of bead packs:

1. If the Home screen is not displayed, select **HOME** to display it.
2. Select the **BEADS** circle.

   **NOTE:** If no bead packs require replacement, proceed to *Labeling and Loading Sample Tubes*, page 2-2.

3. Determine which bead packs on the bead carousel need to be replaced using the information in the Bead Status screen.

## *Using the Bead Status screen*

The Bead Status screen displays the status of all bead packs on the bead carousel. The information displayed in the Bead Status screen includes:

- Bead pack names
- Bead pack lot numbers
- Error messages
- Number of tests remaining in bead packs
- Bead pack positions on the bead carousel

Bead packs are displayed alphanumerically by test code, not by their positions on the bead carousel. Each bead pack on the bead carousel is represented by a square in the Bead Status screen.

### Background Color

The error status of a bead pack is indicated by the color of its square in the Bead Status screen. The following table contains a list of the background colors and the status associated with each color.

| Background Color | Status |
|---|---|
| White | No errors |
| Gray | Empty position on the bead carousel |
| light brown | An error condition exists, but the bead pack can still be used. Errors include the following:<br>• the bead pack has a few test remaining<br>• the adjustment is overdue for this kit |

| Background Color | Status |
|---|---|
| red | An error condition exists which prohibits tests from being run. Error conditions include:<br>• the kit barcode was not entered on the instrument<br>• the bead pack is empty<br>• the bead pack barcode could not be read<br>• a matching reagent wedge is not onboard the instrument<br>• the kit was never adjusted, but it will run |

## Error Messages

If an error occurs for a bead pack, it displays in the square for the bead pack in the Bead Status screen.

- A plus (+) sign at the right of the error message indicates that a second error is associated with that bead pack.
- Two plus (+) signs indicate that two or more additional errors exist for that bead pack.

Details about a bead pack can be viewed in the Bead Detail screen. This screen includes a list of all errors that have occurred for the bead pack. Refer to the next section for information about viewing bead pack detail.

The following table contains some examples of errors and how they display in the Bead Status screen.

| Error Message | Explanation |
|---|---|
| Kit Expired + | The Kit is expired and either the reagent wedge or bead pack is expired or an adjustment is due. |
| Kit Expired + + | The kit is expired and both the reagent wedge and bead pack are expired. |
| Adjustment Due + | An adjustment is due and the number of tests remaining is low. |
| Expired Beads + *or* Expired Matching Beads + | The bead pack is expired and an adjustment is due. |
| Expired Reagent + *or* Expired Matching Reagent + | The reagent wedge is expired and an adjustment is due. |

## Viewing Bead Pack Detail

All details for a bead pack can be viewed in the Bead Detail screen. The information in this screen includes a list of errors that have occurred for the bead pack.

To display the Bead Detail screen for a bead pack while the instrument is in RUN mode, select the square for the bead pack in the Bead Status screen.

If the instrument is in PAUSE or STOP mode, follow these instructions to open the Bead Detail screen:

1. Select **HOME**.
2. Select the **BEADS** circle.

   The Bead Status screen displays.
3. Select **ROTATE**.

   The button changes to the **REVIEW** button.
4. Select the square corresponding to the bead pack to be viewed. The Bead Detail screen displays.
5. Select **CLOSE**.

## Replacing Bead Packs

Follow these instructions to replace a bead pack.

1. Swing the monitor out of the way and open the bead carousel lid.

   The instrument enters BEAD PAUSE mode. If the reagent carousel lid is not closed when the bead carousel lid is opened, a screen displays indicating that the instrument is in Multiple PAUSE Mode.
2. Select the button corresponding to the bead status screen.
3. If assays are running, a warning message displays requiring all doors to be closed and to select **RUN**.

   Depending on the type of assay running and if PAUSE MODE is intentionally enabled, one of the following messages displays:

   ```
   Sample pre-treatment assay detected on board. If you
   put the instrument in pause mode you will need to
   close all doors and press RUN in x minutes and xx
   seconds. Would you like to put the instrument in
   pause now?
   [Yes]   [No]
   ```

   ```
   Sequential assay detected on board. If you put the
   instrument in pause mode you will need to close all
   doors and press RUN in x minutes and xx seconds.
   Would you like to put the instrument in pause now?
   [Yes]   [No]
   ```
4. Select the square for the bead pack to be replaced. The bead carousel rotates so that the selected bead pack is in front of the black arrow.
5. Remove the bead pack to be replaced.
   a. Lift the barcoded edge of the bead pack and tilt it toward the center of the bead carousel.

b. Slide the bead pack away from the center of the carousel until the bead pack plunger clears the opening at the center of the carousel. The bead pack should lift out easily.

6. Load the new bead pack.
   a. Place the bead pack between the carousel dividers with the barcode facing out.
   b. Tilt the side of the bead pack opposite the barcode label down and insert the plunger into the opening at the center of the carousel.
   c. Snap the barcoded side of the bead pack into position on the carousel. Be sure it is locked in place.

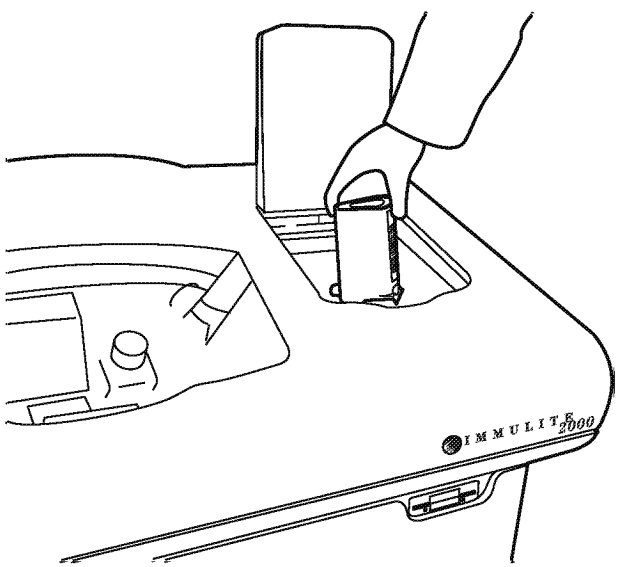



**Figure 2-9 Loading the Bead Pack**

7. Close the bead carousel lid.
8. Select **RUN** to update the Bead Status screen.
   - An error message displays in the Bead Status screen if the kit barcode for the loaded bead pack has not been entered.
     Refer to *Entering a Kit*, page 2-25.
   - Kit components can remain on the instrument until they are empty or expired.
   - Bead packs and reagent wedges expire 90 days after being loaded on the instrument. Kit components should not be used after the expiration date printed on the kit label.
9. Select the **CLOSE** button to close the Bead Status screen and return to the Home screen.

# IMMULITE 2000 XPi Kit Load Report

The Kit Load Report feature of the IMMULITE 2000 XPi helps the operator prepare for the anticipated day's workload by generating a list of tests needed based on current instrument inventory and historical assay consumption. The report provides the estimated daily average of assays processed over a selected period and a list of the recommended number of tests needed to meet the average workload.

## Viewing the Kit Load Report

To generate a Kit Load Report for viewing, do the following:

1. At the tool bar, select **REPORTS**.

   The Reports window displays.

2. At the Reports window, select **KIT LOAD REPORT**.

   The Kit Load Report review window displays.

   **NOTE:** The default period is the selection made when the report was last generated. The default period for initial entry into the report is 4 weeks. The maximum period is 8 weeks.

3. To change the default number of days or weeks, select the number and day or week from the drop-down lists next to "Display average use from last:"

   Example:

   To report the average usage for the last 6 Tuesdays, select 6 from the left drop-down list and Tuesday from the right drop-down list.

4. Select the type of information to display from the following buttons:

| Buttons | Description |
|---|---|
| Immunoassay | Generate report details for immunoassay activity for a selected period. If immunoassay activity occurs during the period being reported, Immunoassay is the default selection. |
| Allergy | Generate report details for allergy activity for a selected period. If no immunoassay activity occurs during the period being reported, Allergy is the default selection. |

5. Select **Refresh**.

   **NOTE:** Kit Load Report details are not refreshed automatically. A box in the upper right corner of the window displays the date and time the report data was last refreshed.

6. To change the sort order, select the appropriate column header.

***Kit Load Report Data***

| Column | Data Description |
|---|---|
| Assay | A list of Assays tested during the period selected. |
| Average Use | The average daily number of tests run per assay for the selected period. |
| Processed Today | The number of tests per assay that have been processed for the current day. |
| Tests Onboard | The number of tests per assay that remain in the kits currently onboard. |
| Load Estimate | The number of assays recommended to meet the estimated workload (Load Estimate = Average Use - Tests Onboard); 0 if sufficient kit components are onboard. |

**NOTE:** The report's default sort order is by Load Estimate, descending quantities.

## Printing the Kit Load Report

To print the Kit Load Report, do the following:

1. At the Kit Load Report window, select **Refresh**.

   **NOTE:** Printing does not refresh the Kit Load Report.

2. At the Kit Load Report window, select **Print**.

   The print configuration window displays.

3. In the ASSAY TYPE box, select one of the following options:

| ASSAY TYPE | Description |
|---|---|
| Immunoassay | Include only a list of immunoassay kits recommended to load. |
| Allergy | Include only a list of allergy kits recommended to load. |
| All Assays | Include a list of all kits recommended to load. All Assays is the default selection. |

4. In the REPORT DATA box, select one of the following options:

| REPORT DATA | Description |
|---|---|
| Exceptions Only | Limit the printed report to only those immunoassay or allergy tests that are estimated to need more kit components. Exceptions Only is the default selection. |
| All | Print a report of all immunoassay and/or allergy tests displayed in the Kit Load Report review window. |

5. To print the report, select **Print Report**.

   The instrument prints the report, and the print configuration window closes.

### Reviewing the Printed Report

The report header details are as follows:

- Instrument ID
- Instrument Name
- The date and time the report was last refreshed.
- The period the usage was averaged over (Display average use from last).
- The type of data (Immunoassay or Allergy).

The printed report data is sorted by the same criteria, and in the same order as the Kit Load Report review window data.

| Data | Description |
|---|---|
| Assay | A list of Assays tested during the period selected.<br>If the Assay name is followed by an asterisk (*), the assay requires diluent onboard to run. |
| Kit Lot | The Kit Lots for each assay onboard are separated by commas.<br>**NOTE:** If no kits are onboard for this assay, the Kit Lot list is empty. |
| Average Use | The average daily number of tests run per assay for the selected period. |
| Processed Today | The number of tests per assay that have been processed for the current day. |
| Tests Onboard | The number of tests per assay that remain in the kits currently onboard. |
| Load Estimate | The number of assays recommended to meet the estimated workload (Load Estimate = Average Use - Tests Onboard);<br>0 if there are sufficient kit components onboard. |

## *Entering a Kit*

**NOTE:** Scan the kit lot barcode before loading reagents onto the system.

Before using a new kit, the new kit lot must be entered on the instrument using the hand-held scanner. After a kit is entered, existing kit information can be reviewed. *Reviewing Kit Information*, page 2-31. Follow the instructions below to enter a new kit.

**NOTE:** Before using a new assay or kit lot number, adjustments must be run. Refer to *Adjusting an Assay*, page 2-33 for instructions.

#### *For Non Allergy Kits*

Scan the 2D barcode located on the inner flap of the kit box. Refer to *Scanning a 2D Kit Barcode Using a 2D Scanner*, page 2-26.

***For Allergy Kits***

If allergy kits are used, follow the instructions for scanning a 2D barcode using an imaging scanner. Follow the instructions below for the appropriate scanner.

- If three different kit lots for the same assay are in the database and a fourth kit lot for that assay is scanned, a prompt displays to select which existing kit lot to delete.
- If a kit lot that is already in the system is re-scanned, a prompt displays asking if the active kit information should be overwritten with the new kit information.
  - If **Overwrite** is selected, the slope and intercept for the kit being overwritten will revert back to the slope and intercept of the Master Curve.
  - If the new kit is not adjusted, patient results are flagged with ADJ. Refer to *Flags Associated with Results*, page H-4.

## Scanning a 2D Kit Barcode Using a 2D Scanner

1. Hold the scanner 2 to 3 inches away from the 2D barcode.
2. Keep the angled face of the scanner parallel to the barcode.
3. Press and hold the trigger button on the scanner.

   An orange beam displays.
4. Begin scanning in the white area above the 2D barcode.
5. Move the scanner at an even rate over the entire barcode.

   A clicking noise during scanning indicates that the barcode is being read. A high-pitched tone sounds when the scan is successful. If the scan was not successful, a low-pitched tone may sound. Rescan the barcode until a high-pitched tone is heard.

   The Kits screen displays information about the kit.

## Scanning a 2D Kit Barcode Using an Imaging Scanner

1. Hold the scanner 5–7 inches away from the 2D barcode.
2. Keep the angled face of the scanner parallel to the barcode.
3. Press and hold the trigger button on the scanner and point the scanner beam at the center of the barcode.
4. Scan at the center of the barcode.

   **NOTE:** Do not move the scanner over the entire barcode as you would with a 2D scanner.

5. Hold the scanner button until a tone sounds to indicate that the barcode was read successfully.

   The Kits screen displays information about the kit.The table below explains each field in the Kits screen.

| Field | Explanation |
|---|---|
| Find button | Used to enter a test code and lot number to display information about a particular assay. |
| Previous Kit/Next Kit buttons | Displays information for the previous kit or next kit in the database.<br>Kit information in the database is displayed for one kit at a time, in alphanumerical order by test code. |
| Allergens / Kits button | Displays information about allergens in the database. The button changes to the Kits button.<br>Select the Kits button to display information about assay kits in the database. The button changes to the Allergens button. |
| Test Code | Code used to indicate a specific assay. |
| Kit Lot | Kit lot number. |
| Bead Lot | Bead lot number used by the kit. |
| Reagent Lot | Reagent lot number used by the kit. |
| Low Adjustor Lot | Lot number of the low adjustor. |
| Low Adjustor CPS | The master curve CPS for the low adjustor. |
| Adjustor Allergen Lot | Lot number of the high adjustor. |
| Control Allergen Lot | Lot number for the kit's control antibody.<br>This field is inactive for immunoassay kits. |
| Last Adjustment | Date of the last adjustment. |
| Next Adjustment | Date a readjustment is due. |
| Adjustment Status | Current kit adjustment status:<br>• Over Due – the kit adjustment is overdue.<br>• Adjusted – the kit is adjusted.<br>• Not Adjusted – the kit barcode was scanned but the kit was not adjusted. |
| Kit Status | Current kit status:<br>• Expired – the kit is expired.<br>• Valid – the kit has been adjusted and is not expired.<br>• New Kit – the kit barcode has been scanned but the kit has not been adjusted. |
| Diluent | Name of the diluent used by the kit. |
| Kit Expiration | Kit expiration date. |
| Slope | Slope calculated for the last adjustment. |
| Intercept | Intercept calculated for the last adjustment. |

| Field | Explanation |
|---|---|
| Slope Limits | Kit-specific slope ranges used to determine if an adjustment was successful.<br>Scanning the 2D kit barcode enters kit-specific slope ranges into the database. This field displays in gray when viewing information about an immunoglobulin kit. |
| Sample Volume µl | Amount of sample needed for the test to run. |
| Parameter 1<br>Parameter 2 | Values used together to define the master curve for this kit lot. |

## Entering Allergens and Allergen Wedges

Every kit contains a reagent wedge that must be loaded on the instrument before performing assays for that kit. If an allergy kit is loaded, enter at least one allergen wedge and place it on the reagent carousel before running allergy tests.

Specific allergens are required to test patient samples for allergic reactions. The vials containing specific allergens must be entered in the system individually using a 2D barcode similar to those for assay kits.

The allergen vials must then be loaded into allergen wedges. One allergen wedge can hold up to six allergen vials. The loaded allergen wedges must then be entered in the system using the imaging scanner.

This establishes the locations of allergens on the instrument when the allergen wedges are placed on the reagent carousel.

Each allergen vial has an affixed barcode label and a corresponding 2D barcode label. Barcode labels identifying the same allergen vial have the same human-readable code, such as d1.

**NOTE:** Do not take the allergen wedges apart. If the allergen wedges are taken apart and re-assembled incorrectly, such as incorrectly matching the pieces together, the instrument will pipette from the wrong allergen vial.

Each allergen wedge is labeled with one barcode on the spine and one on the inner black portion. The barcode labels must match. Otherwise, the wedge location and contents will not be correctly recorded and the vials will be incorrectly pipetted.

Allergen vials are flagged with the 2D barcode label before they are shipped. The 2D barcode contains all the information the system requires to use that vial for allergy tests.

Follow these instructions to enter an allergen wedge.

1. Scan the 2D barcode for each allergen vial to be loaded in the allergen wedge.

   The allergen kit screen displays information about the allergen.

| Field | Explanation |
|---|---|
| Allergens button | Select this button to display information about immunoassay kits in the database.<br>The button changes to the Kits button. |
| Find button | Select this button to enter an allergen code and lot number to display information about that allergen. |
| Previous AGN/ Next AGN | Select these buttons to display information for the previous allergen or next allergen in the database.<br>Allergen information in the database is displayed for one allergen at a time, in alphanumerical order by allergen code. |
| Allergen Code | Code used to indicate a specific allergen. |
| Allergen Lot | Allergen Lot Number |
| Allergen Status | Current allergen status:<br>• Expired – the allergen is expired<br>• Valid – the allergen is not expired |
| Allergen Expiration Date | Allergen expiration date. |

   **NOTE:** When running an adjustor, one of the allergen wedges loaded on the reagent carousel must contain one adjustor antibody. Be sure to scan the 2D barcode for the adjustor antibody just as with any other allergen.

2. Remove the 2D barcode labels from the vials scanned in step 1.

   Be sure the standard barcodes remain affixed to each vial.

3. Replace the cap on each allergen vial with a septum cap, and then place the vial in the allergen wedge.

   Be sure the barcode on each allergen vial faces out, so it is visible when the allergen wedge is closed.

**NOTE:** When storing opened allergen vials off the instrument, replace the septum cap with a new standard cap to prevent evaporation. When using the allergen vial again, replace the standard cap with a new septum cap.

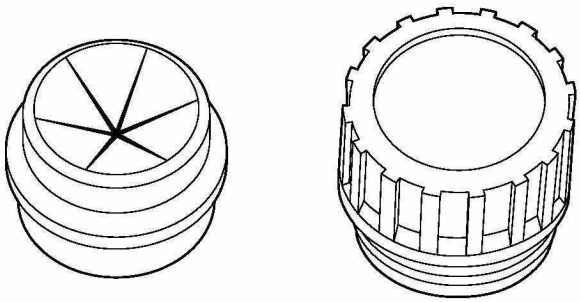


**Figure 2-10 Allergen Vial Caps**

*Figure 2-11* displays how the vials are inserted in the wedge.

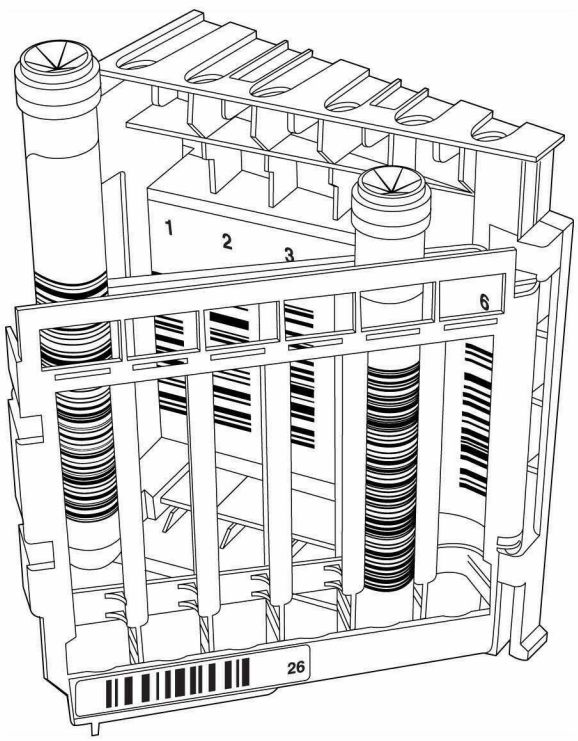



**Figure 2-11 Loading Vials in an Allergen Wedge**

4. Hold the scanner steady, about 5 inches from the allergen wedge, being sure not to obscure any of the barcodes on the allergen wedge or the allergen vials.
5. Press and hold the scanner button.

6. Point the scanner beam at the center of the allergen barcodes.

   The allergen barcodes, the outside allergen wedge barcode, and any barcodes behind the empty vial spaces should be read in a single scan.

   The Allergen Wedge Detail screen displays details about the allergen wedge scanned.

   **NOTE:** If any information in the Allergen Wedge Detail screen displays in red, a scanner misread has occurred. Scan the allergen wedge again.

7. Select the **Close** button to close the Allergen Wedge Detail screen.

   A message displays stating not to swap allergen vials.

8. Select **OK**.

   **NOTE:** If the allergens are changed or the allergen vials are rearranged in an allergen wedge previously scanned, scan the allergen wedge again before loading it on the instrument.

9. Load the allergen wedge on the reagent carousel.

   **NOTE:** Select a position on the carousel to load the allergen wedge.

### Reviewing Kit Information

To review existing kit information, follow the instructions below:

1. Select the **KITS** button on the toolbar.
2. Select one of the following options:
   - Select the **Previous Kit** or **Next Kit** buttons to view information for the kits currently entered in the system.
   - Select the **Find** button.
3. To view the appropriate kit information, type the test code (located on the 2D Barcode label) and the kit lot number, and then select the **Find Kit** button.

   **NOTE:** The kit can also be found by entering just the test code.

4. To toggle back and forth between kit and allergen information, select **Kits** and **Allergen**.

## *Configuring Kit Lot Deactivation*

Follow these steps to deactivate or activate a kit lot:

**NOTE:** Any tests in progress or in queue continue to run and result as usual after a kit lot is deactivated.

1. At the tool bar, select **KITS**.

   The Kits window displays.

   **NOTE:** Use Previous Kit, Next Kit, or Find to locate a particular kit lot.

2. Select **Kit Deactivation**.

   The Kit Lot Deactivation window displays.

3. From the drop-down list, select an assay for which you want to activate/ deactivate kit lots.

4. To deactivate a single kit lot for the selected assay, select its option box in the grid under the headers **Deactivated Patient Samples** or **Deactivated for All Samples**.

   A check mark displays in the box indicating the kit's current status.

   **NOTE:** Alternatively, to activate a single kit lot for the selected assay, select its option box in the grid under the header **Active for All Samples**.

5. To deactivate all kit lots for the selected assay, select the header **Deactivated Patient Samples** or **Deactivated for All Samples**.

   Check marks display for each kit lot in the column.

   **NOTE:** Alternatively, to activate all kit lots for the selected assay, select the header **Active for All Samples**.

| Option | Description |
|---|---|
| **Active for All Samples**: | Can process all orders with this kit lot. |
| **Deactivated Patient Samples**: | Can process only adjustor, control, and verifier orders with this kit lot. |
| **Deactivated for All Samples**: | Cannot process orders with this kit lot. |

   **NOTE:** In integrated mode, if kits are either deactivated for patient samples or all samples, "No Inventory" is displayed for that assay on the VersaCell system.

   **NOTE:** The kit lot is added or removed from the list of Currently Deactivated Kits after selecting **SAVE**.

6. Select **SAVE** to accept the changes or **CANCEL** to ignore them.

7. To configure additional kit lots, select a different assay from the drop-down box next to the "For this TEST:" heading and repeat this procedure.

8. To exit the Kit Lot Deactivation window, select **CLOSE**.

To access the Kit Deactivation window from other windows:

- From the Reagent detail window, select **Kit Deactivation**.

  The Kit Deactivation window displays.

- From the Beads detail window, select **Kit Deactivation**.

  The Kit Deactivation window displays.

### Kit Deactivation Status

Indicators display as follows when a kit lot is deactivated:

| Window | Description |
|---|---|
| KITS | The deactivation status displays in the upper right corner of the KITS window if a kit lot is deactivated. |
| Reagents | Shading of a reagent indicates a deactivated status. Select a wedge for more information. |
| Beads | Shading of a bead pack indicates a deactivated status. Select bead pack for more information. |
| Reagent Detail | The deactivation status displays in the Current Deactivation Status box. If necessary, select **Kit Deactivation** to change the kit's deactivation status. Refer to *Configuring Kit Lot Deactivation* for more information. |
| Bead Detail | The deactivation status displays in the Current Deactivation Status box. If necessary, select **Kit Deactivation** to change the kit's deactivation status. Refer to *Configuring Kit Lot Deactivation* for more information. |
| Consumables Report | The status of a deactivated kit displays on the Consumables Report window. |
| Worklist Display/Edit | Deactivated displays in the Status column when an order cannot run if a kit lot is deactivated. |
| Sample Tubes in Racks | Samples with orders associated with deactivated kits are coded KIT ERROR/DEACTIVATED. |
| Rack Detail | In the textbox, Deactivated displays next to the test code when an order cannot run due to kit deactivation. |

## *Adjusting an Assay*

Before using a new kit lot, an adjustment must be run. This initial adjustment corrects for any variations in performance between your instrument and the manufacturer's instrument.

In addition, kits must be readjusted periodically. The adjustment schedule for a kit is indicated in the kit's package insert. The Reagent Status and Bead Status screens indicate if an adjustment is due. Refer to *Checking the Status of Reagent Wedges and Allergen Wedges*, page 2-12 and *Checking the Status of Bead Packs*, page 2-19.

Follow the instructions below to adjust an assay:

1. Remove the adjustor barcode labels from the kit.
2. Place a label for an A adjustor on one tube and a label for a B adjustor on another tube.

**NOTE:** When a kit contains only one adjustor, use the A adjustor label.

3. Remove the adjustor bottles from the kit and transfer each adjustor to the corresponding tube.
4. To adjust an allergy assay:
   - Enter the adjustor antibody by scanning its 2D barcode.
   - Place the adjustor antibody in an allergen wedge.
   - Enter the allergen wedge using the imaging scanner.
   - Load the allergen wedge on the reagent carousel.

   Refer to *Entering Allergens and Allergen Wedges*, page 2-28 for more information about using adjustor antibodies.
5. Select **HOME**.
6. Select the letter for the sample rack in which to load the adjustors.

   The sample carousel rotates so that the rack is accessible.

   **NOTE:** The instrument must be in PAUSE or STOP mode for the rack to rotate. If the rack does not rotate, open the sample carousel door to initiate the SAMPLE PAUSE mode.
7. Open the sample carousel door and grasp the rack using the finger indentations.
8. Pull the rack forward until it slides out of the sample carousel.

   **NOTE:** Be sure that the bottom of the barcode label is not hidden by the rack. The entire barcode label must be readable.
9. Load the adjustor tubes on the sample rack so the barcodes face out.

   **NOTE:** You may not adjust an assay while the previous adjustment for that assay is still running.
10. Depending on the instrument, perform the following steps:

    For the IMMULITE 2000 system or the IMMULITE 2500 system:

    a. Slide the rack back into the carousel.
    b. Be sure it snaps into position.
    c. Close the Sample Carousel door.

    For the IMMULITE 2000 XPi system:

    a. Set the sample rack into the sample tray.
    b. Close the cover.
11. Select **RUN**.

    The sample carousel is interrogated.

12. When the sample carousel has been interrogated completely, select the **WORKLIST** button.

    The Worklist screen displays.

13. Display the information for the A adjustor in the Worklist screen.

    The A adjustor is level 01.

    a. If adjustors with barcodes have been loaded:

       Browse the records using the **Previous** and **Next** buttons. Locate the record with the adjustor's lot number in the Adjustor Lot # field and 01 in the Adjustor Level field.

    b. If the adjustor barcode is damaged or missing:

    c. Select **Adjustor**.

    d. Select **New**.

    e. Enter the adjustor lot number and the adjustor level.

    f. Associate the tube and its position with the unique sample accession number.

       Refer *Assigning a Tube Position*, page 2-56.

14. Enter the lot number of the kit you are adjusting in the Kit Lot # field.

15. When adjusting an allergy assay, enter the lot number for the adjustor antibody loaded in step 4 in the **Adj Allergen Lot #** field.

16. Select **ACCEPT ADJUSTOR**.

    If the system is in RUN mode, the next barcoded record displays.

    **NOTE:** The A adjustor must be accepted first.

17. If the assay being adjusted has one a B adjustor, repeat steps 13 through 16 to assign a kit lot number to it.

    The B adjustor level is 02.

18. Select **Display/Edit**.

19. At the Display Worklist screen, select the **UPDATE SCREEN** button and use the Status column to determine the status of the samples.

## Adjustment Printout

The adjustment printout displays interpretive information to aid in the evaluation of adjustments. In addition, the adjustment printout indicates whether or not the adjustment is complete. The following table displays information about 2 adjustor assays;

| Calculation | Description |
|---|---|
| Instrument slope range | Plus or minus 20% of the average instrument slope |
| Previous slope range | Plus or minus 10% of the previous successful adjustment for a specific kit lot |

| Calculation | Description |
|---|---|
| Assay average slope | Average slope of all successful adjustments for an assay. |
| Intercept guideline | • Sandwich assays<br>30% of the low adjustor CPS from the kit barcode<br>• Competitive assays<br>2% of curve parameter 1 |

The following table displays information about a single adjustor assay.

| Feature | Description |
|---|---|
| Previous assay adjustment index | Adjustment index of the last successful adjustment |

***Adjustment Complete***

- If the slope for the adjustment does not exceed the rejection limits, the adjustment printout displays this message at the bottom of the page:

  `Adjustment Complete`

- If the CVs of the replicates of the low and high Adjustor are within the acceptable limits, the adjustment displays this message:

  `Adjustment Complete`

- For any adjustment marked Adjustment Complete, review the adjustment guidelines to determine if the adjustment is valid.

***Adjustment was not Successful***

- If the CVs of the replicates are outside the acceptable limits, the adjustment displays this message:

  `CV of High (or Low) adjustors not within limit.`

  Both the low and high adjustors must be run again before running patient samples.

- If the slope is outside the rejection limits, the Adjustment report displays this message:

  `Exceeded rejection limits for slope`

  The slope limit failed.

  **NOTE:** The instrument continues to process and report controls and patient samples on adjustments exceeding rejection limits. Readjust assays exceeding the adjustment rejection limits to ensure accurate patient results.

  **NOTE:** If the adjustment slope fails, patient results are flagged ADJ, and the instrument uses the last valid adjustment slope and intercept for the kit lot to calculate patient results. If no previous valid adjustment is available, the instrument uses the Master Curve.

Refer to *Viewing the Adjustment Log*, page 2-40 for more information.

### Checking Adjustment Validity

When judging adjustment validity, evaluate the control results, slope, and intercept according to the table below:

| Guideline | Description |
|---|---|
| Control results | After control ranges are established, controls must be run to verify kit adjustment before patient samples are processed. If the controls are out of range:<br>• Follow accepted laboratory protocols for investigating QC failure; correct any problems found and run the controls again.<br>• If they are still out of range, and no other problem can be identified, re-adjust the kit.<br>• If the problem persists, contact your local service provider or distributor.<br>Refer to *Master Curve/Two-Point Adjustment*, page 3-1 for more information on Master Curve generation and for more information on the two-point adjustment process. |
| Slope | • Initial adjustment of a new kit lot:<br>The slope should fall within the instrument slope range, meaning plus or minus 20% of the mean slope for that instrument.<br>• Re-adjustment of same kit lot:<br>Within a kit lot, the slope calculated during readjustment should fall within 10% of the previous slope. Refer to *Master Curve/Two-Point Adjustment*, page 3-1. |
| Intercept | Check the intercept of adjustment.<br>The absolute value of the intercept should be less than or equal to the intercept guideline.<br>Refer to *Intercept of Adjustment for an Immunometric (Sandwich) Assay*, page 3-5 for further information on evaluation of intercepts. |

## *Running Assays*

To run the assays, at the instrument screen, select **RUN**.

As tests are completed, results display on the Home screen.

**NOTE:** If not enough kit components (bead packs, reagent wedges, or diluents) are onboard to run the tests, or if a barcode label is missing, the **Consumables** button turns red.

### Checking the Sample Status

Follow the instructions below to check the status of the samples onboard the instrument:

***For IMMULITE 2000 System or IMMULITE 2500 System***

1. At the instrument menu, select **Tools**.
2. Select **Show Sample Tubes in Racks**.
3. Proceed to step 3 in the next section.

***For IMMULITE 2000 XPi System***

1. At the instrument screen, select **MENU**.
2. Select **Sample Tubes in Racks**.
3. To access the Sample Rack Detail screen, select a rack letter.
4. Select a specific sample tube position (1-15) on a rack to access the detailed sample information on the Sample Rack Detail screen.
5. Select **Update** to display the most current information on the samples.
6. Select **Close** to leave the screen.

## Checking the Test Time Remaining

Follow the instructions below to view the test time remaining for assays that meet the search criteria. For example, viewing the test time remaining for all TSH assays.

1. In the Home screen, select **FIND**.

   The Find Sample screen displays.

   The default entry in both the **From** and **To** fields is the current date.
2. Follow the instructions in this step to enter a different date range.
   a. Click the **From** field.

      The calendar view of the Find Sample screen displays.
   b. Use the **Month** and **Year** buttons to display the calendar of the first month in the date range.
   c. Select the day to begin the date range.

      The date changes in the **From** field.
   d. Select the **To** field.
   e. Use the **Month** and **Year** buttons to display the calendar of the last month in the date range.
   f. Select the day to end the date range.

      The date changes in the **To** field.
   g. Select the **OK** button to accept the entries and close the calendar view of the screen.
3. Make any selections in the **Accession #**, **Name, Test Type and Allergen Type** fields to enter other details about the sample.

**NOTE:** Enter a single letter in the **Name** field to find samples with names that begin with that letter.

4. Select **FIND**.

   The Records Found screen displays displaying information about the samples that match the criteria entered.

5. To view historical results for a patient or sample:

   a. Select a record in the Records Found screen.

   b. Select **REVIEW**.

      The Review screen for this patient or sample displays.

## Checking the Tests Ordered and Time Remaining

With the instrument in RUN mode, follow the instructions below to view the tests ordered and the test time remaining for a particular sample.

1. From the Home screen, select the appropriate rack.

   The Sample Rack Detail screen displays, displaying:

   - The samples currently onboard the selected Sample Rack
   - The name, sample type, and tube type for the selected sample
   - The tests running for the selected sample with the time remaining
   - The tests resulted for the selected sample

   The sample description next to the numbers (1-15) indicates the sample type.

| Sample Type | Sample Description |
|---|---|
| Patient | Displays as either the accession number or the patient's name. |
| Adjustor | Begins with ~A. |
| Control | Begins with ~C or can be user-defined. |
| Calibration Verifier | Begins with ~V. |
| Diluent | Begins with ~D. |

2. To select a new sample, select the field to the right of the sample number (1–15).

   The information on the right side of the screen changes.

3. Select the **CLOSE** button to return to the previous screen.

   **NOTE:** Select **SAMPLE TUBES** to return to the Sample Status screen.

## Find Last Tube Location

Follow these instructions to determine the rack and position where a specified tube was last located. This feature is available for barcoded patient samples only.

**NOTE:** At the Configurations – Display Options screen, ensure that Use Barcode Rack Identifier is turned on. The Find Last Tube Location feature will not work unless it is activated.

***For IMMULITE 2000 System or IMMULITE 2500 System***

1. At the instrument menu, select **Tools**.
2. Select **Find Last Tube Location**.
3. Proceed to step 3 in the next section.

***For IMMULITE 2000 XPi System***

1. At the instrument screen, select **MENU**.
2. Select **Find Last Tube Location**.
3. In the Find Last Tube Location window, enter the unique accession number of the tube to search.
4. Select **FIND**.

## Viewing the Adjustment Log

Follow the instructions below to view the adjustment log, displaying the adjustment history.

***For IMMULITE 2000 System or IMMULITE 2500 System***

1. At the instrument menu, select **Tools**.
2. Select **View Adjustment Log**.
3. Proceed to step 3 in the next section.

***For IMMULITE 2000 XPi System***

1. At the instrument screen, select **MENU**.
2. Select **Adjustment Log**.
3. At the adjustment log, select the **FROM** and **TO** dates by clicking in the **FROM** and **TO** fields, and then selecting dates from the calendar.
4. Use the down arrow to the right of the TEST TYPE field, and then select the test.
5. Select **FIND**.

   The Adjustment Log View screen displays a list of adjustments, beginning with the most recent adjustment.
6. To review adjustment data, select an adjustment and select **REVIEW**.
7. At the Adjustment Review screen, select **PRINT** to print the screen.

8. Select **CLOSE** on the Adjustment Review screen.

   The Adjustment Log View screen displays.

9. Select **CLOSE**.

### Viewing Beads and Reagents On Board

Follow the instructions below to view the beads and reagents currently on board the instrument.

**NOTE:** If an adjustment is due in the next 24 hours, the adjustment due date displays in yellow.

***For IMMULITE 2000 System or IMMULITE 2500 System***

1. At the instrument menu, select **Tools**.
2. Select **View Bead Reagents On Board**.
3. Proceed to step 3 in the next section.

***For IMMULITE 2000 XPi System***

1. At the instrument screen, select **MENU**.
2. Select **Bead Reagents Onboard**.

   **NOTE:** If the screen is blank, select the **BEADS ONBOARD** or the **REAGENTS ONBOARD** button.

3. Select **CLOSE**.

### Viewing Allergens On Board

To view information about the Allergens currently on board the instrument, select **View Allergens On Board**.

***For IMMULITE 2000 System or IMMULITE 2500 System***

1. At the instrument menu, select **Tools**.
2. Select **View Allergens On Board**.

***For IMMULITE 2000 XPi System***

1. At the instrument screen, select **MENU**.
2. Select **Allergens Onboard**.

## *Managing Worklist*

A worklist specifies which tests to run for each sample. If the instrument is connected to an LIS, worklists for patient samples are entered automatically.

The operator uses the Worklist screen to do these tasks:

- Add patients to a worklist, if necessary:
  - When the system is not connected to an LIS.
  - If barcodes are damaged or missing.
- Specify tests for control and calibration verifier samples.
- Adjust assays.
- Order dilution samples (onboard and manually).
- Specify STAT samples.
- Check kit components.

Test entry options include the ability to select tests from a list of available tests or panels, assign tests to an entire sample rack, or assign a tube position, if necessary, such as when the barcode is damaged or missing).

Worklist management and display options allow the operator to:

- Display a worklist
- Print a worklist
- Modify a worklist
- Delete worklist entries
- Save a worklist
- Import a previously saved worklist

## *Adding Patients to a Worklist*

**NOTE:** The kit lot barcodes must be scanned before adding or downloading patients to the worklist.

If a sample barcode is damaged or missing, or the instrument is not connected to an LIS, patients must be added to the worklist manually. Depending upon the reason for adding the patients manually, the instructions differ. When there is no LIS connection and samples are barcoded, follow the instructions below. If a sample barcode is damaged or missing, refer to *Damaged or Missing Barcodes*, page 2-44.

**NOTE:** Do not load multiple sample tubes with the same accession number on the sample carousel at the same time. If you do this, the instrument pipettes all tests associated with that accession number from the sample tube in the lowest sample rack position. Keep sample tubes with the same accession numbers on different sample carousels.

### Barcoded Patient Samples

Follow the instructions below to add patients to the worklist when the instrument is not connected to an LIS.

**NOTE:** The samples must be loaded and **RUN** must be selected before proceeding with the steps below.

1. Select **WORKLIST**.

   **NOTE:** If the instrument is paused while viewing the Worklist Entry screen, the screen is cleared.

2. Select **Previous** and **Next** to locate the information about the patient sample to add to the worklist.

   **NOTE:** If the tube has a damaged barcode, refer to *Damaged or Missing Barcodes*, page 2-44.

3. If applicable, enter the patient's name, ID number, and birth date, and the physician's name in the proper fields.

4. Enter the tests to run on the patient sample.

   - Select **TESTS** to open the Available Tests screen and select the tests to run.

     Refer to *Selecting Available Tests*, page 2-53.

   - Order tests one at a time in the Worklist screen.

     To enter a test, enter the code in the TESTS field and then select **Enter**.

     Continue in this manner until all tests are ordered.

   Each entered test displays in the **Tests Ordered** field. The **TESTS** field is cleared for the next entry.

   **NOTE:** To remove a test from the **Tests Ordered** field, select the test name. The test name turns gray. To activate the test again, select the test name. The test name turns black.

5. To order a STAT test, select **STAT**, and then select the test name in the Tests Ordered field.

   The test name turns red.

6. Select **ACCEPT PATIENT**.

   Information about the next barcoded sample on the sample carousel displays in the Worklist screen. If the other samples on the sample carousel have no barcodes, the fields in the Worklist screen are cleared.

7. Repeat steps 4 through 6 until tests are assigned for each patient sample.

   **NOTE:** To specify another test for a patient already added to the worklist, perform one of the following actions:

   - Select **New** and then enter the unique accession number and the new test.
   - Select **Previous** and **Next** to locate the accession number of the previous entry and then enter the new test.

8. Verify that all patient samples have been added to the worklist.

9. Select **Display/Edit**.

   The Display Worklist screen displays.

   - In the Sort List By field, select the **Patients** selection to view patient samples in the worklist.
   - Select **UPDATE SCREEN** to view the most current information.
   - Be sure the tests added display in the worklist.

| LIS Status | Description |
|---|---|
| Time | Time remaining for the test to be completed. |
| Resulted | Test complete; answer has not been sent to LIS. |
| Waiting | The sample is on the instrument, but the test has not started. |
| No Sample | The sample is not on the instrument. |
| Sent | This record was previously sent to LIS. |
| In-Queue | The test is close to being processed. |
| Kit Error | There is a problem with the Bead, Reagent, or Diluent. |
| Sample Error | There is a problem with the Sample Tube, for instance not enough sample or clot detected. |

## Damaged or Missing Barcodes

After the instrument interrogates the sample carousel, the Consumables Report lists samples with damaged or missing barcodes as `no barcodes`. Refer to *Checking Kit Components*, page 2-53.

**NOTE:** The samples must be loaded and **RUN** must be selected before proceeding with the steps below.

Follow the instructions below to add a patient to the worklist when the barcode is missing or damaged.

**NOTE:** Manually assigned tubes need to be identified each time the sample carousel is paused and re-interrogated.

1. Select **WORKLIST**.

   **NOTE:** To select the sample type, use the Manual Entry Options to select **PATIENT, ADJUSTOR, CONTROL**, or **CALIB. VER.** (calibration verifier). The last option selected is automatically selected the next time the Worklist screen is accessed.

2. Select **PATIENT**.
3. Select **New** to clear the screen.
4. If necessary, select the **SKIP NAME** or the **SKIP DEMOGRAPHICS** options.

| Select this... | To do this... |
|---|---|
| SKIP NAME | skip the Name field |

| Select this... | To do this... |
|---|---|
| SKIP DEMOGRAPHICS | skip the demographics fields (Patient ID, Birthdate, and Physician) |

5. Type the accession number in the **Accession #** field.
6. Select **Assign Tube Position**.
7. Under **Select Rack To Use**, select the letter corresponding to the sample rack where the sample is located.
8. Under **Select Position To Use,** a graphical depiction of the positions on the sample rack displays.

   Standard samples are displayed as circles and microsamples are displayed as squares. The sample status is indicated by the color of the numbered circle or square. Refer to the key for the status associated with each color.
9. Under **Select Position To Use**, select the position by clicking on a white circle or square.

   The position turns red and the rack and position display at the bottom of the screen.
10. Select **OK**.

    The Worklist screen displays. The tube position (rack and number) displays to the right of the **Assign Tube Position** button for this sample.
11. If applicable, type the patient's name, ID number, and birth date, and the physician's name in the proper fields.
12. In the TESTS field, type the test name, and then select **Enter**.

    **NOTE:** It may be easier to select from a list of available tests by selecting **TESTS**. Refer to *Selecting Available Tests*, page 2-53.

    The test name is added to the Tests Ordered screen and the **TESTS** field is cleared for the next entry.
13. To deselect a test, select the test name in the Tests Ordered screen.

    The test name is now gray. To select the test again, select the test name in the Test Ordered screen.

## Ordering STATs

1. To indicate a STAT sample, select **STAT**, and then select the test name in the **Tests Ordered** screen.

   The test name turns red, indicating this test now has a STAT priority and runs first.
2. Select **ACCEPT PATIENT**.

## Adding Adjustors to the Worklist

Follow the instructions below to add adjustors to the worklist:

**NOTE:** Adjustors must be loaded with barcodes, and the **RUN** button must be selected before proceeding with the steps below.

1. Select **WORKLIST**.
2. If the ADJUSTOR button is not highlighted, select **ADJUSTOR**.
3. Select **Previous** and **Next** to locate the information about the adjustor to add to the worklist.

   **NOTE:** The A (or 01) level of adjustor must be entered first.
4. Enter the kit lot number in the **Kit Lot** field.
5. To adjust an allergy assay, enter the lot number for the adjustor antibody in the **Adj Allergen Lot #** field.
6. Select **ACCEPT ADJUSTOR**.
7. Repeat steps 2 through 6 for next level of adjustor.
8. Select **Display/Edit**.

   The Display Worklist screen displays.
9. In Sort List By field, select **Adjustors**.

   The adjustors display at the top of the worklist.

   The information from adjustor barcode labels displays in the ACCESSION # column of the Worklist.
   - The first two characters (~A), identify the tube as an adjustor.
   - The next three characters identify the test type.
   - The next five characters identify the adjustor lot and level (the first three identify the adjustor lot and the last two identify the level: 01 for low and 02 for high).
10. If the barcode is damaged or missing, do the following steps
    a. Type in the **Adjustor Lot Number** and **Adjustor Level.**
    b. Associate the tube and its position with the sample accession number. Refer to *Assigning a Tube Position*, page 2-56 for more information.

## Adding Controls to a Worklist

Follow the instructions below to add control tests to the Worklist.

- *Barcoded Controls*, page 2-47.
- *Controls without Barcodes*, page 2-48.

## Barcoded Controls

Follow the instructions below to add control tests to the Worklist.

**NOTE:** Load control samples with barcodes, and select **RUN** before proceeding with the steps below. Tests for control samples are not automatically added to the worklist via the LIS.

1. Select the **WORKLIST** button on the toolbar.

   The Worklist screen displays.

   If the instrument is paused while viewing the Worklist Entry screen, the screen is cleared.

2. Select the **Previous** and **Next** buttons to locate the control record to review.

   If the barcode is damaged or missing, refer to *Controls without Barcodes*, page 2-48.

3. Enter the tests to run on the control sample:

   a. Select **TESTS** to open the Available Tests screen and select the tests to run.

      Refer to ***Selecting Available Tests***, page 2-53.

   b. Enter the code in the **TESTS** field, and then select **Enter**.

   c. Continue until all tests are ordered.

      Tests may be entered one at a time in the Worklist screen.

4. To run an allergy kit control, enter the control antibody in the **TESTS** field.

   When running an allergy kit control, do not enter any other tests.

   Each test added displays in the Tests Ordered field in the Worklist screen.

5. To remove a test from the **Tests Ordered** field, select the test name.

   The test name turns gray. To activate the test, select the test name. The test name turns black.

6. If more than one kit lot for an assay is onboard the instrument, enter the kit lot number in the **Kit Lot #** field to run the control for a particular lot of that assay.

7. If a control antibody was entered in step 3, enter the lot number for the control antibody in the **Agn Lot #** field.

   **NOTE:** You must select **ACCEPT CONTROL** for the worklist entry to be accepted. If you do not, the worklist entry is deleted.

8. Select **ACCEPT CONTROL**.

   Information about the next barcoded sample on the sample carousel displays in the Worklist screen. If the other samples on the sample carousel have no barcodes, the fields in the Worklist screen are cleared.

9. Select **Display/Edit**.

   The Display Worklist screen displays.

10. Select **UPDATE SCREEN** and verify that the controls added display in the worklist.

## Controls without Barcodes

**NOTE:** The samples must be loaded and **RUN** must be selected before proceeding with the steps below.

Follow the instructions below to add a control to the worklist when the barcode is missing or damaged.

1. Select **WORKLIST**.

   A blank Worklist screen displays.

2. If it is not Control is not already highlighted, select **CONTROL**.

3. Enter the accession number for the particular level of control into the **Accession #** field.

   This accession number is the same number that was assigned to a particular level of control when the control information was entered into the system.

   To retrieve this number, do the following:

   a. Select **QC**, and then select **Data Entry**.

   b. Use **Previous Control** or **Next Control** to locate the control material.

   c. Copy the accession number that corresponds to the particular level of control, and paste it into the **Accession #** field of the Worklist screen.

      Alternatively, make a note of the accession number and type it into the Worklist screen.

4. On the keyboard, select the **Enter** key.

   The control name, lot number, and level display on screen.

5. Select **TESTS**, and then order the appropriate tests.

6. Select **Assign Tube Position**.

7. Under **Select Rack To Use**, select the letter corresponding to the sample rack where the sample is located.

8. Under **Select Position To Use,** a graphical depiction of the positions on the sample rack displays.

   Standard samples are displayed as circles and microsamples are displayed as squares. The sample status is indicated by the color of the numbered circle or square. Refer to the key for the status associated with each color.

9. Under **Select Position To Use,** select the position by clicking on a white circle or square.

   The position turns red and the rack and position display at the bottom of the screen.

10. Select **OK**.

11. The Worklist screen displays.

    The tube position (rack and number) displays to the right of the Assign Tube Position button for this sample.

12. Select **ACCEPT CONTROL**.

13. To add an additional level of control, select **New** and repeat steps 3 to 12 for each level of control.

## *Adding Calibration Verifiers to a Worklist*

Follow the instructions below to add calibration verifiers to a worklist:

1. Select **WORKLIST**.

   A blank Worklist screen displays.

2. Select **CALIB. VER.**

   The Calibration Verifier Worklist screen displays.

3. Type the kit lot number, verifier lot number, and verifier level into the appropriate fields.

4. If available, enter the **High Range** and the **Low Range**.

5. Order additional replicates:

   a. Select **TESTS**.

   b. Select the test from the Available Tests screen.

   c. Select **REPLICATES,** and then order the appropriate number of replicates.

   d. Select **OK** to close the Replicates screen.

   e. Select **OK** on the Available Tests screen.

   **NOTE:** To deselect a test, select the test name in the **Tests Ordered** screen. The test name is now gray. To select the test again, select the test name.

6. Select **Assign Tube Position**.

   The Assign Tube Position screen displays.

   a. Under **Select Rack To Use,** select the letter corresponding to the sample rack where the sample is located.

   b. Under **Select Position To Use**, a graphical depiction of the positions on the sample rack displays.

      The sample status is indicated by the color of the numbered circle or square. Refer to the key for the status associated with each color.

   c. Under **Select Position To Use**, select a position by clicking on the white circle or square.

      The position turns red and the rack and position display at the bottom of the screen.

   d. Select **OK.**

The Worklist screen displays. The tube position (rack and number) displays to the right of the Assign Tube Position button for this sample.

7. Select **ACCEPT VERIFIER**.
8. Repeat steps 2 through 7 until tests are assigned for each calibration verifier sample.

   **NOTE:** Calibration verifier reports (as well as other reports) are printed automatically if these options are selected in the Configuration Settings screen.

## *Diluting Samples*

Use this procedure to dilute samples online or you can perform manual dilutions offline and then place the sample onto the instrument.

Do not exceed a combined onboard and manual dilution factor greater than 99,999. Refer to *Diluting Samples Onboard*, page 2-50 or *Specifying Manually Diluted Samples*, page 2-52.

**NOTE:** If a manual dilution was previously assigned, this dilution factor will be included in the automatic dilution factor. Refer to *Specifying Manually Diluted Samples*, page 2-52.

### Diluting Samples Onboard

Follow the instructions below to dilute a sample onboard:

**CAUTION**

Do not use IMMULITE diluent for onboard dilutions. Use only IMMULITE 2000 diluent or IMMULITE 2500 diluent, as appropriate. Use all diluents before the expiration date printed on the packaging.

Predilutions are done automatically for assays that require running prediluted patient samples. The dilution factor is 1 on the Display Worklist screen. If a further dilution is necessary, it must be performed manually. Refer to *Specifying Manually Diluted Samples*, page 2-52 for more information.

1. Find a patient record:
   a. At the Worklist screen, select the **Display/Edit** button.
   b. Select the patient record, and then select the **EDIT RECORD** button. The Worklist screen for that patient displays.
2. Select **Dilution**.
3. Select the assay to dilute in the Tests Ordered screen.

   The Dilution Factor screen displays on the Worklist screen.

   **NOTE:** The barcoded diluent tube must be on the sample carousel.

4. Select one of the listed dilution factors:

| Dilution Factor | Dilution |
|---|---|
| X3 | 1 in 3 |
| X5 | 1 in 5 |
| X10 | 1 in 10 |
| X20 | 1 in 20 |
| X40 | 1 in 40 |
| X100 | 1 in 100 |

After the dilution is selected, the Dilution Factor screen closes and the dilution factor displays on the Worklist screen.

Refer to *Dilution Volume Specifications*, page E-2.

5. Select **ACCEPT PATIENT**.

**NOTE:** If the diluent barcode cannot be read, the diluent can be entered in the Worklist screen (for a patient sample) by assigning a diluent name in the Accession # field.

Select **Assign Tube Position** to define the sample position. Diluents are identified by the prefix ~D, followed by the corresponding diluent name, such as ~DHCG. The diluent name may be found in the Kits screen. Do not assign tests to a diluent tube.

### *Canceling an Onboard Dilution*

Follow these instructions to cancel a dilution:

1. To find a patient record, do the following:
   a. Select **Display/Edit** on the Worklist screen.
   b. Select the patient record, and then select **EDIT RECORD**.
   The Worklist screen for that patient displays.
2. At the Worklist screen, select **Dilution**.
3. Select the assay to dilute in the Tests Ordered screen.
   The Dilution Factor screen displays on the Worklist screen.
4. Select **X1** to change the dilution factor to one.
   The sample will not be diluted.

## Specifying Manually Diluted Samples

If the dilution was prepared manually and then placed on the instrument, follow the instructions below to specify a dilution.

**CAUTION**

Do not use IMMULITE diluent for onboard dilutions. Use only IMMULITE 2000 diluent or IMMULITE 2500 diluent, as appropriate. Use all diluents before the expiration date printed on the packaging.

Use IMMULITE 2000 diluent or IMMULITE 2500 diluent to prepare manual dilutions. IMMULITE 2000 diluent and IMMULITE 2500 diluent are concentrated. Prior to use as a manual diluent, the IMMULITE 2000 diluent and IMMULITE 2500 diluent must be diluted 1 part diluent to 1.5 parts water.

**NOTE:** Do not perform reflexive testing on a manually diluted sample.

Samples that require a dilution factor other than those programmed for onboard dilutions may have a manual dilution factor applied to them. When a manual dilution factor is applied to a sample, all tests ordered on that sample are multiplied by that dilution factor.

If a manual dilution is specified on a panel that has an automatic dilution, the dilution factors are combined.

Do not exceed a combined onboard and manual dilution factor greater than 99,999.

When a patient sample is diluted either manually or onboard, the instrument will automatically calculate the actual concentration of the patient sample by multiplying the diluted patient sample result by the dilution factor.

1. Find a patient record:
   a. Select **Display/Edit** on the Worklist screen.
   b. Select the patient record, and then select **EDIT RECORD**.
      The Worklist screen for that patient displays.
2. At the Tests Ordered screen, select the assay that was diluted offline.
3. Select **Manual Dilution**.
   The Manual Dilution screen displays:
4. Type the manual dilution factor, and then select **OK**.
   For all tests ordered on this sample, the manual dilution factor displays on the Worklist screen under Dilution Factor.

5. Select **ACCEPT PATIENT**.

**CAUTION**

Do not attempt to enter manual dilution factors for samples that are in queue or in progress. The dilution factor is ignored and the result will not be corrected for the manual dilution.

## Checking Kit Components

Follow these instructions to check the status of the kit components onboard the instrument, including the bead packs, reagent wedges, and diluents.

**NOTE:** If the instrument detects that kit components or consumables are needed to run the current worklist, the Consumables button turns red.

1. After the instrument is in RUN mode, select **Consumables** on the Worklist screen.
2. If appropriate, print the report by selecting **Print Report**.
3. Load any needed kit components.
4. Close all instrument covers.
5. Select **RUN** to begin processing.

   **NOTE:** The next time the Consumables button is selected or the next time the sample barcodes are read, the button returns to the original color.
6. To close the Consumables Report screen, select **CLOSE**.

## Test Entry Options

When manually specifying tests, the Worklist screen allows the operator to:

- Select tests from a list of available tests.
- Select a panel from a list of available panels.
- Assign tests to an entire sample rack.

### Selecting Available Tests

It may be easier to select from a list of available tests when selecting the tests to run on a particular sample. Follow the instructions below to select from a list of available tests.

**NOTE:** If the instrument is connected to an LIS, the tests to run for each sample are automatically entered in the worklist.

1. In the Worklist screen, select **TESTS**.

   The Available Tests screen displays a list of available tests.

**NOTE:** Select the **ACTIVE KITS** buttons to view all kits entered in the database.

2. Add immunoassays to the worklist:

   To exclude immunoassays in the worklist, proceed to step 3.

   a. Select the Immunoassay **ON BOARD** button.
      A button for every available immunoassay displays in the center of the screen.
   b. Select the button for each immunoassay to add to the worklist.
      The code for the assay selected displays in the Tests Selected field.

3. Add allergy tests to the worklist:

   To exclude allergy tests in the worklist, proceed to step 4.

   a. Select the Allergy **ON BOARD** button.
      A button for every available allergy test displays in the center of the screen. Selections for universal allergy reagents display below the Test Categories field.
   b. Select the universal reagent, such as SPE, to use for the allergy test added to the worklist.
   c. Select the button for the allergy test to add to the worklist.
      The code for the test selected displays in the Tests Selected field.
   d. Continue selecting universal reagents and tests for each allergy test to add to the worklist.

   **NOTE:** To remove a test selected in the Available Tests screen, select the button for that test. To remove an allergy test, select the universal reagent and then select the button for the allergy test to remove.

4. Specify replicates of the tests added to the worklist.

   Proceed to step 5 if replicates are not needed.

   a. Select a test in the Tests Selected field, and then select **REPLICATES**.
      The Replicates screen displays.
   b. Display the number of replicates to perform using the arrow buttons.
      The number can also be changed using the keyboard.
   c. Select **OK** to enter this number, and then close the Replicates screen.
   d. Repeat this process for all tests that require replicates.

5. When finished selecting tests, select **OK** in the Available Tests screen to save the entries and close the screen.

   The tests selected display in the Tests Ordered field in the Worklist screen.

## Selecting a Panel

Follow the instructions below to select a panel of tests to run for a particular sample.

**NOTE:** The panels are configured on the Panel Configuration screen. Refer to *Panel Configuration*, page 8-18.

1. At the Worklist screen, select **PANELS**.

   The Available Panels screen displays a list of available panels.

2. Select the appropriate **PANEL** button.

   The tests included in this panel display in the Tests Ordered screen.

   **NOTE:** The color of the test name in the Tests Ordered screen corresponds with the panel name.

3. Select other **PANEL** buttons, as applicable.

   To deselect a panel, select the **PANEL** button again.

4. Select **OK**.

   The Worklist screen displays.

## Assigning Tests to an Entire Rack

It may be more convenient to assign tests to an entire sample rack than to specify tests one at a time. Follow the instructions below to assign tests to an entire sample rack of barcoded samples. For non-barcoded samples, refer to *Damaged or Missing Barcodes*, page 2-44.

**NOTE:** If the system is connected to an LIS, the tests to run for each sample are automatically entered in the Worklist.

**CAUTION**

Do not add additional tests to a sample rack while it is between pipetting and incubation.

1. Load the samples on the sample rack, place the rack on the instrument, and select **RUN**.
2. At the Worklist screen, select **Batch Tests by Rack**.
3. Select one or more of the available sample racks.

   **NOTE:** To deselect a sample rack, select the rack again.

4. Perform one of the following options to select the tests to run:
   - Type the test name in the field next to the **TESTS** button and select **Enter**. Continue this process until all tests are ordered.
   - Select **TESTS** to select from a list of available tests.

Refer to *Selecting Available Tests*, page 2-53 for more information.

- Select **PANELS** and select from a list of available panels.
  The tests display in the Tests Selected screen.

**NOTE:** Use the **CLEAR** button to clear the entries from the Tests Selected screen.

5. Select a dilution to be applied to the rack:
   - For onboard dilutions, select **Dilution**.
     The Dilution Factor screen will display. Select the appropriate onboard dilution.

     **NOTE:** When a manual dilution factor is entered for a Sample Rack, the entered dilution factor will be applied to all samples in that rack.
   - For manual dilutions, select **Manual Dilution**.
     The Manual Dilution Factor screen will display. Enter the dilution factor and select **OK**. The sample must be diluted by the operator prior to loading onto the system.

     **NOTE:** Do not exceed a combined onboard and manual dilution factor greater than 99,999.
   - For a combined onboard and manual dilution, the instrument combines the dilution factors.
6. Select **ACCEPT** when finished.

## Assigning a Tube Position

If the barcode is damaged or missing, associate the tube and its position with the sample accession number by following the steps below.

**NOTE:** Manually assigned tubes need to be identified each time the sample carousel is paused and re-interrogated.

1. Enter the sample information on the Worklist screen.
2. From the Worklist screen, select **Assign Tube Position**.
3. Under Select Rack To Use, select the letter corresponding to the sample rack where the sample was placed.
4. Under Select Position To Use, a graphical depiction of the positions on the sample rack displays.

   Standard samples are displayed as circles and microsamples are displayed as squares. The sample status is indicated by the color of the numbered circles or squares. Select the position by clicking on a white circle or square.

   The position turns red.
5. Select **OK.**

   The Worklist screen displays. The tube position (rack and number) displays to the right of the **Assign Tube Position** button for this sample.

## Worklist Management and Display Options

Worklist management and display options allow the operator to:

- Display a worklist.
- Print a worklist.
- Modify a worklist entry.
- Delete a worklist entry.
- Save and import a worklist.

### Displaying a Worklist

At the Worklist screen, view all current records by following the instructions below:

1. Select **DISPLAY/EDIT**.

   The Display Worklist screen displays.

2. Sort the Worklist by selecting one of the options next to Sort List By.

   The Display Worklist can be sorted by:

   - Accession Number
   - Entered Order
   - Test Name in alphabetical order
   - Patient Name in alphabetical order
   - Rack Order
   - Adjustors (to display Adjustors first)
   - Controls (to display Controls first)
   - Patients (to display Patients first)
   - Calibration Verifiers (to display Calibration Verifiers first)
   - Status (to display samples by current status)

   **NOTE:** The Sample Type column displays either A for Adjustor, C for control, P for patient, or V for calibration verifier.

3. To scroll through the Worklist, select the **UP** or **DOWN** buttons.

### Printing a Worklist

Either an individual record or the entire Worklist can be printed from the Worklist screen.

1. From the Worklist screen, select **PRINT ALL**.
2. If necessary, select one of the **Sort Printout By** options.
3. Select the type of record to print by selecting one of the **Print** options.
4. Select **PRINT**.

## Modifying a Worklist Entry

Worklist entries can be modified from either the Worklist or the Display Worklist screen.

### *Modifying a Worklist Entry from the Worklist Screen*

**NOTE:** A record can be modified only if the sample is currently onboard the instrument and that particular test is not in progress.

1. Select **Previous** and **Next** to locate the record.
2. Make any changes and select **ACCEPT PATIENT**.

### *Modifying a Worklist Entry from the Display Worklist Screen*

**NOTE:** Modifications can be made to all records that are not in progress.

1. At the Worklist screen, select **Display/Edit**.
2. Select **Update Screen** to refresh the worklist.
3. Select the record.
4. Select **EDIT RECORD**.

   The Worklist screen displays, displaying the selected record.
5. Make any changes and select **ACCEPT PATIENT**.

   The Display Worklist screen displays.

## Deleting a Worklist Entry

A worklist entry can be deleted from either the Worklist or the Display Worklist screen.

### *Deleting a Worklist Entry from the Display Worklist Screen*

**NOTE:** A record can be deleted only if the sample is currently onboard the instrument.

1. Select **Previous** and **Next** to locate the record.
2. Select **DELETE PATIENT**.

   The record is deleted.

### *Deleting a Worklist Entry from the Display Worklist Screen*

1. At the Worklist screen, select **Display/Edit**.
2. Select the record(s).

   **NOTE:** Select more than one record to delete multiple records at a time.
3. Select **DELETE RECORD**.

   The selected records are deleted.

## Saving and Importing a Worklist

The Save and Import functions are used to save a common worklist for future use.

Follow these instructions to save a worklist.

1. After completing a worklist, select **DISPLAY/EDIT** to view the entire Worklist.

   The Display Worklist screen displays.

2. Select **SAVE WORKLIST**.

   The Export Worklist screen displays:

3. Select **Binary File** (a coded file) or **ASCII File** (a text file).

   **NOTE:** Use ASCII File when the file is to be imported into another application, such as Lotus or Microsoft Office Excel.

4. Select **OK**.

   The Save As screen displays.

5. Double-select on the directory where the worklist file should be stored.

   **NOTE:** The scroll bar may be needed to view all the directories.

6. Type a name in the **Filename** field, and then select **Save**.

   The Save As screen closes and the Worklist is saved.

### *Importing a Worklist*

Follow the instructions below to import a previously saved worklist.

1. From the Worklist, select **DISPLAY/EDIT**.

   The Display Worklist screen displays.

2. Select **IMPORT WORKLIST**.

   The following screen displays.

3. Select the file format used when the file was saved, either **Binary File** or **ASCII File**.

4. Select **OK**.

5. Double-select the directory where the file is stored.

   **NOTE:** The scroll bar may be needed to view all the directories and files.

6. Double-select the filename.

7. The name displays in the **Filename** field.

8. Select **Open**.

   The screen is removed from the Display Worklist screen and the imported Worklist displays.

# Reviewing Results

The results review function is used to review results from a sample previously run. Follow the instructions below to review results.

1. Select **REVIEW**.

   A blank Review screen displays.

   **NOTE:** The default time option is **Today Only.** To change the default time, *Changing the Default Time*, page 2-61.

2. Select one of the option buttons listed below, indicating the result type:
   - All
   - Patient
   - Adjustor
   - Control
   - Verifier (for calibration verifier)

   **NOTE:** The type of data displayed on the Review screen varies depending on whether the result is a patient, control, adjustor, or calibration verifier.

   **NOTE:** If reference ranges were entered, they are displayed for the first test results, which are highlighted. Refer to *Defining Test Ranges*, page 8-12 for information on entering ranges.

3. Use the buttons to view the results or to print a particular patient's results.

   The buttons on the Review screen are described in the table below:

| Button | Description |
|---|---|
| PgUp or PgDn | Displays the previous or next page of results for this patient. |
| Up and Down | Scrolls through the results for a particular patient one by one. |
| Previous and Next | Displays the previous or next patient's results. |
| Print Patient, Adjustor, Control, or Verifier | Prints all the results for the patient with this Accession number. |
| Search | Allows the operator to search for a specific result. Refer to *Searching for a Result*, page 2-62 for more information. The search option is not available if **All** is selected. |

4. Select the appropriate result to view the reference ranges for this test.

## Changing the Default Time

To change the default period for the records displayed, follow the instructions below.

1. From the Review screen, select **Time**.
2. Select the appropriate button according to the information in the table below:

| Button | Function |
|---|---|
| FROM TO | Displays the results from a specified time and date<br>**NOTE:** The operator must enter the times and dates in the From and To fields (using the calendar and the clock) and select the **OK** button. |
| TODAY ONLY | Displays results for the current date. |
| ALL | Displays all the patient control, Adjustor or calibration verifier results (depending on the button selected in step 2). If **ALL** was selected in step 2, all records in the database are displayed. |

3. If the **TODAY ONLY** or **ALL** button was selected in step 2, select **OK**.

   The new default time specification displays to the right of the **Time** button (on the Review screen).
4. If the **FROM TO** button was selected in step 2, select in the **mm/dd/yyyy** field under **From**.

   The Select Time Method screen displays a calendar.
5. To change:
   - The month, select the arrows to the left and right of the month for the previous or next month.
   - The year, select the arrows to the left and right of the year for the previous or next year.
   - The day, select the date.
6. Select in the hh:mm:ss am/pm field under **From**.

   A digital clock displays.

   **NOTE:** The time defaults to 12:00:00 am.
7. Select the up and down arrows to change the time (hours, minutes, or seconds) and select the **OK** button under the clock.
8. Repeat steps 1 though 4 for the **To** date and time fields.

   **NOTE:** The time defaults to 11:59:59 pm.
9. Select the **OK** button.

   The new default time specification displays to the right of the **Time** button on the Review screen.

## Searching for a Result

Follow the instructions below to search for a record.

1. Select **REVIEW**.

   A blank Review screen displays:

2. From the Review screen, select one of the option buttons listed below, indicating the type of result to review:

   - Patient
   - Adjustor
   - Control
   - Verifier (for calibration verifier)

   **NOTE:** A search cannot be performed if **ALL** is selected.

3. Select **Search**.

   **NOTE:** The Search screen varies depending on the record type: patient, control, adjustor, or calibration verifier.

   The Search screen searches for patient results. The search options for adjustor, control, or calibration verifier results are listed in the table below:

| Result Type | The available search options are: |
|---|---|
| Control | • Control Name<br>• Control Lot<br>• Test Type<br>• Allergen Type |
| Adjustor | • Test Type<br>• Kit Lot |
| Calib. Verifier | • Verifier Lot Number<br>• Test Type<br>• Kit Lot<br>• Verifier Level |

4. Select **Time** to set the time frame searched.

   The default is the current date.

5. Type the search information, and then select **OK**.

   The Search Results screen displays the results meeting the search criteria.

   **NOTE:** Select the **Exact Match** option to view the results that identically meet the search criteria. If the **Exact Match** checkbox is not selected, anything similar to the entered data will be displayed.

6. Select a result, and then select **OK**.

   The Review screen for that result displays.

## Reviewing LIS Results

The LIS button is used to review information received from the LIS and the results being sent to the LIS.

Follow the instructions below to display and sort the data received from the LIS and the results to be sent to the LIS.

1. At the instrument window, select **LIS**.

   The LIS screen displays the data.

   The viewing options selected the last time the LIS screen was accessed, determine the information displayed when the **LIS** button is selected.

   **NOTE:** For the data status, refer to the color key along the bottom of the screen.

| LIS Status | Description |
|---|---|
| Time | Time remaining for the test to be completed. |
| Resulted | Test complete; answer has not been sent to LIS. |
| Waiting | The sample is on the instrument, but the test has not started. |
| No Sample | The sample is not on the instrument. |
| Sent | This record was previously sent to LIS. |
| In-Queue | The test is close to being processed. |
| Kit Error | There is a problem with the bead, reagent or diluent. |
| Sample Error | There is a problem with the sample tube, such as not enough sample or clot detected. |

   If applicable, select **Show Sent** to display results already sent to the LIS.

   **NOTE:** The button will change to Hide Sent.

2. Sort the LIS data by selecting the **Sort By...** button.
3. If applicable, specify a period other than **Prior 24 Hours** by selecting **Define Range**:
   - Select the **MM/DD/YYYY** field to access the calendar and select a date.
   - Select the **HH:MM:SS xm** field to access the clock and select a time.
4. To sort the results, select one of the sort buttons:
   - Accession Number
   - Order Created
   - Name
   - Test Type
5. Select **Print List** to print the list.
6. To clear the LIS data, refer to *Clearing LIS Data*, page 2-64.

## Sending Results to the LIS

The system can be configured to send data to the LIS automatically. If the system is not configured to send results automatically, follow the instructions below to send results to the LIS manually.

**NOTE:** Hepatitis test results are held until two reflexive tests are completed. After all three tests complete, the instrument auto-sends the one test result to the LIS and marks all three as sent. However, you may manually send all three test results to the LIS.

1. From the LIS screen, select **Hide Sent** to hide results that were already sent to the LIS.
2. Select the results to be sent by clicking on them or select **Tag All** to tag all results for transmission to the LIS.
3. Select **Send** to transmit the tagged results to the LIS.

   N/A results can not be manually or automatically sent to LIS.

## Resending Data

Results previously sent to the LIS can be resent by following these instructions:

1. From the LIS screen, select **Show Sent**.

   The previously sent LIS results display.
2. Select the results to be sent by clicking on them.
3. Select **Re-Send** to transmit the results to the LIS.

## Clearing LIS Data

**NOTE:** The **Clear** button does not delete records from the database.

To clear records from the LIS window:

1. From the LIS screen, perform one of the following actions to select the records to be cleared:
   - Select the records
   - Select **Tag All.**
2. Select **Clear** at the LIS window.

   The message "Do you wish to permanently Clear ALL selected records from the LIS Screen?" displays.
3. Select **Clear Records**.

   The selected records no longer display in the LIS window.

# 3 Adjusting the System

# Adjusting the System

## Master Curve/Two-Point Adjustment

Instrument calibration uses a stored master curve in conjunction with a two-point adjustment procedure. This section provides an overview of this calibration method.

### Adjustment Overview

Analyte concentration is determined by a stored master curve. This curve is generated by the manufacturer for each lot of reagents and is provided in the kit barcode. Adjustors are then used to correlate the counts per second (CPS) of the customer's instrument to those of the instrument used to generate the master curve.

### Master Curve Generation

Master curves for each lot of reagents are generated on a single instrument by running replicates of a set of standards spanning the reportable range of the assay.

The number of standards varies with the analyte and ranges from six, for Total T4 (range 1 to 24 µg/dL), to 15, for TSH (range 0.002 to 75 µIU/mL). The standards are analyzed multiple times in several runs in random order. Replicates of a low and high Adjustor are included in every run.

Generally, the master curve is fitted using a four-parameter logistic model. For certain reagents, such as the universal reagent for specific allergy assays, a point-to-point curve model is used.

#### Four-Parameter Logistic

For the four-parameter logistic method, the master curve generated is the equation of the line that best fits the master curve data.

**NOTE:** The numerical values of the equation's four parameters vary from reagent lot to reagent lot. These values are encoded in the kit barcode label. The average CPS of the low and high adjustors, which were analyzed at the same time the standards used for the master curve were analyzed, are also encoded in the kit barcode label.

The instrument uses two different forms of the general four-parameter logistic equation:

- Form for competitive assays:

$$CPS = P1 + \frac{P2}{1+EXP(-(P3+P4xLn(Dose)))}$$

  where: P1 = maximum CPS (Bo)
  - P2 = minimum-maximum CPS (NSB - Bo)
  - P3 = intercept of a logit-log plot
  - P4 = - slope of the logit-log plot
- Form for immunometric (sandwich) assays:

$$CPS = P2 + \frac{P1 - P2}{1 + (Dose/P3)^{P4}}$$

  where: P1 = maximum CPS
  - P2 =minimum CPS (NSB)
  - P3 =dose at half the maximum CPS
  - P4 =- slope of the logit-log plot

### Point-To-Point

In the point-to-point curve model, the calibration curve is generated when each standard is connected point-to-point by a straight line.

## *Two-Point Adjustment*

Because the calibration data used to generate the master curve uses a single instrument, the signal (CPS) for any other laboratory instrument must match the signal of the Master Curve instrument to directly use the master curve to calculate results.

Because no two photomultiplier tubes (PMT) give exactly the same measured CPS for the same amount of light, the signal of each laboratory instrument must be adjusted to match that of the Master Curve instrument for the master curve to be used across all instruments. This is done using the two-point adjustment process.

If a full standard curve is run on both the Master Curve and the customer instruments, the relationship between the measured CPS from the two instruments (Master Instrument vs. customer instrument) is consistently linear. For example, possible data for an assay with six standards is displayed in the table below.

| Standard | Master Curve Instrument CPS | Customer Instrument CPS |
|---|---|---|
| Std A | 85,176 | 75,112 |
| Std B | 329,714 | 293,703 |
| Std C | 1,079,469 | 961,223 |
| Std D | 5,112,318 | 4,568,847 |
| Std E | 10,125,798 | 9,050,371 |
| Std F | 25,087,126 | 22,424,222 |

This relationship can be used to modify, or adjust, the CPS obtained on the laboratory instrument to be what they would have been for the same samples run on the Master Curve instrument. Because the relationship between the laboratory instrument and the Master Curve CPS values is a straight line, only two points are required to characterize the line.

These two points are defined by the two adjustors. Comparing the average CPS of the adjustors run on the master instrument (from the kit barcode label) and the CPS run on the customer instrument during an adjustment, the slope and intercept of the linear relationship are calculated. Using the equation below, the slope and intercept are then used to adjust the CPS for any sample to the CPS that would have been observed if the sample was run on the Master Curve instrument.

$$\text{Master Curve CPS} = \text{CPS}_{\text{unknown}} \times \text{Slope} + \text{Intercept}$$

The adjusted CPS can now be used to calculate the result directly from the Master Curve.

The purpose of the initial adjustment of a new kit lot is to correlate the CPS of the laboratory instrument to that of the Master Curve instrument. Subsequent readjustments update the correlation for changes in the reagent enzyme activity over time.

## *Judge Adjustment Validity*

The guidelines listed below can be used to establish whether a given adjustment has been successful. They are presented in order of importance:

1. Control values run immediately following an adjustment.
2. The slope of an adjustment.
3. The intercept of an adjustment.

   If an adjustment does not display to be valid (using these guidelines), readjustment may be necessary.

**NOTE:** The adjustment printout will have a slope, intercept, and message indicating whether or not the adjustment was complete.

### *Controls Run Immediately Following an Adjustment*

Results from quality control samples run immediately following an adjustment are the primary means of validating an adjustment and should be within the established limits for acceptable performance.

Special care should be taken to note situations where all quality control results are at the same (high or low) limit of acceptance as this may indicate a bias in the adjustment.

### *The Adjustment Slope for an Initial Adjustment*

An initial adjustment slope refers to the first slope generated on a new kit lot. The initial adjustment slope generally falls within ± 20% of the mean slope for the instrument.

The mean slope is the average of at least ten initial slopes of adjustment on a single instrument, using one of the following adjustments:

- Initial adjustments of more than one type of assay, excluding assays with single adjustors.
- Initial adjustments of more than one lot of reagent, if only one assay is being used.

**NOTE:** If fewer than ten adjustments are run, an average can still be calculated. However, this average should be regarded as preliminary and must be recalculated when ten adjustments are completed.

For example, using the following data:

| Kit | Lot | Slope |
|---|---|---|
| COR | 109 | 0.687 |
| E2 | 107 | 0.986 |
| E2 | 109 | 0.894 |
| E2 | 110 | 0.983 |
| TSH | 110 | 1.009 |
| TSH | 125 | 0.993 |
| TSH | 127 | 0.989 |
| T4 | 127 | 1.053 |
| T4 | 117 | 1.008 |
| TU | 113 | No slope calculated for TU |
| T3 | 115 | 0.998 |

1. The mean (average) slope is calculated as follows:

   ```
   Mean = Sum of the slopes / 10 = 0.96
   ```

2. The acceptable 20% deviation from the mean is calculated as follows:

   ```
   Deviation = Mean x 0.20 = 0.96 x 0.20 = 0.19
   ```

3. The range for an acceptable slope is calculated as follows:

   High Limit = Mean + 20% = 0.96 + 0.19 = 1.15

   Low Limit = Mean - 20% = 0.96 - 0.19 = 0.77

   Range = Mean +/- 20% = 0.77 to 1.15

### *Intercept of Adjustment for an Immunometric (Sandwich) Assay*

A large intercept affects the calculation of results only at very low concentrations. If no controls are being run at these concentrations, an acceptable intercept may be interpreted as follows:

```
absolute value of the intercept = low Adjustor CPS
of the master curve instrument x 30%
```

The low adjustor CPS refers to the adjustor CPS information found on the Kit screen or the adjustment printout, not to the CPS measured during adjustment.

```
CPS of low Adjustor = 83,000
Acceptable intercept: 83,000 x 0.30 = 24,900
```

The guideline maximum intercept is 24,900.

### *Intercept of Adjustment for a Competitive Assay*

A large intercept can affect values across the curve, especially those in the very high range of the assay.

For competitive assays, an acceptable intercept should be ≤ 2% of curve parameter P1 found on the Kit screen.

```
P1 = 61,500,000
Acceptable intercept: 61,500,000 x.02 = 1,230,000
```

### Summary

- Controls run immediately after an adjustment should be within acceptable limits.
- The slope of an adjustment should fall within ± 20% of the mean slope for that instrument.
- The intercept of an adjustment generally falls below a maximum calculated intercept limit.
- Based on these guidelines, if an adjustment does not display to be valid, readjustment may be necessary.

## Readjustment

Every assay must be periodically readjusted, as indicated in the kit's package insert, to correct for the reagent's normal loss of activity.

#### *Slopes of Readjustment*

Slopes of readjustments should fall within 10% of the previous adjustment.

**NOTE:** Slope variation is caused by normal statistical variation of the assay and a 10–15% loss in enzyme activity over the lifetime of a kit.

#### *Intercepts of Readjustments*

Readjustment intercepts should be judged according to the above criteria.

# *Master Cutoff Generation for Qualitative Assays*

In qualitative assays, the results are classified as non-reactive or reactive, or possibly indeterminate. The results in these assays are calculated by comparing the signal obtained for a patient sample to a cut-off signal.

#### *Immunometric (sandwich) assays*

```
If patient CPS > cutoff, the result is reactive.
If patient CPS < cutoff, the result is non-reactive.
```

#### *Competitive assays*

```
If patient CPS < cutoff, the result is reactive.
If patient CPS > cutoff, the result is non-reactive.
```

Where an indeterminate region is defined, it is usually a percentage above and below the cutoff.

***Indeterminate assays***

```
If the percentage = 10% cutoff, then...
0.9 x cutoff < Indeterminate < 1.1 x cut-off
```

## Measure the Cutoff for an Assay

The cutoff for an assay is usually established in one of two ways:

- A cutoff is determined statistically.

  A cutoff is calculated which achieves the optimal sensitivity and specificity.

  Several hundred patients, both reactive and non-reactive, whose clinical status has been established by another method, are assayed on the instrument.
- An alternate method for choosing cutoff, used especially for allergy assays, is based on the variability in signal response seen with a very large number of non- reactive patient samples.

Qualitative assays have a single adjustor (or calibrator) used to establish the relationship of the master cutoff to an individual instrument. For example, if the cutoff for an assay is determined to be 100,000 CPS, and an adjustor (or calibrator) run at the same time reads 80,000 CPS, a ratio of 1.25 (100,000/ 80,000) is used with the adjustor to correctly establish the cutoff for a specific instrument.

The single adjustor is supplied with the kit, and the ratio of the adjustor CPS to the cutoff value is supplied in the kit barcode label as Parameter 1 (P1). At adjustment, the average CPS of the adjustor obtained from the instrument is multiplied by P1 to determine the specific cutoff for that instrument.

Parameter 2 (P2) and Parameter 3 (P3) are factors used as appropriate to set the upper limit (P2) and lower limit (P3) of the indeterminate region. If an indeterminate region is defined, then `P2 x the adjustor CPS` and `P3 x the adjustor CPS` will give the signal above and below the cutoff defining the indeterminate region. The percentage above and below the cutoff is defined by `P2/P1*100` and `P3/P1*100`. If no indeterminate is defined for an assay, P2 and P3 are 0.

For assays with a single adjustor, an adjustor index is calculated upon adjustment. This is the ratio of the CPS obtained during the adjustment to the CPS of the adjustor on the Master Curve instrument at Siemens, which is found on the kit barcode.

$$\text{Adjustor Index} = \frac{\text{Adjustor CPS}}{\text{Kit Barcode Adjustor CPS}}$$

**NOTE:** The adjustor index is not used in the calculation. Instead, it is calculated as a guideline to the validity of the adjustment. Results obtained with Quality Control samples are still the primary way to judge an adjustment.

## Calculation of Ratios

The instrument can also report qualitative assays by means of a ratio. The instrument can report the numerical ratio, followed by an indication of R, NR, or I representing reactive, non-reactive, and indeterminate, respectively. Ratios are determined by the following calculations:

***Immunometric (Sandwich) Infectious Disease Assays***

$$\text{Ratio} = \frac{\text{CPS of Sample}}{\text{Cutoff}}$$

$$\text{Cutoff} = \text{P1} \times \text{Adjustor CPS}$$

***Competitive Infectious Disease Assays***

$$\text{Ratio} = \frac{\text{Cutoff}}{\text{CPS of Sample}}$$

$$\text{Cutoff} = \text{P1} \times \text{Adjustor CPS}$$

***Qualitative flags are determined by the following equations:***

If the Ratio is greater than or equal to $(1+P2/P1)$, the result is marked as Reactive (R).

$$\text{Ratio} \geq (1+P2/P1)$$

If the Ratio is less than $(1-P3/P1)$, the result is marked as Non-Reactive (NR).

$$\text{Ratio} < (1-P3/P1)$$

If the Ratio is greater than or equal to $(1-P3/P1)$, but less than $(1+P2/P1)$, the result is marked as Indeterminate (I).

$$(1-P3/P1) \leq \text{Ratio} < (1+P2/P1)$$

# 4 Quality Control

# Quality Control

## Entering New Control Information

To enter control identification information, follow the instructions below:

**NOTE:** This information is required for the instrument to calculate and report control data.

1. Select **QC**.
2. Select **DATA ENTRY**.
3. Select **New Control**.
4. Enter a name of the control.

   The name can be no more than six characters in the Name field.
5. Enter the source and lot # for the control.
6. Select **Expiration Date**.

   **NOTE:** The default calendar entries are the current month and year.
7. Select the expiration date for the control from the calendar:

   **NOTE:** The **Expiration Date** must be selected from the calendar in the following order: month, year, and day.

   a. Use the month arrow keys to select a month.
   b. Use the year arrow keys to select a year.
   c. Select a day.
   d. Select **OK**.
8. Select **Add New Tests**.
9. Select **ACTIVE KITS** or **ON BOARD**:
   - If the **ACTIVE KITS** button is selected, a button for every immunoassay or allergy test scanned onto the Instrument displays in the center of the window.
   - If the **ON BOARD** button is selected, a button for every immunoassay or allergy test physically residing on the instrument displays in the center of the window.
10. For Immunoassay, select the appropriate immunoassay button.

    The code for the selected assay displays in the Tests Selected field.
11. For Allergen, do the following steps:

    a. Select the universal reagent, such as SPE, to be used for the allergy test.
    b. Select the appropriate allergen test button.

The code for the selected allergen displays in the Tests Selected field.

Two different kinds of allergy controls may be run:

- Allergy Kit Controls

  This type of control tests the performance of the universal allergy kit. These controls are provided with allergy kits. To run these controls, the Specific-IgE Control Antibody provided with that kit must have been entered and loaded.

  Refer to *Entering Allergens and Allergen Wedges*, page 2-28

- Specific-Allergen Controls

  These controls test the performance of a particular allergen. Specific-allergen controls are available for the most common allergies. To run these controls, the allergen whose performance is to be tested must be entered and loaded.

12. Select **OK**.
13. Enter the control level, and then select **OK**.

    The instrument automatically assigns an accession number to the control level. For a control without a barcode, this accession number must be entered into the Worklist screen to complete the order.

    Refer to *Controls without Barcodes*, page 2-48.

14. If necessary, overwrite the instrument-generated accession number, such as when an LIS control accession number is in use.

    **NOTE:** If the accession number in the software does not match the LIS control accession number, QC data will not be uploaded to the LIS and the QC Levey-Jennings Control Graph.

## Acceptance Criteria

In the upper right corner of the Control Entry window, select one of the acceptance criteria options:

- Control Not for On-Line QC
- Use Single Rule
- Use Multi Rule (not available for allergy controls)

  Refer to *Quality Control Management*, page 4-11.

## Using Controls that Are Not Online QC

If the control is not for online QC, follow these steps:

1. Enter the Mean, SD, and SD Multiplier.
2. Select the **Calculate Range** button to calculate the Low and High Limits.

   The SD Multiplier reflects the range for the standard deviation. The default is 2.

### Using Single Rule QC

If you are using Single Rule QC, follow these steps:

1. Enter the Mean, SD, and SD Multiplier.
2. Select the **Calculate Range** button to calculate the Low and High Limits.

   The SD Multiplier reflects the range for the standard deviation. The default is 2.

### Using Multi Rule QC

If you are using Multi Rule QC, follow these steps:

1. Enter the Mean and SD.
2. Select the appropriate rule options.

   The default is 1(2s) Rule.

### Completing the QC Procedure

1. Select **Save**.

   A confirmation message displays if the accession number for this level of control was changed.
2. Select **Yes** to confirm the change, or **No** to cancel it.
3. Select **OK**.

## *Additional Control Procedures*

- To add another level for the same test, refer to *Adding a Level*, page 4-5.
- To add another test for the same control, follow steps 8 through 16.
- To add a new control, select **New Control** and follow steps 3 through 16.
- To view tests and ranges for other controls, select **Previous Control** and **Next Control**.

## Qualitative Controls

To enter information about a qualitative control, follow the steps in the *Entering New Control Information*, page 4-1 and *Acceptance Criteria*, page 4-2, and then follow the instructions below.

**NOTE:** Each level of qualitative control must be entered as a separate control record in the Control Entry window.

1. Enter the level for the control record in the New Control Level window based upon the information in the following tables:

   For qualitative controls with three levels:

| For this level | Enter |
|---|---|
| Non-Reactive | 1 |
| Low Reactive | 2 |
| Reactive | 3 |

   For qualitative controls with two levels:

| For this level | Enter |
|---|---|
| Non-Reactive | 1 |
| Reactive | 2 |

2. At the upper right corner of the Control Entry window, select **Control Not for On-Line QC**.
3. In the Mean field, enter **1**.
4. In the SD field, enter **1**.
5. In the SD Multiplier field, enter **1**.
6. In the Low Limit field, enter **0.0**.
7. In the High Limit field, enter **1**.
8. Select **Save**.
9. Select **OK**.

## Controls Reported as Ratios

Assay controls that report ratios require entry of the control ranges for the Mean and Standard Deviation. Preliminary values for the Mean and Standard Deviation can be found in the control package insert included with the controls.

As with qualitative control entry, each level of control must be entered as a separate control name in the Control Identification window. The control name must be identical to the name printed on the control barcode label. Follow the steps for *Entering New Control Information*, page 4-1 and enter the control ranges from the package insert.

## Adding a Level

Follow the instructions below to add a level to an existing control in the Control Entry window. To open the Control Entry window, follow steps 1 and 2 of the *Entering New Control Information*, page 4-1.

1. From the Name list, select the control to which to add a level.
2. From the Test Type list, select the assay for which to add a control level.
3. Select **Add New Level**.

   The New Control Level window displays.
4. Enter the new level, and then select **OK**.
5. At the upper right corner of the Control Entry window, select one of the acceptance criteria options:
   - Control Not for On-Line QC
   - Use Single Rule
   - Use Multi Rule (not available for allergy controls)

   Refer to *Quality Control Management*, page 4-11 for more information about the acceptance criteria.

   Based on the option selected in step 5, follow steps 6 through 10:
6. If you selected **Control Not for On-Line QC**, perform the following steps:
   a. Enter the Mean, SD, and SD Multiplier.
   b. Select **Calculate Range** to calculate the Low and High Limits.
      The SD Multiplier reflects the range for the standard deviation. The default is 2.
7. If you selected **Use Single Rule**, perform the following steps:
   a. Enter the Mean, SD, and SD Multiplier.
   b. Select **Calculate Range** to calculate the Low and High Limits.
      The SD Multiplier reflects the range for the standard deviation. The default is 2.
8. If you selected Use Multi Rule, perform the following steps:
   a. Enter the Mean and SD.
   b. Select the appropriate rule options.
      1(2s) Rule is the default.
9. Select **Save**.

10. Select **OK**.

## Changing a Level

Follow the instructions below to change a level for an existing control in the Control Entry window. To open the Control Entry window, follow steps 1 and 2 of the *Entering New Control Information*, page 4-1.

1. From the Name list, select the control level to change.
2. From the Test Type list, select the assay for which to change the control level.
3. Select the test name and level in the Current Test field.

   **NOTE:** A control level cannot be changed to a level that already exists. For example, if a control for levels 4, 5, and 6 was entered, level 6 cannot be changed to level 5.
4. Select **Change Level**.
5. Enter the new control level, and then select **OK**.

   The test name that displays in the Control Level Change Alert message is determined by the test selected in Step 3.
6. Select **Yes**.
7. At the upper right corner of the Control Entry window, select one of the acceptance criteria options:
   - Control Not for On-Line QC
   - Use Single Rule
   - Use Multi Rule (not available for allergy controls)

   Refer to *Quality Control Management*, page 4-11 for more information about the acceptance criteria.

   Based upon the option selected in step 7, follow these steps:
8. If you selected **Control Not for On-Line QC**, perform these steps:
   a. Enter the Mean, SD, and SD Multiplier.
   b. Select **Calculate Range** to calculate the Low and High Limits.
      The SD Multiplier reflects the range for the standard deviation. The default is 2.
9. If you selected **Use Single Rule**, perform these steps:
   a. Enter the Mean, SD, and SD Multiplier.
   b. Select **Calculate Range** to calculate the Low and High Limits.
      The SD Multiplier reflects the range for the standard deviation. The default is 2.
10. If you selected **Use Multi Rule**, perform these steps:
    a. Enter the Mean and SD.

b. Select the appropriate rule options.
1(2s) Rule is the default.

11. Select **Save**.
The Record Saved window displays.
12. Select **OK**.
13. To view tests and ranges for other controls, select **Previous Control** or **Next Control**.

## Editing Control Information

Follow the instructions below to edit existing control information.

1. Select **QC** on the toolbar.
2. Select **DATA ENTRY**.
The Control Entry screen displays.
**NOTE:** If the Use Multi Rule option is selected, the last four results display under the Use Control for QC section.
3. Select the down arrow in the Name field and select the control.
4. Select the down arrow in the Test Type field and select the appropriate assay.
5. Select the test and level.
6. Type the new control identification information.
7. Select **Save**.
Depending on the control identification data changed, a window may display confirming the change. All test types defined for that control are automatically updated.
8. To view other tests and ranges, select **Previous Control** or **Next Control**.

## Reviewing Control Data

Control data can be reviewed by accessing a graph that plots data for different dates.

**NOTE:** Within the date display section, if the selected date range spans two years, each data point in the later year will be dated for the following day. For example, for a date range spanning 2001 and 2002, a QC sample processed on January 2, 2002 displays with a January 3, 2002 date on the QC graph. This issue only occurs in the Date Display on the QC Graph and does not affect the data table and printed reports.

To review control data, follow the instructions below:

1. Select **QC**.

2. Select **GRAPHS**.

   The Controls Graph Selection window displays.

   **NOTE:** When the range is 25 days or less, each date displays on the graph; otherwise, some dates are represented by points.

3. Select the **From** field:

   **NOTE:** The From date must be selected from the calendar in the following order: month, year, and day.

   a. Use the arrow keys to select the appropriate month and year.

   b. Select the appropriate date.

   c. Select **OK**

   **NOTE:** The To date default is today's date. This field can be changed if appropriate.

4. Select the down arrow to the right of the first selection field, to the right of the To field, and select the test.

5. Select the down arrow to the right of the next selection field and select the control name.

6. Select the down arrow to the right of the next selection field and select the control level.

7. Select the down arrow to the right of the last selection field and select the lot number.

   The Controls Graph window displays the plotted data points and the results used to plot the graph.

   The following list describes the content of the plotted graph portion of the screen:

   - Data points can be a square, a circle, or a triangle.
   - Data points of the same color are from the same Kit Lot.
   - Different colors indicate new Kit Lot numbers.
   - Data points of the same color and shape indicate the controls were run on the same Kit Lot, with the same adjustment.
   - Data points of the same color and a different shape indicate the controls were run on the same Kit Lot, with a different adjustment.

   The following list describes the content of the Results Portion of the screen:

   - Results highlighted in pink are out of 4SD range and are not included in the graph.
   - The standard deviation is based on the target mean entered in the Control Entry window.

8. Sort data by selecting a column.

   For example, to sort the data by Z score, select the Z column.

9. For an explanation of the Controls Graph screen, select the **How to read this graph?** button.
10. To review details for an individual data point:
    a. Move the pointer over the data point (with the trackball) and right-click.
    The data corresponding to this data point displays in green on the Results portion of the screen.
    b. Select **Yes** to remove this point from the graph.
    Refer to *Removing Points*, page 4-11.
    The Point Info window closes.
    - On the Results portion of the screen, the data corresponding to this point displays in red and the plus (+) sign changes to a minus (–) sign.
    - On the printout, there is a line through the result corresponding to the removed data point.
11. To copy the graph, print the graph, magnify a portion of the graph, eliminate the graph gridlines, or change the graph title refer to the table below.

| To do this... | Select... |
|---|---|
| Copy the graph, | The camera button.<br>**NOTE:** The graph can be pasted in the Microsoft Paint application and saved as a bitmap file.<br>To access Microsoft Paint, do the following:<br>1. On the Microsoft taskbar, select **Start**.<br>2. Select **Programs**, and then select **Accessories**.<br>3. Select **Paint**. |
| Copy the data, | The scissors button.<br>**NOTE:** The data can be pasted and saved in another application (MS Word or MS Excel). |
| Print the graph, | The printer button.<br>**NOTE:** It is recommended that operators avoid printing graphs while the instrument is in RUN mode. Runtime errors may occur if the operator attempts to print QC graphs while the instrument is performing tests. |
| Magnify part of the screen, | The magnifier button.<br>Select and drag the cursor over the area to magnify.<br>**NOTE:** To restore the screen to its original size, select the magnifier button again. |
| View the screen with the vertical grid lines, | The vertical lines button.<br>**NOTE:** To remove the grid lines, select the vertical lines button again. |
| View the screen with the horizontal grid lines, | The horizontal lines button.<br>**NOTE:** To remove the grid lines, select the horizontal lines button again. |

| To do this... | Select... |
|---|---|
| Change the graph titles, | The graph edit button.<br>In the Titles window, type the titles to display as follows:<br>• At the top of the graph<br>• To the left of the graph<br>• To the right of the graph<br>• At the bottom of the graph |

12. To leave the Controls Graph screen, select another screen.

## Adding Comments

To add a comment to a result on the Controls Graph screen, perform these steps:

1. At the Controls Graph screen, select the **Comment** field for a particular line of data.

   A Comment Selection window displays.

2. Select a comment.

   The comment displays in the Comment field.

## Creating Comments

When none of the available comments are appropriate, create a comment:

1. At the Controls Graph screen, select **Edit Comments List**.
2. Select the **Edit Comments List** window where the comment will display.

   For example, click under the last comment to add the comment to the end of the list.

3. Select **Add New to List**.

   New Comment displays in the window to the left of CLOSE.

4. Type the new comment, and then select **Enter**.
   - Enter alphanumeric characters only.
   - If a non-alphanumeric character, such as an apostrophe, is entered, it can be edited in the **Edit Comments List** window.
5. The new comment displays in the Edit Comments List window, above the original highlighted comment, and the top line of the New Comment window defaults to empty.

   **NOTE:** To remove a comment from the list, highlight the comment and select **Remove from List**.

6. Select **CLOSE** to close the Edit Comments List window.

## Removing Points

An invalid result can be removed so it is not included in the graph.

At the Controls Graph screen, select the plus sign (+) to the left of the control result to be removed.

The data corresponding to this result changes color and the plus sign (+) becomes a minus sign (-), indicating this result is not included in the controls graph.

The graph changes to reflect the change in data, the n value is updated, and the Actual Mean, SD, and CV (%) figures are recalculated. See the Controls Graph displaying results not in the graph.

**NOTE:** To include data previously removed, select the minus sign (-) to the left of the result. The minus sign (-) becomes a plus sign (+), the actual calculations are updated, and the graph is updated to reflect the new data.

## Deleting Tests for a Control

Follow the steps below to delete tests for a control:

1. Select **QC** on the toolbar.
2. Select **DATA ENTRY**.
3. Select the down arrow in the Name field and select the control.
4. Select the down arrow in the Test Type field and select the appropriate assay.
5. Select **Delete Control**.
6. Complete the procedure:
   - To delete all tests for that control, select **Yes**.
   - To delete the highlighted test, select **No**, and then select **Yes** to delete.

## Quality Control Management

The instrument software provides several statistical control options that allow the operator to tailor the system based on the laboratory's specific needs with respect to online quality control. The operator can select either the single rule or multi rule approach to statistical quality control to determine if a control is acceptable. The system can also be configured not to use control results for online quality control.

**NOTE:** Control specifications are configured on the Control Entry screen.

The system can be configured to prohibit unacceptable results from being automatically sent to the LIS. These autosend options are included on the LIS Configuration screen. Refer to *Configuring the System*, page 8-1.

### Control Not for On-line QC

This option is selected on the Control Entry screen when the control result is not to be used for online quality control. If the system is configured to autosend results to the LIS, patient results will be transmitted regardless of the Quality Control status.

The mean, standard deviation (SD), and the standard deviation multiplier (SD Multiplier) are entered and the system calculates the high and low limits.

### Single Rule

The Single Rule method uses a single measurement to determine if the control result is acceptable. The mean, standard deviation (SD), and the standard deviation multiplier (SD Multiplier) are entered. The following formula is used to determine the acceptable range.

```
Range = Target Mean ± (Standard Deviation x Standard
Deviation Multiplier)
```

After the test is complete, the instrument evaluates the control result. If a control result is within range, the control printout displays:

```
Control passed all selected rules.
```

If the system is configured to autosend results to the LIS, patient results will be sent.

If a control result is outside of the range, the control printout displays:

```
Control failed rules.
```

The printout lists the rule that was violated. If the system is configured to autosend results to the LIS, patient results will not be sent.

### Multi Rule

**NOTE:** When Multi rule options are used, the control's range on QC reports is listed as N/A.

The Multi Rule options available on the instrument are based on the Westgard QC Multi Rule system for improving control procedure performance.

The Westgard QC Multi Rule system utilizes up to five control rules simultaneously to decrease the probability of false rejections, while increasing the probability of detecting both random and systematic errors. These rules work most efficiently when analyzing three control materials (or levels).

To utilize the rules, the target mean and standard deviation (SD) are entered on the QC Control Entry screen. Up to five rules may be evaluated for each control result. The number of rules evaluated depends on the number of rules selected on the Control Entry screen.

It is important to note that the same control rules are not automatically applied to all analytes. The instrument supports the use of different control rules for each analyte, for example, the rules used for TSH may be different than the rules used for Estradiol.

The rules are as follows:

| Rule | Description |
|---|---|
| 1 (2s) | This is the entry, or initial rule and compares the QC value to a 2 SD control range.<br>This rule is used as a warning to initiate the evaluation of the control result using subsequent rule(s), if selected. If this rule fails, all other selected control rules are evaluated and reported to the operator. |
| 1 (3s) | After a QC value exceeds the 1 (2s) rule, the system will compare it to a 3 SD control range, if selected. Failure of the 3 SD rule marks the assay out of control. If this rule passes, for example, result within 3 SD range, subsequent selected rule(s) are checked. |
| 2 (2s) | The 2(2s) rule checks for prior, consecutive control value exceeding +/- the same 2 SD control range. Failure of this rule marks the assay as out of control. If this rule passes, subsequent selected rule(s) are checked. This rule is evaluated by looking at the most recent result obtained from the same control material, within the same control material. |
| R (4s) | If the range or span of the most recent, prior, consecutive control value compared to the current QC value exceeds 4 SD, the assay is marked as out of control. If this rule passes, the final rule, if selected, is checked. |
| 4 (1s) | This rule fails when 4 consecutive control values exceed 1 SD on the same side (+/-) of the target mean. The assay will be marked as out of control. As with the 2 (2s) rule, this rule is evaluated historically across controls and within the same control material. |

After the test for the control sample is complete, the IMMULITE 2000 system evaluates the result. If a control result is within range for all the rules selected, the control printout displays:

```
Control passed all selected rules.
```

If a control result is outside of range for any of the selected rules, the control printout displays:

```
Control failed rules.
```

The printout lists which rule failed. The operator then follows laboratory procedures for an out-of-range control. The information regarding the violated rule may help determine the cause of the problem.

# Scheduling QC Assays

**NOTE:** This section refers to the IMMULITE 2000 XPi system only.

The IMMULITE 2000 XPi AutoStart feature allows you to schedule the instrument to perform quality control assays when you select **Run AutoStart** or when a scheduled AutoStart occurs. You can also define selected QC assays for selected days of the week.

This section describes the following procedures:

- Scheduling a QC worklist
- Adding or editing a QC worklist to the schedule
- Adding or editing a control to a QC worklist
- Copying a QC worklist
- Deleting a worklist

## Scheduling a QC Worklist

To schedule a QC worklist to run with AutoStart, perform the following steps:

1. At the instrument window, select **MENU**.
2. In the Tools panel, select **Schedule QC**.

   The Worklist Name dropdown list is blank until you add a QC worklist. The worklist displays in the worklist table:

   - Select the **Samples** tab to view the worklist by the control name.
   - Select the **Orders** tab to view the worklist by individual test order.
3. Select **SCHEDULE**.

   The Scheduled QC screen displays worklists that are currently scheduled. You can use the Day of week dropdown list to display schedules for each day or select **ALL** to display the entire week.
4. Select **Add**.
5. At the Schedule QC Worklist screen, select the QC Worklist Name you want to schedule.
6. At the Schedule Type dropdown list, select **Autostart**.

   Autostart is currently the only selection.
7. Select one or more days to schedule the selected worklist.
8. Select **OK**.

   The Scheduled QC screen displays the added worklist schedule.
9. Select **Close**.

## Adding a QC Worklist

**NOTE:** Controls must be defined on the system before you can create a worklist.

To add a new QC worklist, do the following:

1. At the QC Worklist Display screen, select **ADD**.
2. At the QC Worklist Entry screen, enter a name for the new worklist in the QC Worklist Name textbox.
3. Select **Add Control**.
4. At the QC Control Entry screen, select a control from the Control Name dropdown list.
5. Ensure that the appropriate control level and control lot are selected.
6. Select **TEST SELECTION**.
7. At the AVAILABLE TESTS screen, select the tests to include with the control on this worklist.
8. Select **OK**.
9. At the QC Control Entry screen, set dilutions as necessary, and then select **Accept**.

   The new QC Orders display in the QC Worklist Entry screen.
10. Repeat steps 3 through 9 for each control you add to the QC screen.
11. To save the worklist, select **Save**.

## Editing a QC Worklist

To edit a QC worklist or change a worklist name, do the following:

1. At the QC Worklist Display screen, select the worklist you want to edit.
2. Select **EDIT**.
3. To add or edit a control in your worklist, refer to the next section, *Adding a Control in a QC Worklist*, page 4-15 or *Editing a Control in a QC Worklist*, page 4-16.

## Adding a Control in a QC Worklist

To add a control, do the following:

1. At the QC Worklist Display screen, select the appropriate worklist.
2. Select **EDIT**.
3. At the QC Worklist Entry screen, select **Add Control**.
4. At the QC Control Entry screen, select a control from the Control Name dropdown list.

5. Use the appropriate dropdown lists to select the control level and the control lot.
6. Select **TEST SELECTION**.
7. At the AVAILABLE TESTS screen, select the test to add.
8. Select **OK**.
9. At the QC Control Entry screen, select **Accept**.

   The new control displays in the QC worklist.
10. To save changes, select **Save**.

### Editing a Control in a QC Worklist

To edit a control, do the following:

1. At the QC Worklist Display screen, select the appropriate worklist.
2. Select **EDIT**.
3. At the QC Worklist Entry screen, select the control to edit.
4. Select **Edit Control**.
5. At the QC Control Entry screen, make the necessary changes to the displayed control.
6. At the QC Control Entry screen, select **Accept**.

   The edited control displays in the QC worklist.
7. To save changes, select **Save**.

## *Copying a Worklist*

If you want to create a worklist that is similar to another worklist, you could copy a worklist and modify it as necessary.

To copy a worklist, perform the following steps:

1. At the instrument window, select **MENU**.
2. In the Tools panel, select **Schedule QC**.
3. At the QC Worklist Display screen, select the worklist you want to copy.
4. Select **Copy**.
5. At the New QC Worklist Name screen, enter the name for the new worklist.
6. Select **Save**.

   The QC Worklist Display screen displays the new name for the selected worklist. You can now customize the new worklist.

## Deleting a Worklist

If you want to delete a worklist you first must delete all occurrences of the worklist in the Scheduled QC.

To delete a worklist, perform the following steps:

1. At the instrument window, select **MENU**.
2. Select **Scheduled QC**.
3. Select **Schedule**.
4. Delete each occurrence of the worklist:
   a. Select an occurrence.
   b. Select **Delete**.
   c. Repeat these steps until all occurrences of the worklist are deleted.
5. Select **Close**.
6. At the QC Worklist Display screen, use the Worklist Name dropdown list to select the worklist you are deleting.
7. Select **Delete**.
   The instrument displays a message asking if you want to delete the worklist.
8. Select **Yes**.
9. To exit the QC Worklist Display screen, select **Close**.

# 5 Performing Maintenance

# Performing Maintenance

- Daily maintenance
- Monthly maintenance
- Quarterly maintenance
- As needed maintenance
- AutoStart maintenance (IMMULITE 2000 XPi system only)
- Worksheets

## Daily Maintenance

Perform the required maintenance procedures on a daily basis.

#### *For the IMMULITE 2000 System and the IMMULITE 2500 System*

Perform all daily maintenance tasks as listed in the following sections:

- *Preparing the System for Daily Maintenance*, page 5-2.
- *Performing Maintenance Tasks*, page 5-2.

For images of the IMMULITE 2000 system and IMMULITE 2500 system, refer to the following figures:

- *IMMULITE 2000 System (Overhead View)*, page 1-6
- *IMMULITE 2500 (Overhead View)*, page 1-7
- *IMMULITE 2000 Systems and IMMULITE 2500 System (Front View)*, page 1-8

#### *For the IMMULITE 2000 XPi System*

You may perform daily maintenance tasks as listed in the section for IMMULITE 2000 systems or IMMULITE 2500 systems or you can use the AutoStart maintenance.

If you use the AutoStart for your daily maintenance, you can schedule an AutoStart Maintenance, refer to *AutoStart Maintenance (IMMULITE 2000 XPi System)*, page 5-35, or select **RUN AUTOSTART**.

For images of the IMMULITE 2000 XPi instrument, refer to the following figures:

- *IMMULITE 2000 XPi System (Overhead View)*, page 1-9
- *IMMULITE 2000 XPi System (Front View)*, page 1-10

## Preparing the System for Daily Maintenance

Some of the procedures involve checking the instrument status indicator. The status indicator is located at the bottom of the vertical toolbar at the instrument window. The indicator displays the status of empty and full levels.

1. Select **RUN IMMULITE 2000** or **RUN IMMULITE 2500**.
2. Select **OK** when the system initialization is complete.

   The Home screen and the toolbar display.
3. Scan any allergen wedges that changed on the instrument.

   When scanning an allergen wedge, the Allergen Wedge Detail window displays.
4. Confirm that the information is correct, and then select **OK**.

   Refer to *Replacing Reagent Wedges and Allergen Wedges*, page 2-15.
5. Check the system status indicators.

   Refer to *Checking the Status Indicators*, page 5-6.
6. If necessary, fill the consumables, or empty the waste container(s).
7. Fill the paper supply in the printer, if necessary.
8. Prime the sample and reagent pipettors.

   Refer to *Priming the Sample and Reagent Pipettors*, page 5-13.
9. Prime the water probe.

   Refer to *Priming the Water Probe (IMMULITE 2000 Systems)*, page 5-14
10. Prime the substrate probe.

    Refer to *Priming the Substrate Probe*, page 5-16.
11. Close the main cover.

## Performing Maintenance Tasks

1. Log off the system, if the system has not been turned off in the last 24 hours.

   Refer to *Logging Off the System*, page 5-3.
2. Initialize the Diagnostic software.

   Refer to *Initializing Diagnostics*, page 5-3.
3. Clean the sample and reagent probes.

   Refer to *Cleaning the Sample and Reagent Probes*, page 5-5.
4. Restart the instrument computer.

   Refer to *Restarting the Computer*, page 5-6.

## Logging Off the System

**NOTE:** On the IMMULITE 2000 XPi instrument, if you use the AutoStart procedure, this procedure is performed automatically. If you do not use AutoStart, follow these instructions.

Logging off the system each day automatically initiates a system back-up, which stores current data. This process optimizes software performance and allows recent data to be restored in the event of a serious system error. Log off daily so that if a serious system error occurs, recent data is available when the system is restored.

**NOTE:** Failure to put the instrument in STOP mode before logging off may cause the final reagent and bead test counts to be inaccurately stored.

1. Select **STOP**.

   **NOTE:** If active tubes are in progress, a message displays stating the time-to-completion. Select the appropriate button to either cancel or continue the log-off process.

2. If you are logging off for an extended period, perform these steps:
   a. Remove patient samples, controls, diluent, and adjustors from the sample carousel.
   b. Remove any allergen wedges from the reagent carousel and seal the allergen vials with standard caps before storing them.

3. Select **LOG OFF**.

   The following message displays.

   ```
   Would you like to Log Off of the IMMULITE 2000
   software and return to the Start-Up menu?
   ```

4. Select **OK**.

   The following message displays.

   ```
   Preparing to Back up Files...Please Wait

   You are about to delete all patient records over 62
   days and control, verifier and adjustor records over
   366 days.
   ```

5. Increasing the number of days data is stored, by selecting the **CHANGE DAYS** button, may slow the system response time.

6. Select **CONTINUE**.

   The system logs off.

## Initializing Diagnostics

**NOTE:** On the IMMULITE 2000 XPi instrument, if you use the AutoStart procedure, this procedure is performed automatically. If you do not use AutoStart, follow these instructions.

To initialize the diagnostic software, use the following procedure:

**NOTE:** Diagnostics can not be run if the instrument software is running. If necessary, log off of the instrument software before proceeding.

1. At the Windows desktop, double-select the **Diagnostics** icon.
2. After the instrument initializes, select **Condensed Run Program**.

   The Load Program screen displays. Refer to *Diagnostic Programs*, page 6-4.
3. Select the appropriate option:
   - **Home All Motors – 2000** (IMMULITE 2000 system)
   - **IMM 2500 Home All Motors** (IMMULITE 2500 system)
   - **Home All Motors – 2000 XPi** (IMMULITE 2000 XPi system)
4. Select **RUN**.
5. When Home All Motors is complete, select **Load Program**.
6. Select one of the following options:
   - **Cover Unlock – 2000** (IMMULITE 2000 systems)
   - **IMM 2500 Cover Unlock** (IMMULITE 2500 system)
7. Select **RUN**.

   The cover unlocks automatically during the daily probe cleaning diagnostic.
8. Lift the cover.
9. Select **Load Program** to load the list of diagnostics.
10. Run the appropriate diagnostic.

### *Exiting the Diagnostic Program*

1. If necessary, select **Stop**.
2. Select **Exit**.

   The Diagnostics main menu displays.
3. Select **QUIT**.

## Cleaning the Sample and Reagent Probes

**NOTE:** On the IMMULITE 2000 XPi instrument, if you use the AutoStart procedure, this procedure is performed automatically. If you do not use AutoStart, follow these instructions.

Follow the instructions below to clean the Sample and Reagent Probes. A Probe Cleaning Kit (part number L2KPM) is required to complete these instructions. This procedure maintains optimal performance of the probes and prevents carryover.

**CAUTION**

Do not insert anything into the probe. Permanent damage may occur.

1. If necessary, initialize diagnostics.

   Refer to *Initializing Diagnostics*, page 5-3.

2. Select one of the following options:
   - **Daily Probe Cleaning – 2000**
   - **Daily Probe Cleaning – 2000 XPi**
   - **IMM 2500 Daily Probe Cleaning**
3. Select **RUN**.

   This homes all motors, unlocks the cover, and initializes the diagnostic.
4. Lift the cover after it unlocks.
5. Load a 12 x 75 sample tube containing 1.5 mL of probe cleaning solution onto the sample rack (Position 1-1).

   **NOTE:** Follow the package insert instructions for pipetting the probe cleaning solution into the sample tube.
6. Place an empty reaction tube in the shuttle.

   After the instrument cleans and primes the probes, the cover will unlock automatically. If necessary, lift the cover.
7. Select **Lift Cover, Place an Empty Reaction Tube on the Shuttle** to continue.
8. Select **Lift the Cover and Press to Observe Dispense Angle** and check the dispense angle of the sample probe.
9. Observe the liquid that is dispensed from the sample probe.

   It should be a straight solid stream into blind hole. If not, the sample probe may need to be replaced.
10. Select **PRESS TO STOP DISPENSE** to end the diagnostic.

11. After the screen displays the Program Complete message, verify that the sample probe does not touch the inside wall of the blind hole.
12. Remove the sample tube from the instrument and discard the probe cleaning solution.

    **NOTE:** The reaction tube is automatically removed by the system.
13. To continue running diagnostics, select **Load Program** and load the appropriate diagnostic.
14. To stop running diagnostics, select **EXIT**, and then select **QUIT**.

## Restarting the Computer

**NOTE:** On the IMMULITE 2000 XPi instrument, if you use the AutoStart procedure, this procedure is performed automatically. If you do not use AutoStart, follow these instructions.

Follow these steps to restart the computer. The steps are slightly different depending on the computer's operating system (Windows NT or Windows XP).

1. Select the **Start** button on the lower left-hand corner of the screen.
2. Select **Shut Down** or **Turn Off Computer**.
3. Select **Restart the computer?** and then select **Yes** or **Restart**, depending on which prompt displays.

   **NOTE:** Press **CTRL**, **Alt**, and **Delete** keys simultaneously if prompted by the software after the computer restarts.
4. Press **Enter** at the Log on Information window.

   A password is not required.

## Checking the Status Indicators

At the instrument window, check the status indicator on the vertical toolbar and refill or empty reservoirs as necessary. Refer the next sections for maintaining system reservoirs:

- *Filling the Reaction Tube Hopper*, page 5-6.
- *Checking and Filling the Water Bottle*, page 5-7.
- *Checking and Filling the Probe Wash*, page 5-9.
- *Checking and Filling the Substrate*, page 5-10.
- *Checking the Waste Containers*, page 5-11.

## Filling the Reaction Tube Hopper

When the reaction tube hopper is empty, the instrument goes into PAUSE mode automatically. To fill the reaction tube hopper, follow these instructions:

1. Open the front cabinet doors.

2. Grasp the reaction tube hopper handle and swing it towards you.
3. Fill the reaction tube hopper.

   **NOTE:** Reaction tubes are single use only. Dispose of after each use. Do not fill above the tube hopper fill-level mark.

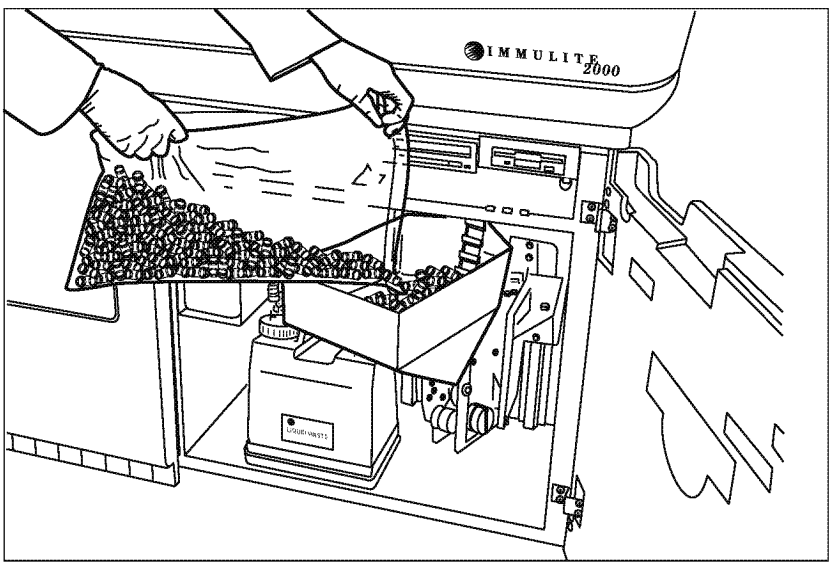



**Figure 5-1 Filling the Reaction Tube Hopper**

4. Swing the hopper back into place until it clicks.
5. Close the front cabinet doors or continue performing maintenance.

## Checking and Filling the Water Bottle

Check the status indicator. If the water bottle needs to be filled, follow these instructions:

1. Open the front cabinet doors.
2. Locate the water bottle.
3. Pull the water bottle forward until the screw cap at the front of the bottle is accessible.

   The bottle remains seated on the load scale, held in place by the molded notch on the bottom of the bottle that engages the front edge of the load scale platform.

   **NOTE:** Do not disconnect the tubing from the valve at the back of the water bottle while the instrument is in RUN mode. For detailed instructions on disconnecting the water bottle, refer to *Disconnecting and Reconnecting Water and Probe Wash Bottles*, page 5-8.

4. Unscrew the cap and fill the water bottle with distilled/de-ionized water from a clean container.
5. Replace the cap and gently slide the water bottle back into place until it is seated properly on the load scale.
6. Ensure that the tubing is not constricted so that water can flow freely.
7. Close the front cabinet doors or continue performing maintenance.

## Disconnecting and Reconnecting Water and Probe Wash Bottles

To disconnect (and reconnect) the water or probe wash bottles from the instrument, follow the instructions below:

**NOTE:** Do not disconnect the tubing while the instrument is in RUN mode.

1. Press the silver button to release the valve and remove the tubing.
2. Remove the bottle from the instrument.

**Figure 5-2 Disconnecting the Water Bottle**

3. Reconnect by inserting the valve at the end of the tubing until it clicks into place.

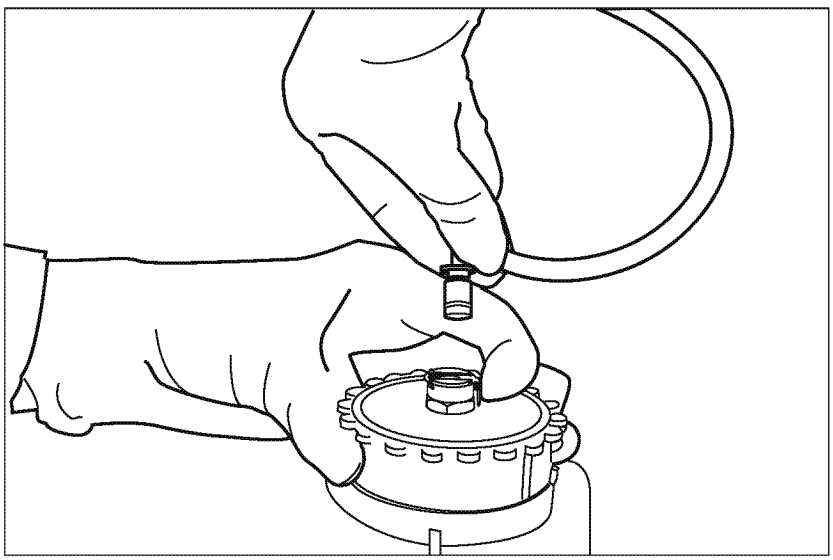


**Figure 5-3 Disconnecting the Probe Wash Bottle**

4. Prime at least ten times to remove air from the system.

## Checking and Filling the Probe Wash

Check the status indicator. If the probe wash bottle needs to be filled, follow the instructions below.

1. Open the front cabinet doors.
2. Locate the probe wash bottle.

   **NOTE:** Do not disconnect the tubing from the valve at the back of the probe wash bottle while the instrument is in RUN mode. For detailed instructions on disconnecting the probe wash bottle, refer to *Disconnecting and Reconnecting Water and Probe Wash Bottles*, page 5-8.

3. Unscrew the cap and fill with probe wash.
4. Replace the cap and gently slide the probe wash bottle back into place until it is seated properly on the load scale.
5. Ensure that the tubing is not constricted so that probe wash can flow freely.
6. Close the front cabinet doors or continue performing maintenance.

## Checking and Filling the Substrate

Check the status indicator. If the substrate reservoir needs to be filled, follow the instructions below.

**CAUTION**

Do not leave substrate on the instrument for more than 30 days. Leaving substrate on the instrument for more than 30 days could affect results.

**NOTE:** Do not overfill the substrate bottle. The indicator strip on the substrate bottle displays the substrate level.

1. Allow the substrate to reach room temperature.

   Remove the substrate from the refrigerator 20 minutes before using. For more information, refer to the package insert.

2. Open the cover over the Dual Resolution Dilutors (DRD) priming accessories and locate the substrate reservoir.

3. Lift the tab on the substrate reservoir.

**WARNING**

Do not add fill the substrate reservoir beyond the maximum capacity of 1000 tests. Filling the substrate reservoir beyond the maximum capacity may cause substrate to enter the $CO_2$ scrubber and cause a blockage. This can result in damage to the instrument and possible misreporting of results. Each bottle of chemiluinescent substrate contains enough material for 1000 tests.

4. Pipette the appropriate amount of substrate from the refill bottle into the substrate reservoir.

   Do not exceed the 1000 tests mark.

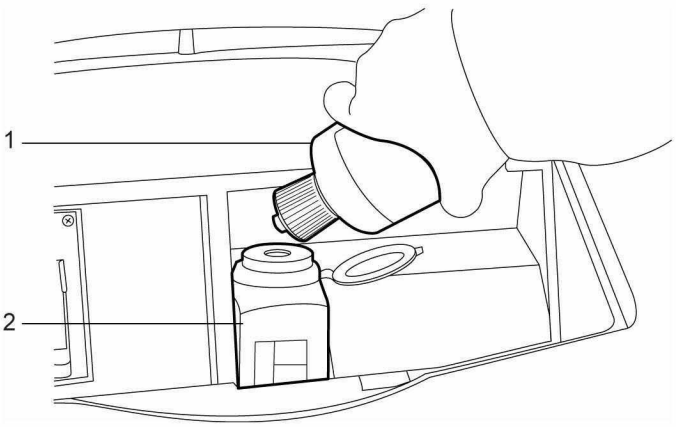



**Figure 5-4 Filling the Substrate**

5. Close the tab on the substrate bottle and close the cover.

**CAUTION**

Do not leave substrate spills on the load scale. Spilled substrate may cause the load scale to stick and the substrate status indicator to appear full when the substrate reservoir is empty. This could affect results. Immediately clean up any substrate spills using moistened tissues.

## Checking the Waste Containers

The instrument has a solid waste and a liquid waste container. Check the status indicator. If the solid or liquid waste needs to be emptied, follow the instructions below:

**BIOHAZARD**

Wear personal protective equipment. Use universal precautions. Refer to *Safety Instructions*, page A-1 for recommended precautions when working with biohazardous materials.

### Solid Waste

1. Open the front cabinet doors.
2. Locate the solid waste container.
3. Remove the solid waste container and flip back the tube deflector.

4. Remove the biohazard bag filled with used reaction tubes and dispose the bag into a biohazard container.
5. Put a new biohazard bag (part number 10-901807) in the solid waste container, spreading out the bag so it lies against the sides of the container.
6. Be sure the bag is fully opened so the used reaction tubes can drop to the bottom of the container.
7. Flip the tube deflector forward and replace the container in the system, with the deflector at the back end.
8. Close the front cabinet doors or continue performing maintenance.

## Liquid Waste

**BIOHAZARD**

Wear personal protective equipment. Use universal precautions. Refer to *Safety Instructions*, page A-1 for recommended precautions when working with biohazardous materials.

1. Open the front cabinet doors.
2. Locate the liquid waste bottle.
3. Push the dark gray button with one hand to release the valve, while pulling the tube out with the other hand.
4. Remove the liquid waste bottle.

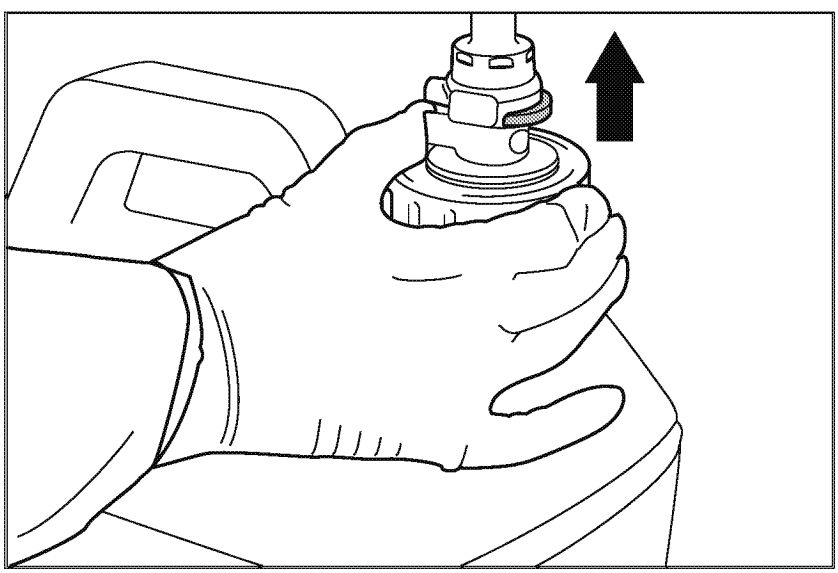


**Figure 5-5 Removing the Liquid Waste Bottle**

5. Empty the liquid waste bottle and place it on the instrument.

   **NOTE:** Do not pour waste from the gray connection. Open the white cap to empty the waste.

6. Reconnect by inserting the valve at the end of the waste line tubing until it clicks into place.

**WARNING**

Do not leave the valve until it clicks into place. If it does not click into place, liquid waste could back up in the waste tubing and overflow onto the floor.

7. Close the front cabinet doors or continue performing maintenance.

## *Priming the Sample and Reagent Pipettors*

**NOTE:** Priming the sample and reagent pipettor is part of the AutoStart maintenance procedures for the IMMULITE 2000 XPi instrument.

**NOTE:** The instrument must be in STOP mode to open the cover. If necessary, select the STOP button before proceeding with the instructions below.

The following procedure primes the sample and reagent pipettors, as well as the water probe on the IMMULITE 2500 system. The water probe on the IMMULITE 2000 systems must be primed separately.

To prime the sample and reagent pipettors, follow these instructions:

1. Select **COVER** to release the lock.
2. Swivel the monitor out of the way and raise the main cover.
3. Press the green **PRIME** button until priming starts.

   Alternatively, the PRIME button on the monitor can be used instead of the green PRIME button.

4. Continue priming until there are no bubbles in the dual resolution dilutors or the tubing.

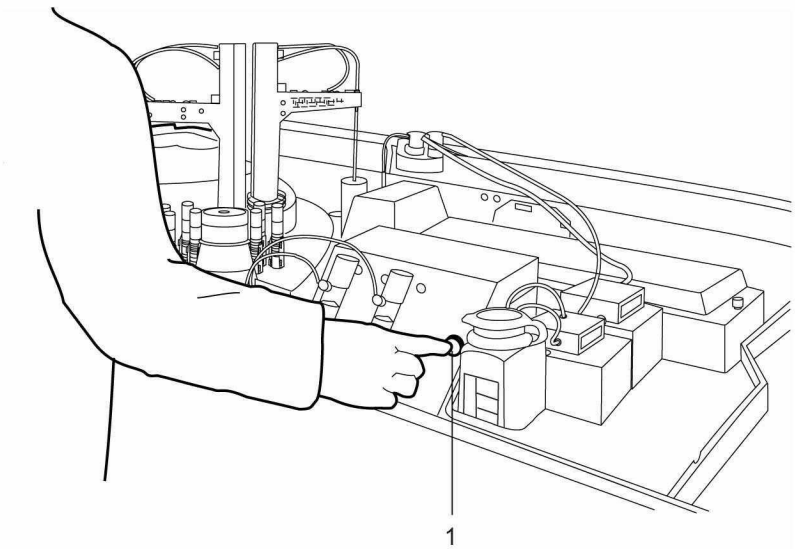



**Figure 5-6 Priming the Sample and Reagent Pipettors**

## *Priming the Water Probe (IMMULITE 2000 Systems)*

Follow these steps to prime the water probe on the IMMULITE 2000 systems.

**NOTE:** The water probe on the IMMULITE 2500 is primed automatically during when the sample and reagent pipettors are primed. Refer to *Priming the Sample and Reagent Pipettors*, page 5-13.

1. Remove the water probe from the bead/tube wash station.

**WARNING**

Do not lift the water probe unless you are standing away from the reagent pipettor drain. The reagent pipettor automatically moves away from the reagent pipettor drain when the water probe is lifted.

2. Hold the water probe over the reagent pipettor drain.

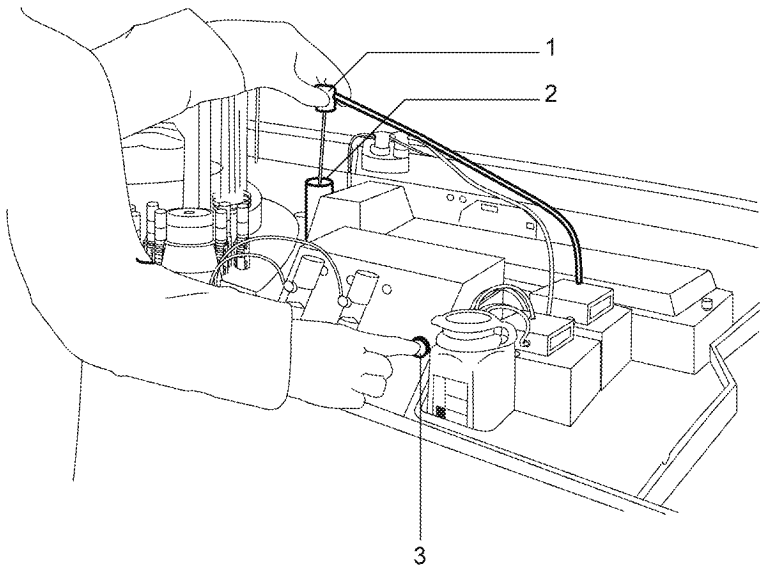



**Figure 5-7 Priming the Water Probe**

3. Press and release the green **PRIME** button.

   The pump primes four times.

4. Continue to prime until there is a steady stream of water and no air in the tubing.
5. Allow the priming sequence to complete and then place the water probe back into the bead/tube wash station.
6. Be sure that the probe is fully seated.

   The reagent pipettor moves back to its original position.

### Priming the Substrate Probe

To prime the substrate probe, follow the instructions below:

**CAUTION**

Do not insert anything into the probe. Permanent damage may occur.

1. Remove the substrate probe from its holder next to the bead/tube wash station.

**WARNING**

Do not lift the substrate probe unless you are standing away from the reagent pipettor. The reagent pipettor automatically moves away from the reagent pipettor drain when the substrate probe is lifted.

2. Check for white precipitate at the end of the substrate nozzle.

   If necessary, gently wipe the nozzle with a clean swab or lint-free, dry tissue.

3. Hold the substrate probe over a clean beaker or other external container.

   **NOTE:** Do not prime the substrate probe into the reagent pipettor drain.

4. Press and release the green **PRIME** button.

   The pump primes four times.

5. Continue to prime until there is a steady stream of substrate and no air in the tubing.

6. Place the substrate probe back into its holder.

   **NOTE:** The reagent pipettor returns to its original position.

## Weekly Maintenance

The maintenance procedures described below should be performed on a weekly basis. Refer to *Worksheets*, page 5-37 for maintenance records that can be copied and used to keep track of maintenance items.

### Cleaning the Waste Tube (IMMULITE 2000 Systems)

Follow these instructions to clean the liquid waste tube on the IMMULITE 2000 systems. Refer to *Cleaning the Waste Tube (IMMULITE 2500 System)*, page 5-17 for the IMMULITE 2500 procedure.

1. If necessary, initialize diagnostics.

   Refer to *Initializing Diagnostics*, page 5-3.

2. Select **Waste Tube Cleaning - 2000**.

3. Select **RUN**.
4. When the program is finished initializing, place a sample tube with 3 mL probe cleaning solution into position 1 of the sample rack.
5. Add 3 mL of probe cleaning solution to compartment A of the probe cleaning wedge and place the wedge into position 1 of the reagent carousel.
6. Select **Press When Sample Tube and Reagent Wedge are Loaded**.
7. Allow the program to complete its running cycle.

   Approximate time to completion is 20 minutes. Program Complete displays on the screen.
8. To continue running diagnostics, select **Load Program** and load the appropriate diagnostic.
9. To stop running diagnostics, select **EXIT**, and then select by **QUIT**.

## *Cleaning the Waste Tube (IMMULITE 2500 System)*

Follow the instructions below to clean the liquid waste tube on the IMMULITE 2500 system.

1. If necessary, initialize diagnostics.

   Refer to *Initializing Diagnostics*, page 5-3.
2. Select **IMM 2500 Waste Tube Cleaning**.
3. Run the program by selecting **RUN** at the top of the window.
4. When the program is finished initializing, place a probe cleaning wedge containing at least 10 mL of the probe wash solution into position 1 of the reagent carousel.
5. Select **Press to Continue**.

   Remove two reaction tubes from the Tube Hopper.
6. Select **Press to Continue**.

7. Load 1 reaction tube into the shuttle.

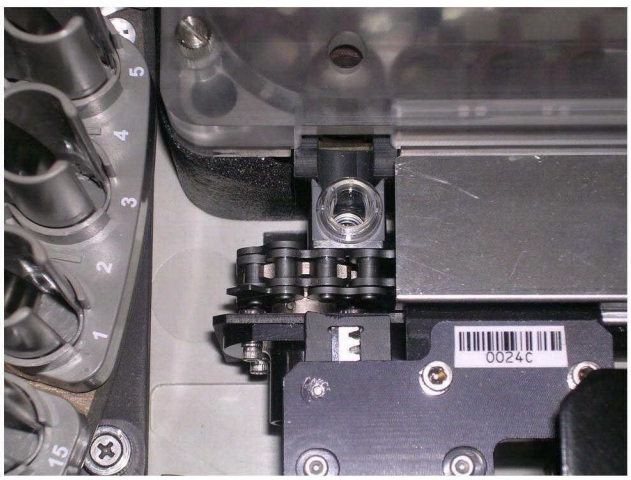



**Figure 5-8 Reaction Tube in Shuttle Position**

8. Select **Load tube in Shuttle**.

   The reaction tube is pushed into the shuttle.

9. Repeat steps 7 and 8 for the second tube.

10. Allow the program to complete its running cycle.

    Approximate time to completion is 20 minutes. Program Complete displays on the screen.

11. To continue running diagnostics, select **Load Program** and load the appropriate diagnostic.

12. To stop running diagnostics, select **EXIT**, and then select **QUIT**.

## *Performing the Probe Angle Diagnostic*

**NOTE:** Perform this procedure weekly if you are using AutoStart on your IMMULITE 2000 XPi instrument.

To check the sample probe angles, follow these instructions:

1. Log off the system.

   Refer to *Logging Off the System*, page 5-3.

2. Depending on the instrument, perform one of these options:

   - For IMMULITE 2000 instruments and IMMULITE 2500 instruments, initialize diagnostics, and continue with step 3.

     Refer to *Initializing Diagnostics*, page 5-3.

   - For IMMULITE 2000 XPi instruments, proceed to step 8.

3. At the Windows desktop, double-select the **Diagnostics** icon.

4. After the instrument initializes, select **Condensed Run Program**.
5. Select **Home All Motors**, and then select **RUN**.
6. Select **Cover Unlock** and lift the instrument cover.
7. At the monitor, select **Load Program**.
8. Select **Sample Probe Angle**, and then select **RUN**.
9. To begin, at the monitor, select **Press to Dispense Water**.
10. Visually check the liquid the sample probe is dispensing.

    It should be a straight solid stream. If not, refer to *Diagnostic Programs*, page 6-4.
11. To end the test, at the monitor, select **Press to Stop**.
12. To close the sample probe angle diagnostic program, select **EXIT**.
13. To exit Diagnostics, select **Quit**.

# Monthly Maintenance

Maintenance procedures to perform monthly are listed and described below. Refer to *Worksheets*, page 5-37 for maintenance records that can be copied and used to keep track of maintenance items.

## Checking the Dispense Angle of the Reagent Probe

Follow the instructions below to check the reagent probe dispense angle.

1. If necessary, initialize diagnostics.

   Refer to *Initializing Diagnostics*, page 5-3.
2. Select one of the following options:
   - **Reagent Probe Dispense Angle – 2000**
   - **IMM 2500 Reagent Probe Dispense Angle**
   - **Reagent Probe Dispense Angle – XPi**
3. Select **RUN**.
4. Select the **Press to Dispense Water** button to begin.
5. Observe the liquid that is dispensed from the reagent probe.

   It should be a straight solid stream.
6. Select the **Press to End Program** button.
7. To continue running diagnostics, select **Load Program** and load the appropriate diagnostic.
8. To stop running diagnostics, select **EXIT**, and then select **QUIT**.

## *IMMULITE 2000/2000 XPi Water TestPM*

This feature tests the instrument for alkaline phosphatase contamination. An updated copy of the IMMULITE 2000, 2500, and 2000 XPi Monthly and Quarterly Maintenance Record log is included with this document.

Before performing the Water TestPM, follow the instructions below to prepare the instrument:

1. If necessary, initialize diagnostics.

   Refer to *Initializing Diagnostics*, page 5-3.

2. If necessary, prime the substrate probe.

   Refer to *Priming the Substrate Probe*, page 5-16.

Follow the instructions below to test the instrument for alkaline phosphatase contamination:

1. To load the list of diagnostics, select **Load Program**.
2. At the Diagnostic Program window:
   - For the IMMULITE 2000, select **WatertestPM – 2000**.
   - For the IMMULITE 2000 XPi, select **WatertestPM – 2000XPi**.
3. Select **RUN**.

   The instrument automatically homes all motors.
4. When prompted, place a clean, empty 12 x 75 tube in position 1 of a sample rack.
5. Place the sample rack in position 1 of the Sample Carousel.
6. After the tube is loaded on the instrument, select **Load tube and press to continue**.
7. When prompted, remove the Water Probe from the Wash Station.
8. Place the Water Probe in the tube (from Step 4).
9. Select **Place Water Probe in tube 1-1**.
10. Select **Press to dispense from the Water Probe**.

    Collecting Water from the Water Probe displays.

    **NOTE:** If the Water Probe touches the water inside the sample tube, wipe the Water Probe with a lint-free cloth before returning it to the Wash Station.
11. When prompted, remove the Water Probe from the tube and return it to the Wash Station.
12. Select **Replace Water Probe**.

The instrument primes the Sample and Reagent Probes, pipettes water, transfers the reaction tubes to the Luminometer, and dispenses substrate. Subsequently, the Photomultiplier Tube (PMT) reads the reaction tubes.

After the instrument reads the tubes, Program Complete displays, and the instrument generates a report of the results. Table 5-1 is an example report of the results.

**Table 5-1 Example Water TestPM Results for the IMMULITE 2000/2000 XPi Systems**

```
IMMULITE 2000 (XPi)

WATER TEST PM
mm-dd-yy hh:mm:ss

Serial Number: nnnnnn

Operator: _____________________

NOTE: All results have been multiplied by the PMT factor.

Subtract the Substrate Only CPS from the individual water CPS

Sample Probe CPS: xxx.x - ________ (Substrate Only) = ________

Reagent Probe CPS: xxx.x - ________ (Substrate Only) = ________

Water probe CPS: xxx.x - ________ (Substrate Only) = ________

Substrate Only CPS: xxx.x
```

13. When the instrument finishes generating the report, fill in the operator's name.

    Using the results, refer to *Evaluating Water TestPM Results*, page 5-24.

14. To continue running diagnostics, select **Load Program** and load the appropriate diagnostic.

15. To stop running diagnostics, select **EXIT**, then select **QUIT**.

## IMMULITE 2500 Water TestPM

This feature tests the instrument for alkaline phosphatase contamination. An updated copy of the IMMULITE 2000, 2500, and 2000 XPi Monthly and Quarterly Maintenance Record log is included with this document.

Before performing the Water TestPM, prepare the instrument:

1. If necessary, initialize diagnostics.

   Refer to *Initializing Diagnostics* in the IMMULITE 2000/2500/2000 XPi Operator's Guide.

2. If necessary, prime the substrate probe.

   Refer to *Priming the Substrate Probe* in the IMMULITE 2000/2500/2000 XPi Operator's Guide.

Follow the instructions below to test the instrument for alkaline phosphatase contamination:

1. To load the list of diagnostics, select **Load Program**.
2. At the Diagnostic Program window, select **IMM 2500 WatertestPM**.
3. Select **RUN**.

   The instrument automatically homes all motors.
4. When prompted, load a reaction tube into the shuttle.
5. Select the **Load tube in Shuttle then press to continue**.

   Repeat this 6 more times until the prompt and button disappear.

   **NOTE:** Although 7 reaction tubes are loaded on the instrument, only 5 results generate. The instrument adds water from the wash station to the other 2 tubes and later discards them.

The Instrument primes the Sample and Reagent probes and distributes water and substrate as needed. After the incubation completes, the PMT reads the reaction tubes.

When the process completes, the instrument generates a report of the results. Table 5-2 on page 5-23 is an example report of the results.

**Table 5-2 Example Water TestPM Results for the IMMULITE 2500 System**

```
IMMULITE 2500

WATER TEST PM
mm-dd-yy hh:mm:ss

Serial Number: nnnnnn

Operator: _____

NOTE: All results have been multiplied by the PMT factor.

Subtract the Substrate Only CPS from the individual water CPS

Sample Probe CPS: xxx.x - _____ (Substrate Only) = _____

Reagent Probe CPS: xxx.x - _____(Substrate Only) = _____

Water probe1 CPS: xxx.x - _____(Substrate Only) = _____

Water probe2 CPS: xxx.x - _____(Substrate Only) = _____

Substrate Only CPS: xxx.x
```

6. When the instrument finishes generating the report, fill in the operator's name.

   Using the results, refer to *Evaluating Water TestPM Results*, page 5-24.

7. To continue running diagnostics, select **Load Program** and load the appropriate diagnostic.
8. To stop running diagnostics, select **EXIT**, then select **QUIT**.

### Evaluating Water TestPM Results

This section explains how to evaluate the Water TestPM results.

Table 5-1 on page 5-21 displays an example of a report generated by IMMULITE 2000/2000 XPi systems.

Table 5-2 on page 5-23 displays an example of a report generated by an IMMULITE 2500 system.

To evaluate an IMMULITE system, do the following:

1. Ensure the CPS measurement for each reaction tube meets the following criterion appropriate for the system:
   - For the IMMULITE 2000/2000 XPi systems, < 1100 CPS
     If the Open CPS measurement of any reaction tube is > 1100, the instrument may be contaminated.
   - For the IMMULITE 2500 system, < 1250 CPS
     If the Open CPS measurement of any reaction tube is > 1250, the instrument may be contaminated.

   If necessary, repeat the WatertestPM.
2. Enter the Substrate Only CPS value in the first blank on the line for each tube.
3. Subtract the Substrate Only CPS from the individual water CPS.
4. Enter the result in the second blank on the line for each tube.

If the difference between the CPS measurement of each tube and the Substrate Only CPS measurement is ≤ 200 CPS, the water test passed.

## *Cleaning the Fan Filter*

Follow the instructions below to clean the Fan Filter:

1. Move the monitor out of the way.
2. Open the cover.

3. Press down on the screw while turning to release the screw.

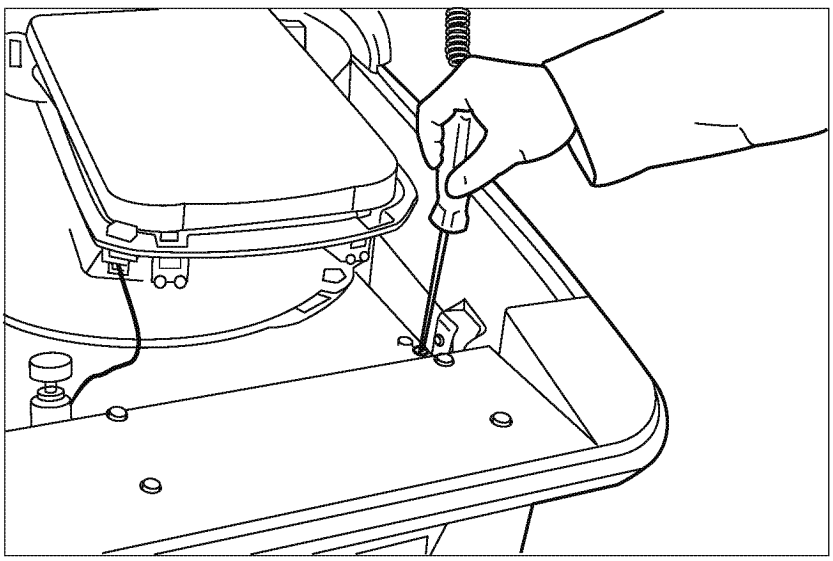


**Figure 5-9 Cleaning the Fan Filter**

4. Pull the side door panel open.
   The door is held in place magnetically and opens easily.

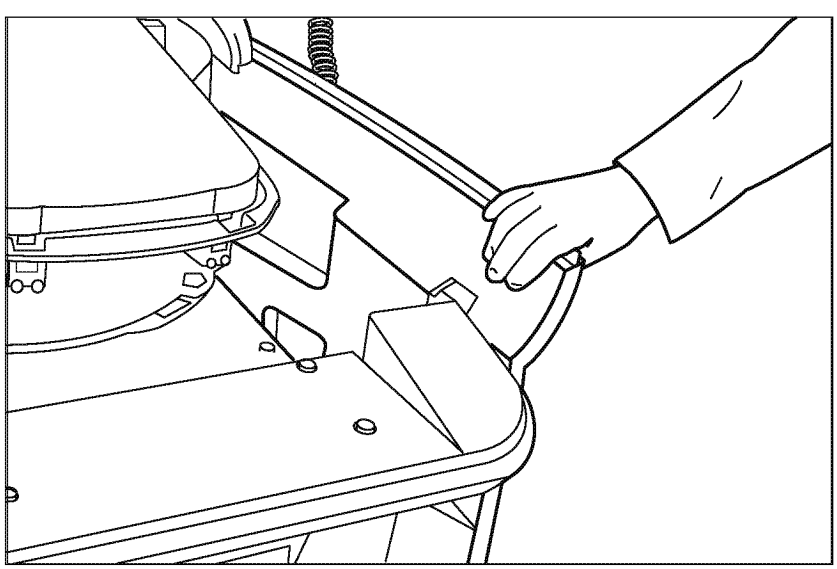


**Figure 5-10 Pulling Open the Side Door Panel**

5. Remove the fan filter guard by unscrewing the top and bottom screws.

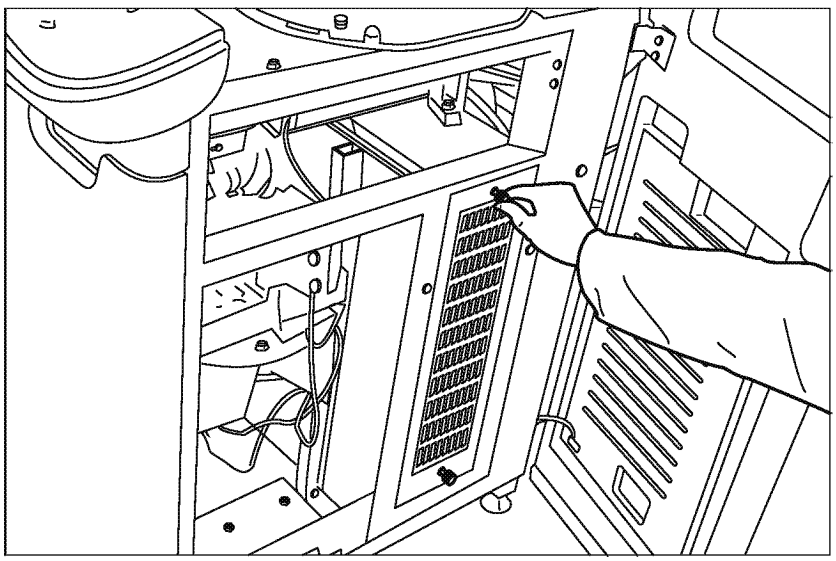


**Figure 5-11 Removing the Fan Filter Guard**

6. Remove the fan filter from the instrument.

   **NOTE:** If necessary, gently move the silver frame of the fan filter to loosen it.

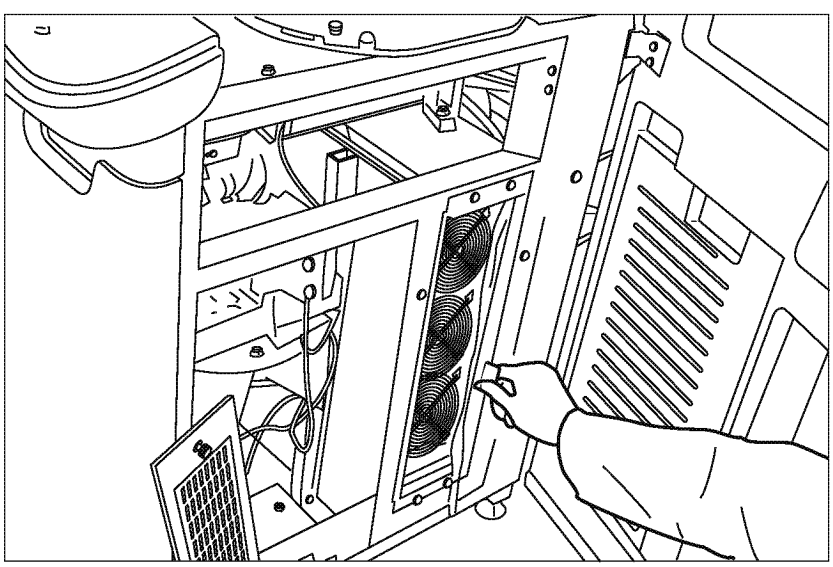


**Figure 5-12 Removing the Fan Filter**

7. Clean the fan filter by holding it under running water and rubbing gently to remove the dust.

**NOTE:** The fan filter can be vacuumed, instead of running it under water.

8. Blot the fan filter dry and place it back on the instrument.
9. Replace the fan filter guard, using the top and bottom screws.
10. Finger tighten the screw that holds the side door panel in place.

## Decontaminating the Clot Detection Transducer

Decontaminate the clot detection transducer following these instructions:

1. If necessary, initialize diagnostics.

   Refer to *Initializing Diagnostics*, page 5-3.

2. Select **Transducer Decon - 2000**, **IMM 2500 Transducer Decon**, or **Transducer Decon - 2000 XPi**
3. Select **RUN**.

   Follow the prompts on the screen. A prompt displays instructing the user to place a 12 x 75-mm sample tube with 2.5 mL of 0.1 M sodium hydroxide (NaOH) in position 1.

   - Use only NaOH for this procedure.
   - When you order this diagnostic, the instrument places the correct rack for easy access.

4. Place the tube in position 1.

**BIOHAZARD**

Wear personal protective equipment. Use universal precautions. Refer to *Safety Instructions*, page A-1 for recommended precautions when working with biohazardous materials.

5. Select **Press to Continue** after the tube is in place.

   Watch the prompts. The Program Complete prompt indicates when the program is finished.

6. To continue running diagnostics, select **Load Program** and load the appropriate diagnostic.
7. To stop running diagnostics, select **EXIT**, and then select **QUIT**.

## Decontaminating the Bottles and Lines

Clean the probe wash bottle, water bottle, and lines according to the procedures below.

To test for water contamination, refer to one of these topics:

- *Water Test Procedure (IMMULITE 2000 System)*, page 5-32.
- *Water Test Procedure (IMMULITE 2500 System)*, page 5-33.

Obtain the materials needed to decontaminate the bottles and lines:

- Empty beaker
- Decontamination bottles (included with instrument)
- 350 mL of probe wash (prepared 10X dilution) or 0.1M NaOH
- Fresh distilled/de-ionized water

## Decontaminating the Bottles

1. Thoroughly rinse the inside the probe wash and water supply bottles with 70% isopropyl alcohol to decontaminate them.
2. Rinse well with distilled/de-ionized water.
3. Let dry until ready to use.
4. Refill water bottle with fresh distilled/de-ionized water.
5. Refill probe wash bottle with freshly prepared probe wash.

## Decontaminating the Lines

**NOTE:** Do not use alcohol to decontaminate water and probe wash lines. Use alcohol only to clean bottles.

1. If necessary, initialize diagnostics.

   Refer to *Initializing Diagnostics*, page 5-3.

2. Select **Decontamination - 2000** or **IMM 2500 Decontamination**, and then select **RUN**.

   A prompt instructs the user to run **Home All Motors** before proceeding.

3. Select **Read Alert Message**. **Click to Continue**.

   A prompt displays:

   ```
   Place the water probe into the reagent pipettor
   drain.
   ```

4. Depending on the instrument, do one of the following:

**WARNING**

Do not lift the water probe unless you are standing away from the reagent pipettor drain. The reagent pipettor automatically moves away from the reagent pipettor drain when the water probe is lifted.

   a. For the IMMULITE 2000 systems, remove the water probe.

b. For the IMMULITE 2500 system, remove two reaction tubes from the tube hopper and place them in front of the shuttle.

5. After the water probe is removed from the bead/tube wash station, the following prompt is displayed:

   `Disconnect water and probe wash lines. Place them into an empty beaker. Press button when ready.`

   **NOTE:** For detailed instructions on disconnecting the probe wash and water bottles, *Disconnecting and Reconnecting Water and Probe Wash Bottles*, page 5-8.

6. Complete the prompt instructions and select the **Press to Continue** button.

   The pumps will be emptied.

7. When prompted, connect the water and probe wash lines to the decontamination bottle containing 350 mL of prepared probe wash.

   **NOTE:** 0.1M NaOH may be used.

8. Select **Press to Continue**.

   Probe wash will be pumped through the lines. The following prompt displays:

   `Disconnect water and probe wash lines. Place them into an empty beaker. Press button when ready.`

9. Complete the prompt instructions and select **Press to Continue**.

   The pumps will be emptied and the following prompt displays:

   `Please connect the Water and Probe Wash lines to the bottles. Press button when ready.`

10. Follow the instructions and then select **Press to Continue**.

    The system primes the water and probe wash into the lines.

11. Select **Replace Water Probe** when prompted.

12. To continue running diagnostics, select **Load Program** and load the appropriate diagnostic.

13. To stop running diagnostics, select **EXIT**, followed by **QUIT**.

14. Close the front cabinet doors.

# Quarterly Maintenance

## Replacing the CO2 Scrubber

Replace the $CO_2$ scrubber quarterly (every three months), following the instructions below. Blockage of the $CO_2$ scrubber may affect the dispense of substrate from the reservoir. The location of the scrubber may vary from the figure below.

Refer to *Worksheets*, page 5-37 for maintenance records that can be copied and used to keep track of maintenance items.

1. Remove the old $CO_2$ scrubber by pulling the tube away from the holding clips.
2. Write the date on the new $CO_2$ scrubber.
3. Take the clear plastic end off the new $CO_2$ scrubber, connect it to its tubing and insert it into the tube into the holding clips.

   **NOTE:** To maintain proper airflow and to reduce the chance of developing an obstruction, the bottom end of the $CO_2$ scrubber tube must not touch the load scale plate.

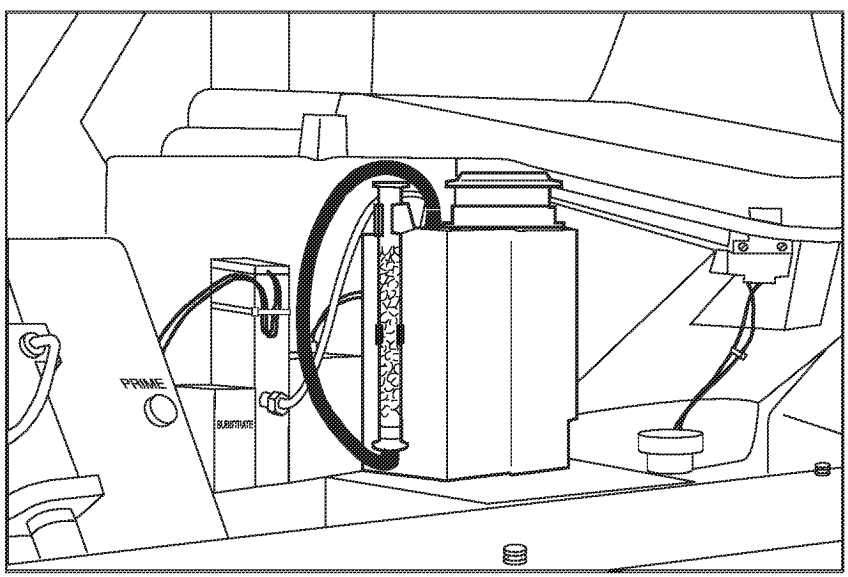



**Figure 5-13 Substrate Reservoir and $CO_2$ Scrubber**

# As Needed Maintenance

## Cleaning the Monitor

Clean the monitor as needed:

1. Turn off the monitor.
2. Wipe the monitor with a damp cloth.

## Cleaning the Trackball

Follow the instructions below to clean the trackball:

1. Remove the trackball by grasping it and pulling it straight up.

2. Clean the ball using a 70% isopropyl alcohol solution.
3. Dry the trackball with a lint-free wipe and place it back in the holder.

## Maintaining the Sample Racks

Follow these instructions to clean the sample racks:

1. Clean the sample racks with warm soapy water.
2. Rinse the sample racks thoroughly before using.
3. Ensure the barcode labels are not cracked or peeling.

### Replacing Sample Rack Labels

When you have to replace a sample rack barcode label, ensure that you use the correct label type for the sample rack.

- Standard sample racks use barcode labels that display uppercase letters.
- Tube top sample racks use barcode labels that display lowercase letters.

## Water System Routine Maintenance

The routine maintenance required for the instrument water system consists of flushing. The water system is self-contained and has no operator serviceable parts.

**NOTE:** This procedure is only applicable to instruments that have the optional Direct Water Feed option installed.

Minimal daily use of the IMMULITE 2000 systems and IMMULITE 2500 system, running 300 tests per day or more, will aid in preventing contamination of the system with alkaline phosphatase producing organisms. Flushing of the water system will eliminate most contamination.

The water system needs to be flushed if:

- The instrument has not been run for 48 hours or more.
- Less than 300 tests per day have been performed.

### Flushing Procedure

1. Open the left front door, and lift the water bottle off its load cell.
2. Disconnect the inlet and outlet tubings at the quick disconnect fittings.
3. Unplug the sensor wires leading to the float switch at the quick disconnect.
4. Unscrew the large, white cap from the water bottle.
5. Pour the water from the water bottle into a sink or drain.
6. Place the empty bottle back on the water load cell and allow the bottle to automatically refill.
7. Repeat steps 5 and 6 two times.

8. Reconnect the cleaned water bottle to the tubings and sensor wires.

   **NOTE:** Assure the electrical connector is dry before reconnecting.

9. Return the bottle to the instrument and allow the water system to refill with water.

## *Water Test Procedure (IMMULITE 2000 System)*

Follow the instructions below to test the water for alkaline phosphatase contamination.

1. If necessary, initialize diagnostics.

   Refer to *Initializing Diagnostics*, page 5-3.

2. Select **Cover Unlock – 2000**.
3. Select **RUN**.

   The cover unlocks.

4. Lift the cover.
5. Select **Load Program** to load the list of diagnostics.
6. Select **SUBSTRATE PRIME - 2000**.
7. Select **RUN**.
8. Remove the probe when prompted.
9. Hold the probe over a clean beaker or other external container and select **Press to Prime**.

   The substrate will begin to prime.

10. When a clean, straight stream is dispensed, select **Press to stop priming**.
11. Replace the probe when prompted.
12. Select **Load Program** to return to the Diagnostic Program screen.
13. Select **WATERTEST - 2000**.
14. Select **RUN**.
15. Select **Press to Start Initialization.**
16. At the next prompt, pipette 50 µl of water into the first of two reaction tubes.

    **NOTE:** The procedure requires manually pipetting 50 µL water (from the water source) into a reaction tube and loading the tube on the tube processor shuttle. No bead is required in this tube.

17. Place the tube into the shuttle.
18. Select **Load tube in shuttle**.

19. Place an empty reaction tube into the shuttle and select **Load tube into shuttle**.

    The following messages display:

    ```
    Loading tube in luminometer
    Adding Substrate
    Starting a 5 minute substrate incubation
    Reading tubes at PMT
    ```

20. After 5 minutes, when prompted, select the **Test complete press to stop** button to stop the diagnostic and generate a printout.

The Water Test procedure calculates results using the PMT factor. Table 5-3 on page 5-34 displays an example of a report generated by IMMULITE 2000/2500/2000 XPi systems.

## *Water Test Procedure (IMMULITE 2500 System)*

Follow the instructions below to test the water for alkaline phosphatase contamination.

1. If necessary, initialize diagnostics.

   Refer to *Initializing Diagnostics*, page 5-3.

2. Select **IMM 2500 Cover Unlock**.
3. Select **RUN**.

   The cover unlocks.

4. Lift the cover.
5. Select **Load Program** to load the list of diagnostics.
6. Select **IMM 2500 SUBSTRATE PRIME**.
7. Select **RUN**.
8. Remove the probe when prompted.
9. Hold the probe over a clean beaker or other external container and select **Press to Start Priming**.

   The substrate will begin to prime.

10. When a clean, straight stream is dispensed, select **Press to Stop Priming**.
11. Replace the probe when prompted.
12. Select **Load Program** to return to the Diagnostic Program screen.
13. Select **IMM 2500 WATERTEST**.
14. Select **RUN**.
15. At the next prompt, pipette 50 µL of water into the first of two reaction tubes.

**NOTE:** The procedure requires manually pipetting 50 µL water (from the water source) into a reaction tube and loading the tube on the tube processor shuttle. No bead is required in this tube.

16. Place the tube into the shuttle.
17. Select **Load tube in shuttle**.
18. Place an empty reaction tube into the shuttle and select the **Load Tube** button.

    The following messages display:

    ```
    Transferring to Luminometer
    Dispensing Substrate
    Program Running
    ```

19. When the process is complete, a printout is generated.

Table 5-3 on page 5-34 displays an example of a report generated by IMMULITE 2000/2500/2000 XPi systems.

## *Evaluating WATERTEST Results*

**Table 5-3 Example Water Test Results for the IMMULITE 2000/2500/2000 XPi systems**

```
IMMULITE (2000) (2500) (2000 XPi)

WATER TEST
mm-dd-yy hh:mm:ss

Serial Number: nnnnnn

Operator: _____

NOTE: All results have been multiplied by the PMT factor.

Subtract the Substrate Only CPS from the Source Water CPS

Source Water CPS: xxx.x - _____ (Substrate Only) = _____

Substrate Only CPS: xxx.x
```

This section explains how to evaluate the Water Test results.

Table 5-3 on page 5-34 displays an example of a report generated by IMMULITE 2000/2500/2000 XPi systems.

To evaluate the water test results, do the following:

1. Ensure the CPS measurement for each reaction tube meets the criterion appropriate for the system:

- For the IMMULITE 2000/2000 XPi systems, < 1100 CPS
  If the Open CPS measurement of any reaction tube is > 1100, the source water may be contaminated.
- For the IMMULITE 2500 system, < 1250 CPS
  If the Open CPS measurement of any reaction tube is > 1250, the source water may be contaminated.

If necessary, repeat the Water Test Procedure.

2. Enter the Substrate Only CPS value in the first blank on the line for the Source Water.
3. Subtract the Substrate Only CPS from the Source Water CPS.
4. Enter the result in the second blank on the line.

If the difference between the CPS measurement of the source water and the Substrate Only CPS measurement is ≤ 200 CPS, the water test passed.

# AutoStart Maintenance (IMMULITE 2000 XPi System)

Starts the following routine maintenance tasks automatically:

- Restarts the computer.
  This is only when the instrument is running for more than 24 hours.
- Runs probe clean routine.
- Primes instrument water and wash stations.
  If any of the following conditions are true, the instrument continues with the maintenance procedures:
  - The Auto Substrate Dispense routine is successful.
  - The instrument has been running continuously.
  - You manually dispensed substrate in the last 2 hours.

  As long as the Substrate Dispense procedure is performed within 2 hours of AutoStart maintenance.
- Starts and initializes instrument.
- Runs scheduled control samples (optional).
  The instrument must be in STOP mode or logged off for processing to begin.

**NOTE:** The substrate must be manually primed or programmed for auto dispense to run the QC Worklist. To access information about scheduling controls, refer to *Scheduling a QC Worklist*, page 4-14.

## AutoStart Configuration

The AutoStart Configuration screen allows you to schedule automated maintenance procedures by day and time, and enable or disable automatic substrate dispensing. Refer to *AutoStart Configuration Screen*, page 8-22.

## Manual AutoStart

Use the manual AutoStart feature to begin processing routine tasks when the instrument is in STOP mode or logged off.

You can use the AutoStart button at the Startup screen or Menu screen:

1. Load probe clean on the instrument and ensure the consumables are full.
2. Load control materials, optional, on the instrument.
3. Prime the substrate probe.
4. At the Startup screen or Menu screen, select **Run AutoStart**.

## AutoStart Countdown

Five minutes before an AutoStart is scheduled, the AutoStart Countdown window displays a countdown of time remaining before the instrument automatically begins processing.

You can allow the countdown to proceed or select one of the following options:

- To begin processing immediately, select **Start Now**.
- To stop the instrument from automatically processing, select **Cancel**.

## AutoStart Monitor

The AutoStart Monitor window displays after the instrument begins processing automatically. A progress bar allows you to see the status and the specific task currently running.

**NOTE:** Selecting Abort may not stop the procedure. The AutoStart procedure may be at a point in the procedure where it must continue to the end.

Select **Abort** to discontinue automatic processing.

## *Worksheets*

This section includes the following worksheets:

- IMMULITE 2000 systems and IMMULITE 2500 system Adjustment Log
- IMMULITE 2000 systems and IMMULITE 2500 system Daily and Weekly Maintenance Record
- IMMULITE 2000 systems and IMMULITE 2500 system Monthly and Quarterly Record

These items can be copied and used as needed.

# *IMMULITE 2000 Systems and IMMULITE 2500 System Adjustment Log*

**Serial #**_____

**Guidelines**

1. QUALITY CONTROL
2. SLOPE
   - Initial adjustment should be within Instrument Slope Range
   - Readjustment should be within +/- 10% of Previous Slope
3. INTERCEPT should be less than or equal to the intercept guideline

| Date | Test | Kit Lot | Controls | Slope | Intercept | Adj. Valid | Tech |
|---|---|---|---|---|---|---|---|
| | | | | | | | |
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# IMMULITE 2000/2500
## Daily & Weekly Maintenance Record

**Serial #:** _____
**Month:** _____

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Daily Maintenance:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Log off System | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Clean Probes/Check Sample Probe Dispense Angle | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Restart the Computer | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Check/Fill Reaction Tube Hopper | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Check/Fill Water | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Check/Fill Probe Wash | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Check/Fill Substrate | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Check/Empty Waste | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Prime Sample and Reagent Probes | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Prime Water Probes (IMMULITE 2000 only) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Prime Substrate Probe | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Operator initials:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

| **Weekly Maintenance:** | **week 1** | **week 2** | **week 3** | **week 4** | **week 5** |
|---|---|---|---|---|---|
| Clean Waste Tube (liquid) | | | | | |
| **Operator initials:** | | | | | |

**Supervisor's Signature**_____

# IMMULITE 2000 XPi
## Daily & Weekly Maintenance Record

**Serial #:** _____
**Month:** _____

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Daily Maintenance:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Check/Fill Reaction Tube Hopper | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Check/Fill Water | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Check/Fill Probe Wash | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Check/Fill Substrate | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Check/Empty Waste | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Perform AutoStart | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Prime Substrate Probe (if not configured to automatically dispense) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Operator initials:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

| **Weekly Maintenance:** | **week 1** | **week 2** | **week 3** | **week 4** | **week 5** |
|---|---|---|---|---|---|
| Clean Waste Tube (liquid) | | | | | |
| Check Sample Probe Dispense Angle | | | | | |
| **Operator initials:** | | | | | |

**Supervisor's Signature**_____

## IMMULITE 2000/2500/2000 XPi
## Monthly & Quarterly Maintenance Record

**Serial #**_____

Monthly and Quarterly maintenance for the year beginning _____ month , _____ year to the year ending _____ month , _____ year

| Monthly Maintenance List | JAN | FEB | MAR | APR | MAY | JUN | JUL | AUG | SEP | OCT | NOV | DEC |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Clean Water Bottle and Probe Wash bottle | | | | | | | | | | | | |
| Decontaminate the Lines | | | | | | | | | | | | |
| Transducer Decontamination | | | | | | | | | | | | |
| Reagent Probe Angle | | | | | | | | | | | | |
| Clean the Fan Filter | | | | | | | | | | | | |
| Water TestPM | | | | | | | | | | | | |
| **Operator Initials** | | | | | | | | | | | | |
| **Supervisor Initials** | | | | | | | | | | | | |

| Quarterly Maintenance List | Replacement Date 1 | Replacement Date 2 | Replacement Date 3 | Replacement Date 4 |
|---|---|---|---|---|
| Replace $CO_2$ Scrubber | | | | |
| **Operator Initials** | | | | |
| **Supervisor Initials** | | | | |

# 6 Identifying Instrument Problems

# Identifying Instrument Problems

Instrument troubleshooting uses the following screens:

- Error Report screen
- View Event Log screen
- Day Error Log screen
- Temperature screen

This section also includes the list diagnostic programs. Refer to *Viewing the Adjustment Log*, page 2-40 for procedures on viewing the adjustment log, beads and reagents on board, and allergens on board. For information on exporting data, refer to *Data Management*, page 7-1.

**NOTE:** When the instrument detects a jam, the instrument software program may be minimized. If this occurs, select the close button (x) to exit the instrument software. Relaunch the program by double-selecting the IMMULITE 2000 icon or the IMMULITE 2500 icon from the Windows desktop. Select **View Event Log** to determine the cause of the jam.

## Viewing the Error Report Screen

The Error Report screen lists the current system errors. It displays automatically when the instrument detects an error.

**NOTE:** You can move the scroll bar to the right to view the end of a long error message.

The buttons on the Error Report screen are described in the table:

| Button | Function |
|---|---|
| Help | Provides help for correcting the problem that caused the error. |
| Sound On<br>Sound Off | When Sound On is selected, the system will beep when the Error screen displays. The button changes to Sound Off.<br>When Sound Off is selected, the system will not beep when the Error screen displays. The button changes to Sound On. |
| Close | Closes the Error screen. |
| Print Errors | Prints the current errors. |

# Viewing the Error/Event Logs

There are two Error Log screens:

- View Event Log
- Day Error Log

## Viewing the Event Log

The View Event Log screen provides an event and error history, recording the error messages from the past 90 days. Follow the instructions below to view the event log. For more information about reading the error log and the error messages that may display, refer to Appendix E.

**NOTE:** If tests are in progress, they will be lost when **STOP** is selected.

1. Select **STOP**.

   A warning message displays to confirm the stopping of the instrument.
2. Select **Log Off**.
3. Select **OK**.
4. Select **CONTINUE**.
5. The system logs off and the Startup screen displays.
6. Select **View Event Log**.
7. Under TIME RANGE, select **Whole Event Log** to view the entire error history or select **Selected Time Range** to specify a date and time.

   **NOTE:** Error messages are stored for 90 days.

   If you select **Selected Time Range**, do the following:

   a. Select the **Start Date** field, and then select a date from the calendar.

   b. Select the **Start Time** field, and then select a time from the clock.

   c. Select the **End Date** field, and then select a date from the calendar.

   d. Select the **End Time** field, and then select a time from the clock.
8. Under **ERRORS**, select **All Error Types** to view all errors or **Selected Range** to view specific errors, for example, only pipettor tip jam errors.

   If you select **Selected Range**, enter the displayed event numbers for the errors in the From and To windows.
9. Under **SEVERITY**, select **All Severity Levels** to view all errors or **Selected Levels** to view only a certain level of error.

   If you select **Selected Levels**, select the **WARNINGS**, **ERRORS**, or **SEVERE ERRORS** button.

   **NOTE:** More than one button can be selected. Severe errors are errors that affect test results or interrupt instrument operation.

10. Sort the errors by either **Date And Time** or **Event Number** by clicking the appropriate option under Sort Order.
11. Select **SEARCH**.

    The View Event Log screen displays listing the errors that meet the criteria selected on the View Event Log Specification screen.
12. Select the **Previous Page**, **Next Page, Home,** and **End** buttons to scroll through the event messages.

    **NOTE:** This log may be hundreds of pages long; selecting the **Print Error Log** button will print every page. Before printing, refine the search and print only the relevant events.
13. Select **Print Error Log** to print the Error Log.
14. Select **CLOSE**.

## *Day Error Log*

The Day Error Log screen displays the error messages for the current day only. Follow these instructions to view the Day Error Log.

### *For IMMULITE 2000 System or IMMULITE 2500 System*

1. From the instrument drop-down menu, select **Tools**.
2. Select **View Day Error Log**, and proceed to step 2 in the next section.

### *For IMMULITE 2000 XPi System*

1. At the instrument window, select **MENU** and **Day Error Log**.
2. Use the **Previous Page** and **Next Page** buttons to page through the errors.

   **NOTE:** Select the **Home** and **End** buttons to move to the beginning and end of the error list respectively.
3. Select **CLOSE**.

## *Viewing Instrument Temperatures*

Follow the instructions below to view the current instrument temperatures and the humidity level.

### *For IMMULITE 2000 System or IMMULITE 2500 System*

1. From the instrument drop-down menu, select **Tools**.
2. Select **View Temperature**, and proceed to step 2 in the next section.

***For IMMULITE 2000 XPi System***

1. At the instrument window, select **MENU** and **Temperatures**.
   The Temperatures and Humidity screen displays.
2. Select **PRINT** or **CANCEL**.

## Diagnostic Programs

Diagnostic programs are used to diagnose or correct system problems. After loading a program, instructions display which are specific to that program.

For information about initializing the diagnostic software, refer to *Initializing Diagnostics*, page 5-3.

**NOTE:** Diagnostics can not be run if the instrument software is running. If necessary, log off of the instrument software before proceeding. Refer to *Logging Off the System*, page 5-3.

## Diagnostic Program Descriptions

The diagnostic programs are listed and described in the table below.

**NOTE:** Diagnostic programs have different names on the IMMULITE 2000 systems and IMMULITE 2500 system.

- For the IMMULITE 2000 systems, each diagnostic name ends with – 2000.
- For the IMMULITE 2500 system, each diagnostic name begins with IMM2500.

| Program Name | Description |
|---|---|
| Substrate & Water Prime | Primes the substrate and water probe.<br>**NOTE:** The program includes prompts to remove the substrate and water probes from the bead/tube wash station before each is primed. |
| SUBSTRATE PRIME | Primes the substrate probe.<br>**NOTE:** The substrate probe must be removed from the bead/tube wash station before priming. |
| Transducer Decon |  **BIOHAZARD**:<br>Wear personal protective equipment. Use universal precautions. Refer to *Safety Instructions*, page A-1 for recommended precautions when working with biohazardous materials.<br>In its solid form, sodium hydroxide is caustic. when using a sodium hydroxide solution, avoid contact with skin or clothing. With either the solid or the solution, take customary laboratory precautions.<br>Decontaminates the clot detection mechanism using 0.1M NaOH in a 12 x 75-mm sample tube. After loading Transducer Decon, follow the instructions on the screen.<br>**NOTE:** A prompt displays instructing the operator to place a 12 x 75-mm sample tube with 2.5 mL of 0.1 M sodium hydroxide (NaOH) in position 1. |
| Tube Chute Test | Tests the sensors in the exit tube chute. |
| Waste Tube Cleaning | Takes probe cleaning solution from the sample carousel and reagent wedge and cleans the waste tube from the wash/spin station. Part of weekly maintenance.<br>Refer to *Weekly Maintenance*, page 5-16. |
| Water Probe Prime | Primes the water probe.<br>**NOTE:** The water probe must be removed from the bead/tube wash station before priming. |

| Program Name | Description |
|---|---|
| WATERTEST | **NOTE:** WATERTEST uses *two* reaction tubes.<br>Used to test the water for alkaline phosphatase contamination. After loading WATERTEST, follow the on-screen instructions. For detailed instructions (including how to evaluate the results).<br>Refer to *Water Test Procedure (IMMULITE 2000 System)*, page 5-32 or *Water Test Procedure (IMMULITE 2500 System)*, page 5-33. |

## Electrical Power Loss

**NOTE:** The Uninterruptible Power Supply (UPS) battery backup unit is optional for customers outside the U.S.

The instrument is equipped with a UPS battery backup unit and will continue operation for a limited time after loss of power. The duration of battery backup for a fully charged UPS is approximately 30 minutes.

It is recommended that the operator stop the run as soon as possible and then power off the instrument. This allows the system to shut down safely and avoids possible damage to the database that may occur if the battery backup is allowed to completely discharge. Turning the power off will also avoid a possible surge when the main power returns.

**NOTE:** Although the instrument will continue to operate on battery power for a limited time after the loss of power, no new tests should be put on the instrument.

In the event of an unexpected loss of electrical power, perform the following steps as soon as possible:

1. Restart the computer.

   Refer to *Restarting the Computer*, page 5-6.

2. Depending on the amount of time before power is restored, note the following:
   - For up to one hour of power loss, the instrument will need about one hour to re-stabilize all temperatures.
   - For 6 to 12 hours of power loss, the instrument will need two or more hours to stabilize temperatures and humidity levels.
   - If you anticipate 12 to 24 hours of power loss, remove and refrigerate all reagent wedges.
   - For 24 hours of power loss or more, remove the bead packs and protect them against adverse humidity levels.

## *Probe Replacement*

**BIOHAZARD**

Wear personal protective equipment. Use universal precautions. Refer to *Safety Instructions*, page A-1 for recommended precautions when working with biohazardous materials.

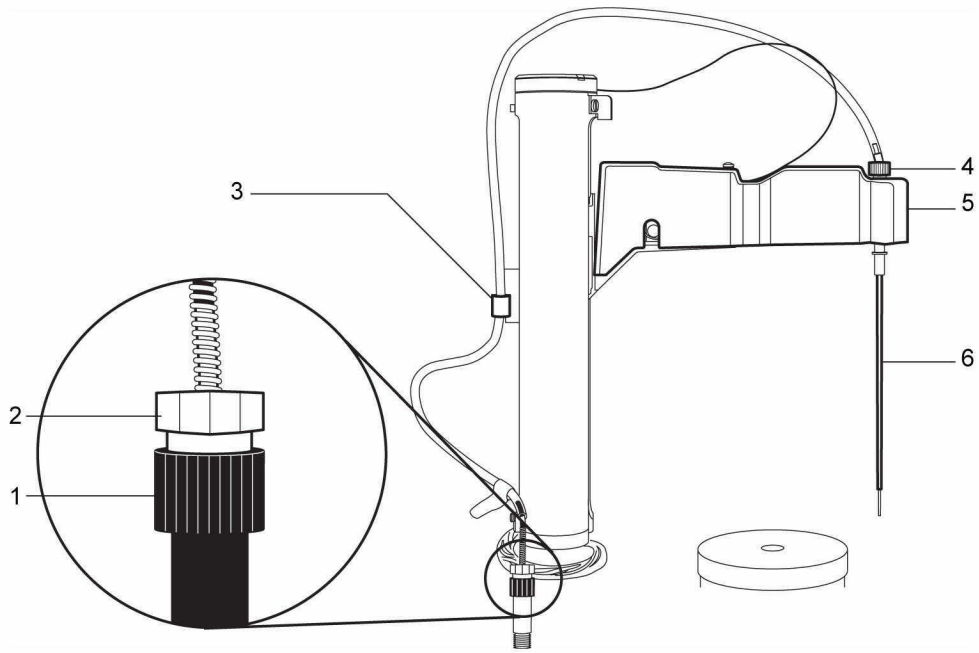
If a probe fails the probe angle test, replace the probe following the instructions below.

1. Remove the probe tube retaining clip from the reagent/sample arm column.
2. Unscrew the probe from the arm mount, and remove the probe from the arm.
3. Unscrew the black probe extension from the manifold block, turning both the entire probe and extension piece together.
4. Unscrew the probe extension from the probe.

   The extension piece will be reused to mount the new probe.
5. Properly discard the old probe.
6. Attach the probe extension to the fitting of the new probe.
   a. Hold the probe fitting secure with a 5/16" wrench while turning the extension only.
   b. Ensure a secure fit.
7. Attach the probe extension to the manifold block by turning both the entire probe and the extension piece together.

   **NOTE:** Take care to prevent twisting or kinking the probe tubing.
8. Insert the probe into the arm mount and tighten securely.
9. Verify the tubing is on the left side of the sample/reagent arm.

10. Attach the probe tubing to the inside of the retaining clip on the reagent/ sample arm.




**1** Probe extension
**2** Probe fitting
**3** Retaining clip
**4** Arm mount
**5** Probe arm
**6** Probe

**Figure 6-1 Probe in Arm Mount**

11. Secure the probe tubing with the retaining clip.
12. Properly prime all air from the new probe.

## *Waste Chute Clean Out Tool*

Follow the instructions below to safely clear a solid waste chute jam. This procedure requires the waste chute clean out tool (Part Number 400918).

**BIOHAZARD**

Wear personal protective equipment. Use universal precautions. Refer to *Safety Instructions*, page A-1 for recommended precautions when working with biohazardous materials.

1. Put the instrument in **Stop** mode and open the instrument top cover and the front panel doors.

**CAUTION**

Do not insert the waste chute clean out tool into the top of the waste chute. Inserting the waste chute clean out tool into the top of the waste chute may damage the instrument.

2. Remove the solid waste container and check to see if it is full.

**WARNING**

Do not replace the red biohazard bag improperly or place the solid waste container in backward. Replacing the bag improperly or putting the solid waste container in backwards can cause the solid waste to back up in the waste chute. Use care in replacing the biohazard bag and solid waste container.

3. Place a shallow container or an absorbent cloth over the solid waste load scale, toward the back wall.

   This will protect the load scale and catch any reaction tubes. It also prevents falling beads from rolling under the load scale.

4. Locate the waste chute opening in the upper left-hand corner of the solid waste container area.
5. Insert the waste chute clean out tool or flexible tubing such as Tygon (approximately 15 inches in length and ¾ inch in diameter) into the waste chute opening from the bottom.
6. Dislodge the jam by using repeated short up and down movements.
7. Remove the tool.

   The jammed reaction tubes and beads will fall onto the shallow container or absorbent pad.

Located on top of the instrument behind the wash spin station is the waste chute cover.

8. Remove the waste chute cover.
9. Using a flashlight, look into the opening for the presence of reaction tubes.

   None should be visible.
10. If tubes are present, manually remove them.
11. To make sure that the blockage was removed, drop an empty reaction tube marked with an x down the solid waste chute.

    The marked reaction tube should travel freely down the chute to the tray or cloth in the solid waste container area.
12. If the marked reaction tube does not drop through, repeat steps, as necessary.

# Detecting and Correcting Clots

## System Clot Detection

The system differentiates between two types of clots: sample clots and clinging clots.

### Sample Clots

Sample clots occur when the clot remains in the sample. The system successfully draws a slug of air after the clot is detected, indicating the pipettor is not obstructed.

1. Select **WORKLIST**.
2. Select **Display/Edit**.

   The Display Worklist window displays sample errors.
3. Locate the clotted sample on the worklist.

   Sample Error displays in the status column.
4. Remove the sample rack from the instrument.

   For the IMMULITE 2000 system or the IMMULITE 2500 system, perform the following steps:

   a. Open the sample access door.
      The system enters SAMPLE PAUSE mode.
   b. Select the rack letter where the clotted sample is located.
      The rack moves to the front.
   c. Remove the rack.

   For the IMMULITE 2000 XPi system, eject the rack using the rack loader.
5. Remove the sample rack from the instrument.

6. Remove the clotted sample and return the sample rack.

***For the IMMULITE 2000 Instrument or the IMMULITE 2500 Instrument***

1. Close the rack loader door.
2. Press **RUN** to resume instrument operation.

### Clinging Clots

A clinging clot occurs when the clot is stuck to the sample pipettor. The system is unsuccessful when it draws a slug of air, indicating the pipettor is obstructed. No additional samples are pipetted until the clot is removed.

Three possibilities can be observed:

- Gel clot

  The pipettor entered the gel in a gel separator tube.
- Hanging clot

  A clot is hanging on the end of the pipettor.
- Air in the system

  Air is present in the clot detection module.

## *Handling Clots on the IMMULITE 2000 System and the IMMULITE 2500 System*

### Gel Clots

1. Select **PAUSE**.

   The system enters PAUSE mode.
2. Select **COVER** to open the instrument cover.
3. Visually inspect the probe.
4. Replace the probe if it entered the gel barrier of a tube.

   Refer to *Probe Replacement*, page 6-7 for more information.
5. Select **PRIME** to prime the DRDs.
6. Locate and remove the clotted sample.
7. Close the cover.
8. Select **RUN**.

## Hanging Clots

Follow these steps to remove a hanging clot.

**CAUTION**

Do not insert anything into the probe. Permanent damage may occur.

1. Select **CLOSE** on the red error message box.
2. Select **PAUSE**.
   The system enters PAUSE mode.
3. Select **COVER** to open the instrument cover.
4. Visually inspect the probe.
5. Use a lint-free wipe to remove the clot with a downward wiping motion.
6. Select **PRIME** to prime the DRDs.
7. Locate and remove the sample.
8. Close the instrument cover.
9. Select **RUN** to resume instrument operation.

## Air in the Clot Detection Transducer

Follow these steps to remove air from the clot detection module.

1. Select **PAUSE**.
   The system enters PAUSE mode.
2. Select **COVER** to open the instrument cover.
3. Visually inspect the probe.
4. Allow the samples in progress to complete.
5. Select **STOP**.
6. Select **PRIME** to prime the DRDs.
7. Log off of the instrument.
8. Initialize diagnostics.
   Refer to *Initializing Diagnostics*, page 5-3.
9. Select **Clot Prime** diagnostic.
10. Allow the diagnostic to run for several minutes to ensure that all of the air is eliminated.

## Handling Clots on the IMMULITE 2000 XPi System

### Gel Clots

1. Open the pipettor cover.
   The instrument enters SAMPLE PAUSE mode.
2. Visually inspect the probe.
3. Replace the probe if it entered the gel barrier of a tube.
   Refer to *Probe Replacement*, page 6-7 for more information.
4. Close the pipettor cover.
5. Select **PRIME** to prime the DRDs.
6. Locate and remove the clotted sample.
7. Select **RUN**.

### Hanging Clots

Follow these steps to remove a hanging clot.

**CAUTION**

Do not insert anything into the probe. Permanent damage may occur.

1. Select **CLOSE** on the red error message box.
2. Open the pipettor cover.
   The instrument enters SAMPLE PAUSE mode.
3. Visually inspect the probe.
4. Use a lint-free wipe to remove the clot with a downward wiping motion.
5. Close the pipettor cover.
6. Select **PRIME** to prime the DRDs.
7. Locate and remove the sample.
8. Close the pipettor cover.
9. Select **RUN** to resume instrument operation.

### Air in the Clot Detection Transducer

Follow these steps to remove air from the clot detection module.

1. Open the pipettor cover.
   The instrument enters SAMPLE PAUSE mode.
2. Visually inspect the probe.

3. Allow the samples in progress to complete.
4. Select **STOP**.
5. Select **PRIME** to prime the DRDs.
6. Log off of the instrument.
7. Initialize diagnostics.
   Refer to *Initializing Diagnostics*, page 5-3.
8. Select **Clot Prime** diagnostic.
9. Allow the diagnostic to run for several minutes to ensure that all of the air is eliminated.

# Quick Reference Assay Troubleshooting Guide

These tables may be used as a helpful guide when investigating unusual results.

**NOTE:** Factors such as instrument maintenance and onboard consumables will affect results if not properly maintained.

### *Sandwich Assays*

| Condition | Expected Result |
|---|---|
| No Bead | Error or < lower assay limit |
| No Sample | < lower assay limit |
| No Reagent | Error; < assay limit; Extremely low results |
| No Substrate | Error and CPS will be < 100 CPS |

### *Competitive Assays*

| Condition | Expected Result |
|---|---|
| No Bead | Error |
| No Sample | < Lower assay limit |
| No Reagent | Error; > Upper assay limit |
| No Substrate | Error; CPS will be < 100 CPS |

***Pre-Treated Assays***

| Condition | Expected Result |
|---|---|
| No Bead | Error |
| No Sample | < Lower assay limit |
| No Reagent (1) Pretreatment | < Lower assay limit |
| No Reagent (2) | Error; > upper assay limit |
| No Substrate | Error; CPS will be < 100 CPS |

## Troubleshooting Controls Post Adjustment

| Controls | Slope | Intercept | Recommended Troubleshooting |
|---|---|---|---|
| Exceed acceptable limits | > 10% previous adjustment or outside slope range | Exceeds limit | Adjustors |
| Within acceptable limits | > 10% previous adjustment or outside slope range | Exceeds limit | Reagent wedge |
| Exceed acceptable limits or biased compared to historical performance | Within 10% of previous adjustment or within slope range | Within limits | Controls |

# 7 Data Management

# Data Management

## Exporting Data

Export data when troubleshooting a problem:

- Data resulted during a specific time period
- A particular type of data, such as patient or adjustor
- Data for a particular test

Follow the instructions below to export data.

***For IMMULITE 2000 System or IMMULITE 2500 System***

1. From the instrument drop-down menu, select **Tools**.
2. Select **Export Data**, and proceed to step 2 in the next section.

***For IMMULITE 2000 XPi System***

1. At the instrument window, select **MENU** and **Export Data**.
2. In the START panel:
   a. Select the **Date** field and select the start date from the calendar.
   b. Select the **Time** field and select the start time from the clock.
3. In the END panel:
   a. Select the **Date** field and select the end date from the calendar.
   b. Select the **Time** field and select the end time from the clock.
4. In the Data panel, select the data type, **Patient**, **Adjustor**, **Control**, **or Verifier**, or select **All** to export all data types.
5. Under Test Type, select the test type or select **ALL** to export all test types.
6. Under Export Method, select one of these options:
   - **Screen** to view the selected data on the screen.
   - **File** to export the selected data to a file.
   - **Printer** to print the selected data.
7. If **File** was selected as the Export Method, the Save As window displays:
   a. Select the **Save in:** dropdown menu to display all available directories. You can also select **Desktop** if you are going to save the file to a CD or DVD.
   b. Select the directory to store the file.

      **NOTE:** The scroll bar may be needed to view all the directories and files.

c. Type a name in the Filename field, and then select the **Save** button.
The Save As window closes and the file name displays under File Information.

d. At the Field Delimiter prompt, select a delimiter:
- Select **Tab** to separate the data with tabs.
- Select **Comma** to separate the data with commas.

**NOTE:** Formatting a floppy disk erases any information stored on the disk.

8. Select the **PERFORM EXPORT** button to export the data.

**NOTE:** The error message "Error writing export file, disk full. Please refer to the operator's manual" may occur during export. This indicates that the floppy disk has run out of sufficient space to complete the operation. Try the export again with a new, unused floppy disk or reformat the current disk.

## *Saving Files to CD or DVD*

Follow these steps to save data files to a CD or DVD using the CD/DVD burner.

**NOTE:** The CD/DVD burner is not available on all instruments.

1. Export the necessary data to the desktop.
Refer to *Exporting Data*, page 7-1.

**NOTE:** The instrument must be logged off before using this software.

2. Log off the instrument.
3. Double-select the **Nero StartSmart** icon on the Windows desktop.
The Nero window displays.
4. Depending on the disc format in use, select **CD or DVD**, from the upper right corner.
5. Select **Data**, and then select **Make Data Disc**.
The Disc Content window displays.
6. Select the **Add** button to select the files to burn to disc.
7. Select the appropriate file(s) to add to the disc.
8. Select **Add**.
9. Continue to select and add files as necessary.
10. Select the **Finished** button after adding files.
The Disc Content window displays listing the files to be written to disc.
11. Confirm all appropriate files are listed.
12. Select **Next**.
The Final Burn Settings window displays.

13. Enter the name of the disc in the Disc name field.
14. Set the Writing speed to **48x (7,200 KB/s)**.
15. Select the Number of copies to burn.
16. Select **More**.

    The Final Burn Settings window expands to display more options.

    **NOTE:** Do not select the Allow files to be added later (multisession disc) field.
17. Select the **Finalize Disc** checkbox.

    No additional data can be written to the disc after it is finalized.
18. Insert a blank CD/DVD into the burner.
19. From the Final Burn Settings window, select the **Burn** button.

    After the burn process begins, a status window displays.
20. At the status window, follow these steps:
    a. Select **Burn new CD using Nero StartSmart**.
    b. Check the **Always do the selected action** box.
    c. Select the **OK** button.
21. From the Burn Process window, select **Next**.
22. Remove the CD/DVD from the burner.
23. Select **Exit**.
24. If prompted to save the project, select **No**.
25. At the Nero window, select the button to exit the software.

## *Saving Files to a USB Storage Device*

USB storage devices are also known as thumb drives or flash drives. They are devices you can insert into a USB port for the purpose of transferring data.

Follow these steps to save data files to a storage device.

**NOTE:** USB ports are not available on all instruments.

1. At the instrument window, select **MENU**.
2. Insert the USB storage device into the USB port on the keyboard tray.
3. Select **Export Data**.
4. In the START panel:
    a. Select the **Date** field and select the start date from the calendar.
    b. Select the **Time** field and select the start time from the clock.

5. In the END panel:
   a. Select the **Date** field and select the end date from the calendar.
   b. Select the **Time** field and select the end time from the clock.
6. In the Export Data panel, select **File**

   The Save As window displays:
   a. Select the **Save in:** dropdown menu to display all available directories.

      The USB directory is usually drive E:. It may take a few moments to display.
   b. Select the USB directory.
   c. Type a name in the Filename field, and then select the **Save** button.

      The Save As window closes and the file name displays under File Information.
   d. At the Field Delimiter prompt, select a delimiter:
      - Select **Tab** to separate the data with tabs.
      - Select **Comma** to separate the data with commas.
7. Select the **PERFORM EXPORT** button to export the data.
8. When the export is complete, use the pointing device to locate the new hardware icon on the Windows taskbar.

   The icon usually displays a downward pointing green arrow. When you rest the pointer on it, the icon displays the following popup message:

   ```
   Safely Remove Hardware
   ```
9. Select the icon, and then remove the USB device.

## *Viewing Results and Sending Data to the LIS*

Follow the instructions below to view results and send data to the LIS.

1. Select **LIS** on the toolbar.

   The LIS screen displays the data. The last selected viewing options, Hide Sent, Show Sent, or Sort By, determine the information displayed when the **LIS** button is selected.
   a. To hide data sent to the LIS, select the **Hide Sent** button.

      The button changes to Show Sent.
   b. To display all data, select the **Show Sent** button.

      The button changes to Hide Sent.
2. Sort the LIS data by selecting the **Sort By...** button.

   The Sort By screen displays.

3. If appropriate, specify a period other than Prior 24 Hours by selecting **Define Range**:
   a. Select the **Start Time MM/DD/YYYY** field to select a date from a calendar.
   b. Select the **Start Time HH:MM:SS** field to select a time from a clock.
   c. Repeat this process with **End Time.**
4. To sort the data, select one of the sort buttons listed below:
   - Accession Number
   - Order Created
   - Name
   - Test Type

   **NOTE:** Select the **Print List** button to print the list.
5. If the system is not configured to send data automatically:
   - From the LIS screen, select the **Hide Sent** button to hide data that was already sent to the LIS.
     The button changes to Show Sent.
   - Select the records to be sent by clicking on them or select the **Tag All** button to tag all results for transmission to the LIS.
     If **Tag All** is selected, the button changes to **Un-Tag All.**
   - Select the **Send** button to transmit the tagged results to the LIS.
     If **Clear** is selected, it will permanently clear all selected data information from the database.

## *Restarting the System*

Logging off the system each day automatically initiates a system back-up, which stores current data. This process optimizes software performance and allows recent data to be restored in the event of a serious system error. Log off daily so that if a serious system error occurs, recent data is available when the system is restored.

**NOTE:** Failure to put the instrument in STOP mode before logging off may cause the final reagent and bead test counts to be inaccurately stored.

1. Select **STOP**.
   If active tubes are in progress, a message displays stating the time-to-completion.
2. Select **Continue**.
3. Remove patient specimens, controls, diluent, and adjustors from the sample carousel.
4. Remove any allergen wedges from the reagent carousel and seal the allergen vials with standard caps before storing them.

5. Select **LOG OFF**.

   The following message displays.

   ```
   Would you like to Log Off of the IMMULITE 2000
   software and return to the Start-Up menu?
   ```

6. Select **OK**.

   The following messages display.

   ```
   Preparing to Back up Files...Please Wait
   ```

   ```
   You are about to delete all patient records over 62
   day and control, verifier and adjustor records over
   366 days.
   ```

   **NOTE:** If you select **CHANGE DAYS** and increase the number of days data is stored, it can slow the system response time.

7. Select **CONTINUE**.

   The system logs off.

8. Select **Start** on the lower left-hand corner of the screen.

9. Select **Shut Down** or **Turn Off Computer**.

10. Select **Restart the computer?** and then, depending on which prompt displays, select **Yes** or **Restart**.

# 8 Configuring the System

# Configuring the System

The system must be configured upon receipt of the instrument. You also use the configuration screens to update system functions.

## Configuring the System

This section describes the screens and options available for configuring the system.

### Selecting Display Options

The Display Options screen allows the operator to specify how text, numbers, times, and dates are displayed. Follow the instructions below to configure this screen.

**NOTE:** The instrument must be in STOP mode to make changes to this screen. You must Log off, and log on again, for changes in the Display Options screen to take effect.

#### *For IMMULITE 2000 System or IMMULITE 2500 System*

1. At the instrument window drop-down menu bar, select **Configurations**.
2. Select **Configure**.
3. Proceed to step 3 in the next section.

#### *For IMMULITE 2000 XPi System*

1. At the instrument window, select **MENU**.
2. At the Menu screen, select **Configure**.
3. Select **Display Options**.
4. In the Time Format box, select a format:
   - Select **12 Hour** to display time using am and pm.
   - Select **24 Hour** to display time in a 24-hour format.
5. In the Date Format box, select a format for displaying the date.
   - MM/DD/YYYY
   - DD/MM/YYYY
   - YYYY/MM/DD
6. In the Number Format box, select a number format:
   - Select **1,234.56** to display one thousand, two hundred thirty-four and fifty-six one hundredth as 1,234.56.

- Select **1.234,56** to display one thousand, two hundred thirty-four and fifty-six one hundredth as 1.234,56.

7. Select a language.
8. Select the **Use barcode rack identifier** option to display the sample's location on the instrument by the rack letter.

   **NOTE:** Select the use barcode rack identifier to use the Find Last Tube Position feature.

   Leave this option blank to display the sample's location by position. Position 1 on the carousel displays as Position A on the rack.
9. Select the **Hide Names** option to hide patient names on the data review screens.

   Leave this option blank to display patient names on the data review screens.

   **NOTE:** The Kit Expiration Flag is enabled when the software is installed, but can be disabled. The Kit Expiration Flag always displays at the Kits window whether it is disabled or not. The Kit Expired Flag does not display for Allergens.
10. To Configure the Kit Expiration Flag, do the following:
    a. At the instrument window, select **MENU**.
    b. At the Menu screen, select **Configure**.
    c. Select **Display Options**.
    d. To disable the Kit Expiration Flag, select **Disable Kit Expiration Flag**.
    e. Select **Save**.
       If the Kit Expired Flag is disabled and the kit is Immunoassay or confirmatory, Expired displays in blue in the Kit Status field at the KITS window.

    **NOTE:** When the instrument is connected to an LIS, a letter (or letters) identifying the laboratory may be part of the accession number.
11. To remove this letter (or letters):
    a. Select **Number of Characters To Trim From Left (or Right) of Accession Number**.
    b. Select all appropriate trim options.

    **NOTE:** If further changes are planned for the ID Information, Configuration Settings, or LIS screens, select **Save** after all changes have been made. Access another screen by selecting the appropriate button on the Display Options screen.
12. Select **Save**.

## Configuring Auto Dilutions

The Auto Dilutions screen is used to specify the automatic dilution factor for out-of-assay-range samples. Specify dilution factors for each test according to the instructions below.

**NOTE:** The *Dilution Volume Specifications*, page E-2 displays the amount of sample, water, and diluent used for onboard dilutions.

### *For the IMMULITE 2000 System or IMMULITE 2500 System*

1. At the instrument window drop-down menu bar, select **Configurations**.
2. Select **Configure**, and proceed to step 3 in the next section.

### *For the IMMULITE 2000 XPi System*

1. At the instrument window, select **MENU**.
2. At the Menu screen, select **Configure**.
3. Select **Auto Dilutions**.
4. Select the **Test Name** field.

   A list of the test codes for all the tests in the system displays.
5. Select a test.

   **NOTE:** Tests only display if the new kit was entered using the 2D or imaging scanner.

   The test displays in the Test Name field and the dilution factors display.

   **NOTE:** Samples that require a dilution factor other than those programmed for onboard dilutions may have a manual dilution factor applied to them. When a manual dilution factor is applied to a sample, all tests ordered on that sample are multiplied by that dilution factor.

**CAUTION**

Do not type a value in the Dilution Factor field. Typing in a value that is not supported will perform the assay without any dilutions and will display as > assay limit. Only those dilution factors listed are supported.

6. Select one of the listed dilution factors:

| Dilution Factor | Dilution |
|---|---|
| X3 | 1 in 3 |
| X5 | 1 in 5 |
| X10 | 1 in 10 |
| X20 | 1 in 20 |
| X40 | 1 in 40 |
| X100 | 1 in 100 |

After the dilution is selected, the Dilution Factor screen closes and the dilution factor displays on the Worklist screen.

Refer to *Dilution Volume Specifications*, page E-2.

7. Select **Save**.

## Configuring ID Information

The ID Information screen is used to enter customer information. The hospital or laboratory name displays on patient and adjustment reports. Follow the instructions below to enter this information.

### *For the IMMULITE 2000 System or IMMULITE 2500 System*

1. From the drop-down menu bar, select **Configurations**.
2. Select **Configure**.
3. Proceed to step 3.

### *For the IMMULITE 2000 XPi System*

1. At the instrument window, select **MENU**.
2. At the Menu screen, select **Configure.**
3. Select **ID Information**.
4. In the Customer Name field, type the hospital or laboratory name.

   This name displays on Adjustment and Patient Reports.
5. Type the instrument serial number in the **Instrument ID** field.
6. Select **Save**.

## Using the Configuration Settings Screen

The Configuration Settings screen is used to specify system settings that affect how the instrument operates in relation to testing and reporting. Follow the instructions below to configure this screen.

***For the IMMULITE 2000 System and IMMULITE 2500 System***

1. At the instrument window, select **Configurations**.
2. Proceed to Step 2 in the next section.

***For the IMMULITE 2000 XPi Instruments***

1. At the instrument window, select **MENU**.
2. Select **Configure**.
3. Select **Configuration Settings**.
4. Select options according to the table below:

| Option | Description |
|---|---|
| Default Sample Tube Type | The tube type normally used can be selected.<br>• Primary tube<br>Blood collection tube in which the serum is separated from the blood cells by a gel barrier. Selecting this configuration causes the probe to stop before penetrating the gel barrier.<br>Refer to the *Primary Tube Sample Guide* (Part Number 901835) sent with the instrument for more information.<br>• Secondary tube<br>Sample tube in which the serum is aliquotted to a different tube. Selecting this configuration causes the probe to move further into the tube before aspirating the sample.<br>**NOTE:** You must make changes to the Default Sample Tube Type setting before placing samples on the system. Otherwise, it is necessary to log off the software and delete the worklist after changing the Default Sample Tube Type. |
| Automatically Print the Following Reports | Select which report type(s) are to be printed automatically when results are completed.<br>Select the checkbox to select the report(s) to be printed. All reports, individual report(s) or no reports can be selected.<br>**NOTE:** Controls must be selected. If controls are not selected, QC results will not be evaluated against the selected QC rules or ranges. Further, patient results may not be sent to the LIS. |
| Results Statistics | • Mean<br>Displays the mean of the replicates on the Review screen and on the report printout.<br>• CV<br>Displays the % CV of the replicates on the Review screen and on the report printout. |

| Option | Description |
|---|---|
| Auto Eject Options | Configures Auto Eject when to eject rack(s) automatically. Select whether to eject when samples in a rack are:<br>• Pipetted<br>• Resulted<br>• To disable Auto Eject, select **None**. |
| Testing Options | • Reflexive Testing<br>The system will automatically perform another test if the result from the first test falls outside, or within, a specified range. This option must be selected to activate reflexive testing.<br>• Auto Dilution<br>Automatically dilutes out-of-assay-range samples. This option must be selected to activate Auto Dilution.<br>**NOTE:** Dilution instructions are entered via the Auto Dilutions window. |
| Low Test Flag | Designates when a warning message displays on the Bead or Reagent Status screens based on the number of tests remaining in a bead pack or a reagent wedge.<br>For example, if `10` is entered in this field, a warning displays when a bead pack or reagent wedge has sufficient volume for only nine more tests. Applies to all bead packs and reagent wedges on board. |
| Large Allergen Low Test Flag | Designates when a warning message displays in the Reagent Status screen based on the number of tests remaining in a 40-test allergen vial.<br>For example, if 10 is entered in this field, a warning displays when an allergen vial has sufficient volume for only nine more tests. |
| Small Allergen Low Test Flag | Designates when a warning message displays in the Reagent Status screen based on the number of tests remaining in a 20-test allergen vial.<br>For example, if 2 is entered in this field, a warning displays when an allergen vial has sufficient volume for only one more test. |
| Allergen Reagent(s) in use | Displays scanned allergy kits. Multiple kits can be selected.<br>**NOTE:** Selected reagents are displayed by default in the Available Tests window. |

| Option | Description |
|---|---|
| Allergen Results and Scoring Type | The selections made in this field determine how the results of allergy tests are reported when they are displayed on the screen and printed.<br>• Concentration<br>If this selection is marked, the antibody concentration in patient samples will be included in the results for allergy tests.<br>• Standard Class<br>If this selection is marked, allergy test results will be based on Standard Class scoring criteria.<br>• Extended Class<br>If this selection is marked, allergy test results will be based on Extended Class scoring criteria. |
| Report Qualitative Infectious Disease Assay Results | • Qualitative Only<br>Infectious Disease results will be reported as either Reactive, Non-Reactive, or Indeterminate.<br>• Qualitative and Ratio<br>Infectious Disease results are reported as a ratio, and as either Reactive, Non-Reactive, or Indeterminate. |

5. Select **Save**.

## *LIS*

The LIS Configuration window is used to configure the system to communicate with the LIS. Follow these instructions to enter LIS information in the software.

### *For the IMMULITE 2000 System or IMMULITE 2500 System*

1. At the instrument window drop-down menu bar, select **Configurations**.
2. Select **Configure**.
3. Proceed to step 3 in the next section.

### *For the IMMULITE 2000 XPi System*

1. At the instrument window, select **MENU**.
2. Select **Configure**.
3. At the Display Options screen, select **LIS**.
4. In the LIS Host Query Mode box, select the type of interface used for communication between the instrument and the LIS.
   - None
   - Uni-Directional
   - Bi-Directional

**NOTE:** If you select **Bi-Directional Query**, the Query Control and Re-Query Patients fields are enabled.

- Bi-Directional Query

**NOTE:** If **Bi-Directional Query** is selected, the Query Control and Re-Query Patients fields are enabled.

5. In the LIS Allergen Results and Scoring Type box, select the allergy test result information that should be transmitted to the LIS.

   You can select to transmit antibody concentration as well as standard and extended class scoring.

   **NOTE:** For allergy tests, concentration information is always sent to the LIS.

6. Enter the appropriate information in the fields on the left side of the window based upon the explanations in the following table.

| Field | Description |
|---|---|
| Password | The LIS Password.<br>**NOTE:** Contact your LIS provider for this information. |
| Receiver ID | A name identifying the LIS.<br>**NOTE:** Contact your LIS provider for this information. |
| Sender ID | A name identifying the instrument.<br>**NOTE:** Contact your LIS provider for this information. |
| Baud Rate | The baud rate (line transmission speed) provided by the LIS.<br>**NOTE:** Acceptable entries include 1200, 2400, 4800, or 9600, or 115200 when connected to the VersaCell system. |
| COM Parameters | An alphanumeric character identifying the parity, bits, and stop bits. |
| Serial Port | The serial port number for the LIS connection. |
| Diagnostics | The value should be left at 0. |

7. Mark the appropriate selections in the window based upon the explanations in the following table:

| Field | Description |
|---|---|
| Hide Sent | Hides results previously sent to the LIS. |
| Auto Send Patient Results | Automatically sends patient results to the LIS.<br>Results associated with an overdue adjustment, failed control, review range failure, error, and N/A results are not sent. When this option is selected, the Send button on the LIS screen changes to the Auto Send button. |
| Auto-Send Invalid Adjustment | Allows results associated with an overdue kit adjustment to be sent to the LIS. |

| Field | Description |
|---|---|
| Auto-Send Invalid Control | Allows results associated with an out-of-range control to be automatically sent to the LIS.<br>Control results are evaluated based on the type of QC rule selected, such as Single Rule, Multi Rule. |
| Auto-Send Invalid Range | Allows results that are out-of-review range to be automatically sent to the LIS. |
| Auto Send Control Results | Automatically sends control results to the LIS. |
| Display Controls on LIS Screen | Displays control results on the LIS Data Management screen. Control results are not displayed on the LIS Data Management screen unless configured to do so. |
| Query Controls | Provides another method of sending QC orders from the LIS to the instrument.<br>**NOTE:** If the **Query Controls** checkbox is selected, the Re-Query Controls field is enabled. |
| Re-Query Patients | **NOTE:** Bi-directional Query must be selected.<br>Allows the LIS to be re-queried when patient tube barcodes are re-read on the sample carousel, allowing test requests to be re-sent.<br>A dropdown list allows one of the following functions to be performed on the LIS:<br>• No Requery<br>• All Orders<br>• New Orders only<br>**NOTE:** LIS system must be able to support re-query function. Check with your LIS provider. |
| Re-Query Controls | Bi-directional Query must be selected.<br>Allows the LIS to be re-queried when controls are re-read on the sample carousel, allowing test requests to be re-sent.<br>A dropdown list allows one of the following functions to be performed on the LIS:<br>• No Requery<br>• All Orders<br>• New Orders only<br>**NOTE:** LIS system must be able to support re-query function. Check with your LIS provider. |

| Field | Description |
|---|---|
| Report Qualitative Assay Results | Select how results of qualitative infectious disease are to be sent to the LIS. Results can be sent as either:<br>• Qualitative Only<br>• Ratio Only<br>For the Displayed on the LIS Screen as field, select how results will be displayed on the instrument LIS screen. Results can be displayed as either:<br>• Qualitative Only<br>• Qualitative and Ratio<br>For the Sent aHB and BcM to the LIS as field, select how aHB and BcM results are sent to the LIS. Results can be sent as either:<br>• Qualitative Only<br>• Concentration Only<br>For the Display aHB and BcM on the LIS screen as field, select how aHB and BcM results are displayed on the Instrument LIS screen. Results can be displayed as either:<br>• Qualitative Only<br>• Qualitative and Concentration |

8. Select **Save**.

   **NOTE:** For the changes you entered in the Configuration window to take effect, select the **Log Off** button and exit the software, then restart the software.

## *FSE Configuration*

The FSE Configuration screen is a password-protected screen used by authorized personnel to change the default mode for sample processing. To request a processing mode change, contact your local service provider or distributor.

Assays are assigned a priority with regard to the stability of the analyte in the patient sample. The priority number is contained in the kit barcode and is transferred to the database when the kit is scanned.

### Processing Modes

**NOTE:** The order in which samples are processed will vary, depending on the mode selected.

- Random Access (default)

  The instrument pipettes patients in the most efficient order.

- Batch

  The instrument pipettes patients in alphabetical order by test code, going from sample to sample.

- User Entered Order

  Tests are processed in the order in which they were entered on the Worklist.

### Password Protected Modes

- Load Scale

  The Load Scale screen is a password-protected screen used by authorized personnel. Contact your local service provider or distributor.

- Instrument Mode

  The Instrument Mode screen is a password-protected screen used by Siemens personnel. Contact your local service provider or distributor.

## Configuring System Functions

This section allows you to perform the following configurations:

- Resetting the Load Scale
- Defining Test Ranges
- Defining Allergen Ranges

### Resetting the Load Scale

Use this section to reset the load scale that monitors the levels of liquid and solid waste, water, probe wash, and substrate. If there is a discrepancy between the consumable indicator on the HOME screen and the actual volume available, the load scales may be reset.

**NOTE:** If the instrument is not in STOP mode, a reminder message displays.

#### *For the IMMULITE 2000 System and IMMULITE 2500 System*

1. Place the instrument in STOP mode.
2. At the instrument window drop-down menu bar, select **Configurations**.
3. Select **Configure**.
4. Proceed to step 3 in the next section.

#### *For the IMMULITE 2000 XPi Systems*

1. Place the instrument in STOP mode.
2. At the instrument window, select **MENU**, and then select **Configure**.
3. Select **Reset Load Scale**.
4. Select the load scale to be reset, using the Previous or Next arrows.

   The Name field changes accordingly with all associated data.
5. After the appropriate load scale is selected, select the **Reset Scale** button.
6. Remove the container from the selected load scale.
7. Select **OK**.

   The Reset Load Scale message displays.
8. Place the container back on the load scale, and select **OK**.

   To reset a different container, repeat steps 5 to 8, or select **Cancel** to return to the HOME screen.

## *Defining Test Ranges*

The Test Ranges screen is used to specify the reference ranges for test results that display in the Patient Review window and print on the chartable patient report. Follow the instructions below to specify reference ranges.

**NOTE:** Test ranges do not apply to allergens. Allergen ranges can be set up in the Allergen Ranges window.

#### *For the IMMULITE 2000 System and IMMULITE 2500 System*

1. At the instrument window, select **Configurations**.
2. Select **Test Ranges**.
3. Proceed to step 2 in the next section.

#### *IMMULITE 2000 XPi Instruments*

1. At the instrument window, select **MENU**.
2. Select **Test Ranges**.
3. Select a test from the Test Name list.

   The ranges for the selected test display in the range fields. The units of the range values display at the right side of the window.
4. For the Normal range, enter the Low and High limits in the appropriate fields.
5. In the Range 2 through Range 7 fields, enter the additional ranges to be displayed in the Patient Review window.
6. If the system is configured to send results to the LIS automatically, you can enter Low and High values in the Review Range fields.

If a result is outside of the review range, it is not be sent to the LIS.

If the low and high values of Range 1 (Normal) are within the low and high values of the review range, patient results that are outside of range 1 (normal) are not be flagged. Refer to the example below:

- Normal Range = 0.4 to 4.0
- Review Range = 0.2 to 6.0
- Result 5.0

Because the result is within the review range, it would not be flagged even though it is higher than the normal range.

7. Select **Save**.

## Defining Allergen Ranges

The Allergen Ranges window displays the ranges of immunoglobulin concentrations for allergic reactions. You can use this window to specify the concentration for a class 0/I reaction. You can enter the concentration for both standard and extended scoring.

The other ranges displayed in this window cannot be changed. They are entered when you scan the 2D barcode on the kit. The ranges in this window display for allergy tests in the Patient Review screen and on reports. Follow the instructions below to specify the Class 0/I reference ranges for allergy tests.

### *For the IMMULITE 2000 System and IMMULITE 2500 System*

1. At the instrument window, select **Configurations**.
2. Select **Allergen Ranges**.
3. Proceed to step 3 in the next section.

### *For IMMULITE 2000 XPi Instruments*

1. At the instrument window, select **MENU**.
2. Select **Allergen Ranges**.
3. In the Test Name list, select the allergy kit for which to enter the Class 0/I reference range.

   Default reference ranges for the kit selected displays in the Class fields. The units for the range values display at the right side of the window.

   The classes of allergic reactions are listed on the left side of the window. The class names are aligned between the fields that contain their range values.

   For example, the first field in the Standard column contains a 0. The field beneath it could contain 0.20. Class 0 is the name next to these two fields. Therefore, in the Patient Review screen and on reports, a Standard Class 0 result would be displayed for antibody concentrations of 0 to 0.20 IU/mL.

4. Enter the reference range values in the Class 0/I Cutoff fields.

   You can enter values for Standard and Extended scoring.

5. Select **Save**.

# Reflexive Tests

Follow the instructions in this section to specify tests to run automatically if a result is either below, within, or above a specified range.

**NOTE:** Reflexive testing cannot be performed on a manually diluted sample.

## Activating Reflexive Testing

Follow these instructions to activate reflexive testing:

### *For the IMMULITE 2000 System and IMMULITE 2500 System*

1. From the drop-down menu bar, select **Configurations**, and then select **Configure**, and proceed to step 2.

### *For the IMMULITE 2000 XPi instruments*

1. At the Menu screen, select **Configure**.
2. Select **Configuration Settings**.
3. Select the **Reflexive Testing** option in the Testing Options box.
4. Select **Save**.

## Setting up Reflexive Testing

Follow these instructions to set up reflexive testing for assays or allergens:

### *For the IMMULITE 2000 System and IMMULITE 2500 System*

1. If necessary, activate reflexive testing.
2. At the menu bar, select **Configurations**.
3. From the Configurations menu, select **Reflexive Tests**.
4. Proceed to step 3 in the next section.

### *For the IMMULITE 2000 XPi instruments*

1. At the instrument window, select **Menu**.
2. At the Menu screen, select **Reflexive Tests**.

3. Select a **Principle Test Selection**.

   This selection determines what tests display in the Principle Test field.

| Principle Test Selection | Description |
|---|---|
| **Immunoassay – All Available** | All assays scanned into system |
| **Immunoassay – Configured for Reflex** | Assays configured for reflexive testing |
| **Allergy – All Available** | All allergens and universal reagents scanned into the system |
| **Allergy – Configured for Reflex** | Allergens/universal reagent combinations configured for reflexive testing |

4. Select a **Principle Test** and **Universal Reagent**, if applicable.
5. Select a type of new range:
   - Only one Below range and one Above range can be configured per assay, or allergen and universal reagent combination.

     The Below and Above ranges cannot overlap.
   - Unlimited Within ranges can be configured if the values do not overlap with the Below and Above ranges.
   - The New Range options for qualitative assays are Non Reactive, Indeterminate, and Reactive.

     Only one of each may be added.
6. Select **Add Range**.
7. Enter the **Reflex Range** value(s) based on the type of range that was selected in step 5.

   The Reflex Range field is not available for qualitative assays. Proceed to step 8.
8. Select the **IMMUNOASSAY** or **ALLERGY** button in the TEST CATEGORIES box.

   If **ALLERGY** is selected, select the appropriate universal reagents.
9. Select the buttons that correspond to the individual reflexive tests for this range (up to 15 tests per reflexive range).

   If necessary, use the Next Page and Previous Page buttons to locate additional tests.

   **NOTE:** The Do Not Autosend option will be enabled if a reflexive test matching the principle test is selected. Select the Do Not Autosend option to prevent the results of the principle test and the matching reflexive test from being sent to the LIS. For example, if HCG reflexes to HCG and TSH and Do Not Autosend is selected, only the TSH result will be sent to the LIS.

10. To add a dilution for a reflexive test:
    a. Select a test under the Tests Selected heading.
    b. Select the **DILUTION** button.
       The Dilution Factor window displays.
    c. Select the dilution factor.
11. Select **Save** after selecting all of the necessary reflexive tests.
12. Repeat steps 5 though 11 to configure additional ranges for a principle test, or steps 2 through 11 to order reflex tests for a different assay or allergen.
13. To print the contents of the Current Ranges box, select **Print**.
14. Select **Close** to close the Reflexive Testing Configuration screen.

## *Editing Reflexive Testing Configurations*

Follow these instructions to edit existing reflexive testing configurations:

***For the IMMULITE 2000 System and IMMULITE 2500 System***

1. At the instrument window menu bar, select **Configurations**.
2. Select **Reflexive Tests** and then proceed to step 2 in the next section.

***For the IMMULITE 2000 XPi instruments***

1. At the Menu screen, select **MENU**, and then select **Reflexive Tests**.
2. Select one of the following options:
   - **Immunoassay - Configured for Reflex**
   - **Allergy - Configured for Reflex**.
3. Select a **Principle Test** and **Universal Reagent**, if applicable.
4. Select the range to edit in the Current Ranges box on the right side of the screen.
   Update the reflex range depending on the selection.
5. Select **Edit**.

## *Using Reflexive Tests*

Follow these procedures to order additional reflexive tests, add a dilution factor, or remove a reflexive test:

### Ordering Additional Reflexive Tests for a Range

Select the buttons that correspond to the individual reflexive tests for this range. To switch between assays and allergens, select the **IMMUNOASSAY** or **ALLERGY** button in the TEST CATEGORIES box.

## Adding or Editing a Dilution Factor

1. Select the test under the Tests Selected heading
2. Select the **DILUTION** button.
3. Select the dilution factor.

## Removing a Reflex Test

1. Select the test under the Tests Selected heading, and then select the **REMOVE** button.
2. After all edits to this range are complete, select the **SAVE** button.
3. Repeat steps 2 through 7 to edit additional reflexive testing configurations.
4. To print the contents of the Current Ranges box, select the **Print** button.
5. Select the **Close** button to close the Reflexive Testing Configuration screen.

## Deleting a Reflexive Test Range

Follow these instructions to edit existing reflexive testing configurations.

### *For the IMMULITE 2000 System and IMMULITE 2500 System*

1. At the instrument window drop-down menu, select **Configurations**.
2. Select **Reflexive Tests**.
3. Proceed to step 3 in the next section.

### *For the IMMULITE 2000 XPi instruments*

1. At the instrument window, select **MENU**.
2. Select **Reflexive Tests**.
3. Select one of the following options:
   - **Immunoassay - Configured for Reflex**
   - **Allergy - Configured for Reflex**.
4. Select a **Principle Test** and **Universal Reagent**, if applicable.
5. Select the range to edit in the Current Ranges box on the right side of the screen.
6. Select the **Delete** button.
7. Select the **Yes** button.
8. Repeat steps 3 through 7 to delete additional ranges.
9. To print the contents of the Current Ranges box, select the **Print** button.
10. Select **Close** to close the Reflexive Testing Configuration screen.

# Panel Configuration

A panel may be used to group tests that are routinely ordered together. The Panel Configuration window is used to create a panel or edit an existing panel. The operator assigns a panel name and the tests to include in the panel. Up to one hundred tests may be assigned to a panel.

## Creating a New Panel

Follow the instructions below to create a new panel.

### *For the IMMULITE 2000 System and IMMULITE 2500 System*

1. At the instrument window drop-down menu, select **Configurations**.
2. Select **Panels**.
3. Proceed to step 3 in the next section.

### *For the IMMULITE 2000 XPi instruments*

1. At the instrument window, select **MENU**.
2. Select **Panels**.
3. Select **ADD NEW PANEL**.
4. Enter a panel name in the Panel Name field.

   The panel name can have no more than 10 characters.
5. Select one of the Panel Color buttons, 1 through 15.

   The color selected distinguishes the tests belonging to this panel in the Available Panels window.
6. Select the **Test Name**.
7. Select **ACTIVE KITS** or **ON BOARD**.
   - If **ACTIVE KITS** is selected, every immunoassay or allergy test scanned onto the instrument displays in the center of the window.
   - If **ON BOARD** is selected, every immunoassay or allergy test physically residing on the instrument displays in the center of the window.

### Immunoassay

Select the appropriate immunoassay.

The code for the selected assay displays in the Tests Selected field.

### Allergen

1. Select the universal reagent, such as SPE, to be used for the allergy test.

2. Select allergen test.

   The code for the selected allergen displays in the Tests Selected field.

## Defining Allergen Controls

Two different kinds of allergy controls may be run:

- Allergy kit controls
- Specific-allergen controls

### Allergy Kit Controls

This type of control tests the performance of the universal allergy kit. These controls are provided with allergy kits. To run these controls, the Specific-IgE Control Antibody provided with that kit must have been entered and loaded.

### Specific-Allergen Controls

These controls test the performance of a particular allergen. Specific-allergen controls are available for the most common allergies. To run these controls, the allergen whose performance is to be tested must be entered and loaded.

1. Specify replicates of the tests in the panel.

   If replicates are not to be ordered, proceed to Step 8.

2. Select the test in the Tests Selected field, and then select **REPLICATES**.
3. Change the number of replicates to be performed using the arrow buttons.

   The number can also be entered using the keyboard.

4. Select **OK** to enter the number displayed, and then close the Replicates window.
5. Repeat this process for all tests that require replicates.
6. To save the entries and close the window, select **OK** in the Available Tests window.
7. At the Panel Configuration window, specify any dilution factors necessary to apply to the immunoassays in the panel to be created.
8. Select **Dilution Factor**.
9. Select the immunoassay in the Tests Selected field to apply the dilution selected to that test.
10. Repeat these steps for each onboard dilution needed.

    **NOTE:** The *Dilution Volume Specifications*, page E-2 displays the amount of sample, water, and diluent used for onboard dilutions.

11. Select **SAVE PANEL**.

## Editing a Panel

Follow the instructions below to edit an existing panel.

***For the IMMULITE 2000 System and IMMULITE 2500 System***

1. At the instrument window drop-down menu, select **Configurations**.
2. Select **Panels**.
3. Proceed to step 3 in the next section.

***For the IMMULITE 2000 XPi instruments***

1. At the instrument window, select **MENU**.
2. Select **Panels**.
3. Select **EXISTING PANELS**.
4. Select the panel from the Panel Name list, and then select **ACCEPT**.

   The panel you select displays in the Panel Configuration window. Follow the appropriate instructions below for the changes to be made.

### To Add a Test to the Panel

1. Select **Test Name**.
2. Follow step 7 in *Creating a New Panel*, page 8-18.

### To Remove a Test from the Panel

In the Panel Configuration window, select the test to remove in the Tests Selected field.

### To Change the Dilution Factor for an Immunoassay

1. In the Panel Configuration window, select the dilution factor needed.
2. Select the test in the Test Selected field to which to apply the dilution.

   The *Dilution Volume Specifications*, page E-2 displays the amount of sample, water, and diluent used for onboard dilutions.
3. Select **SAVE PANEL** in the Panel Configuration window to save the changes entered.

### Deleting a Panel

Follow the instructions below to delete an existing panel.

***For the IMMULITE 2000 System and IMMULITE 2500 System***

1. At the instrument window drop-down menu, select **Configurations**.
2. Select **Panels**.

3. Proceed to step 3 in the next section.

***For the IMMULITE 2000 XPi instruments***

1. At the instrument window, select **MENU**.
2. Select **Panels**.
3. Select **EXISTING PANELS**.
4. Select the panel to be deleted from the Panel Name list.
5. Select **ACCEPT**.

   Information about the selected panel displays in the Panel Configuration window.
6. Select **DELETE PANEL**.
7. Select **Yes**.

## Units Configuration

The Units Configuration screen allows the operator to change the reporting units for a specific test. To change from the default units, follow the instructions below.

**NOTE:** Changing the reporting units for a specific assay will cause the software to recalculate all results automatically in the database for that assay, including Quality Control results and reference ranges. Subsequent printouts of Quality Control results, export data, or reprints of patient results will display with re-calculated results and the updated units.

***For the IMMULITE 2000 System and IMMULITE 2500 System***

1. At the instrument window drop-down menu, select **Configurations**.
2. Select **Units**.
3. Proceed to step 3 in the next section.

***For the IMMULITE 2000 XPi instruments***

1. At the instrument window, select **MENU**.
2. Select **Units**.
3. Select the arrow to the right of Test Name window.

   The drop-down window displays the available tests.
4. Select the test.

   The units options for this particular test display, with the current reporting unit selected.

   Up to four different units may display.
5. Select the unit.

6. Select **Save**.
7. Select **Done**.

# AutoStart Configuration Screen

**NOTE:** This feature is only available on the IMMULITE 2000 XPi system.

The AutoStart Configuration screen allows you to schedule automated maintenance procedures by date and time, and enable or disable automatic substrate dispensing.

Use the AutoStart Configuration screen to define your automatic procedures:

- Select the days of the week for AutoStart to run.
- View control worklists to run during schedule AutoStart procedure.

To configure the instrument to AutoStart:

1. At the instrument window, select **MENU**.
2. Select **AutoStart Configuration**.

   The AutoStart Configuration screen displays.
3. Select the day(s) of the week to schedule AutoStart.
4. For each day of the week you selected, enter the time of day to schedule AutoStart.
5. To see the Scheduled QC worklists assigned for a particular day, select **View Worklist** next to the appropriate day of the week.

   Refer to *Scheduling QC Assays*, page 4-14.
6. Select **Substrate Dispense ON** or **Substrate Dispense OFF**.

   Refer to the section below, *Automatic Substrate Dispense*.
7. Select **Save**.

## Automatic Substrate Dispense

**NOTE:** When the probe is inactive for more than 2 hours, the operator must manually prime the first time for this routine to continue.

Every 2 hours the Substrate Dispense ON selection automatically moves a reaction tube into the substrate station and dispenses substrate material into the tube, then clears the tube off of the instrument to ensure the probe is clean.

The Substrate Dispense OFF selection disables the substrate from automatically dispensing. This option is only recommended if you perform automated maintenance tasks, and will not be running the automated QC Worklist. Additionally, if the instrument is running tests up until AutoStart begins, the substrate will have recently dispensed during the course of processing tests; therefore, the probe will be ready.

### Communications

The Communications screen is used to configure the instrument to communicate via informatics applications, such as RealTime Solutions.

## Reports

Follow the instructions below to configure reports.

1. Ensure the instrument is in STOP mode.
2. At the instrument window, select **REPORTS**.
3. Select **CONFIGURE REPORT**.
4. To automatically print this report:
   - In short format, select the **Short Format** option.
   - In chartable format, select the **Chartable Format** option.
5. Select **SAVE** to save this change.
6. Select **CLOSE**.

### Editing Chartable Patient Reports

Follow the instructions below to edit the chartable patient report.

#### *For IMMULITE 2000 System or IMMULITE 2500 System*

1. Ensure the instrument is in STOP mode.
2. At the instrument window, select **REPORTS**.
3. Select the **CONFIGURE REPORT** button.
4. Select **Chartable Format**.
5. Select the **Edit Template** button.
6. Single select one of the four corners of the box to resize the **Property Toolbox**.
7. When the black double arrow displays, drag the box to increase or decrease the box size.

   Do not close the Property Toolbox. To display it, press the F4 key on the keyboard.
8. Click on a field label to edit.

   A text box will surround the field label.

## Configuring the Laboratory Name

The laboratory name is stored in the database and must be configured separately, as follows.

**NOTE:** Do not modify the section headings, PageHeader, GroupHeader, Detail, PageFooter, or GroupFooter1.

1. Select the appropriate property, for example Caption, in the Property Toolbox.
2. Edit the field.

   If a field extends beyond the printable range, a red line displays, indicating that each page will print on two pieces of paper. Adjust fields accordingly to avoid this behavior.
3. Press **Enter**.
4. Select the Font section in the Property Toolbox to edit the font type and size.
5. Select **PREVIEW** to view the changes.
6. Select **Print** icon while previewing the template to print a sample report.
7. Select **SAVE** to save any changes.

## Enabling or Disabling Fields

Follow the instructions below to enable or disable fields and field labels in the chartable patient report.

1. Ensure the instrument is in STOP mode.
2. At the instrument window, select **REPORTS**.
3. Select **CONFIGURE REPORT**.
4. Select **Chartable Format**.
5. Select **Edit Template**.

   The Design screen displays.
6. Select the appropriate field or field label.

   A text box surrounds the field.
7. Select the Visible field in the Property Toolbox.

   A drop-down arrow displays.
8. Select the drop-down arrow and select and option:

   Although hidden on the report, the field label displays in the template.
   - **True** - to enable the field.
   - **False** - to hide the field.
9. Select **PREVIEW** to view the changes.
10. Select the **Print** icon while previewing the template to print a sample report.

11. Select the **SAVE** button to save any changes.
12. Repeat steps 1 - 6 as necessary for all fields and field labels.

### Moving Fields

Follow the instructions below to arrange field labels and fields.

1. Ensure the instrument is in STOP mode.
2. At the instrument window, select **REPORTS**.
3. Select **CONFIGURE REPORT**.
4. Select **Chartable Format**.
5. Select **Edit Template**.

   The Design screen displays.
6. Select the appropriate field or field label.
7. Select a field or field label to move it to the appropriate position.

   To select multiple fields, select and hold the **CTRL** key while clicking on fields/field labels, or select and drag a selection box around the fields/field labels.
8. While pressing the mouse button, drag the field or field label to the new location.
9. Release the mouse button.

   The field label displays in the new location
10. To change the size of a field or field label, select the field and click and drag the black squares to resize the field.
11. Select **PREVIEW** to view the changes.
12. Select the **Print** icon while previewing the template to print a sample report.
13. Select **SAVE** to save any changes.

    **NOTE:** Text and data in fields will word wrap in the report. Avoid overlapping fields on the template. Overlapping fields may result in overlapping text and data in the chartable patient report.

## *Manually Printing the Chartable Patient Report*

Follow the instructions below to manually print the chartable patient report. This feature allows the operator to test-print the chartable patient report without waiting for it to automatically print.

1. Ensure the instrument is in STOP mode.
2. At the instrument window, select **REPORTS**.
3. Select **PRINT REPORT**.

4. Enter the Accession Number.
5. Select the Patient Name from the dropdown list.

   The report cannot be printed if all tests are not resulted for the selected accession number and patient.
6. Enter any additional information to display on the report in the Comment field.
7. Select **PRINT**.

## Restoring the Template

Follow the instructions below to delete the customized template and overwrite it with the Siemens provided template.

1. At the instrument window, select **REPORTS**.
2. Select **CONFIGURE REPORT**.
3. Select **Restore Template**.
4. Select **YES** to restore the Siemens template, or select **NO** to cancel.

## Changing Windows Settings

The Windows settings are configured by the Siemens personnel when the system is installed. Refer to *Resetting the Date and Time*, page 8-26 and *Changing the Sound*, page 8-27 to adjust these settings.

### Resetting the Date and Time

Follow the instructions below to reset the computer's date and time.

**NOTE:** Do not follow these instructions when a Daylight Savings time change is needed. A prompt will display to change the time on the proper date.

1. Select **Start** at the lower left corner of the screen.

   **NOTE:** Do not change the Regional Settings on the Control Panel.
2. Use the trackball to highlight Settings, and then select **Control Panel**.

   The Control Panel screen displays the Control Panel icons.
3. If necessary, select the **Date & Time** tab.
4. Double select the **Date/Time** icon.
5. At the Date/Time Properties window, select the **Time Zone** tab.
6. Select the arrow to the right of the month field and highlight the current month.
7. If the year is incorrect, use the up and down arrow buttons to the right of the year field to display the current year.

8. On the calendar, select the current date.
9. Type the current time in the time field.
   - If the time zone at the Current time zone prompt is incorrect, continue with the instructions below for setting the time zone.
   - If the time zone at the Current time zone prompt is correct, select the **OK** button to close the Date/Time Properties screen.
10. Select the close button (**x**) at the upper right corner of the Control Panel.

### Setting the Time Zone

1. Select **Start** at the lower left corner of the screen.

   **NOTE:** Do not change the Regional Settings on the Control Panel.
2. Use the trackball to highlight Settings, and then select **Control Panel**.

   The Control Panel screen displays showing the Control Panel icons.
3. At the Date/Time Properties screen, select the **Time Zone** tab.
4. Select the down arrow to the right of the time zone.
5. A list of time zones display.
6. Select the time zone.
7. Select **OK** to close the Date/Time Properties window.
8. Select the Close button (**x** at the upper right corner of the Control Panel screen).

   The Control Panel window closes.

### Changing the Sound

**CAUTION**

Do not use the Windows NT volume control located on the desktop task bar. A known Windows issue may adversely affect the operating system.

Sounds are used to call attention to the instrument. Use the volume controls located on the monitor to raise or lower the sound volume or turn the sound off.

## *Calibrating the Touchscreen*

Follow the instructions below to calibrate the touchscreen.

1. Select the **Start** button at the lower left corner of the screen.
2. Use the trackball to highlight **Settings** and select **Control Panel**.

   The Control Panel screen displays showing the Control Panel icons.

3. Double select the **Touchscreen** icon.

   The Touch Selection screen displays.

4. Select the **Calibrate** button.

   The Touch Calibration screen displays.

5. Follow the instructions on the screen, selecting the target.

   The following message displays:

   ```
   Touch different areas on the screen.

   Does the cursor jump to your fingertip?
   ```

6. Select the **Yes** button.

   The Touch Calibration screen closes and the Touch Selection screen redisplays.

7. Select the **OK** button.

   The Touch Selection screen closes.

8. Select the **Close** button (x) in the upper right corner of the Control Panel to close this screen.

## *Updating the System*

The system arrives with the latest version of the instrument software installed. CD ROMs containing software updates or new releases are sent periodically. To install new software, follow the instructions accompanying the CD.

# Appendix A: Safety Instructions

This information summarizes the established guidelines for handling laboratory biohazards. This summary is based on the guidelines developed by the Centers for Disease Control, the Clinical and Laboratory Standards Institute Document M29-A3, *Protection of Laboratory Workers from Occupationally Acquired Infections*, and the Occupational Safety and Health Administration's Bloodborne Pathogens Standard.[1 – 3]

## Protecting Yourself from Biohazards

Use this summary for general information only. It is not intended to replace or supplement your laboratory or hospital biohazard control procedures.

By definition, a biohazardous condition is a situation involving infectious agents biological in nature, such as the hepatitis B virus, the human immunodeficiency virus, and the tuberculosis bacterium. These infectious agents may be present in human blood and blood products and in other body fluids.

The following are the major sources of contamination when handling potentially infectious agents:

- needlesticks
- hand-to-mouth contact
- hand-to-eye contact
- direct contact with superficial cuts, open wounds, and other skin conditions that may permit absorption into subcutaneous skin layers
- splashes or aerosol contact with skin and eyes

To prevent accidental contamination in a clinical laboratory, strictly adhere to the following procedures:

- Wear gloves while servicing parts of the instrument that have contact with body fluids such as serum, plasma, urine, or whole blood.
- Wash your hands before going from a contaminated area to a noncontaminated area, or when you remove or change gloves.
- Perform procedures carefully to minimize aerosol formation.
- Wear facial protection when splatter or aerosol formation are possible.
- Wear personal protective equipment such as safety glasses, gloves, lab coats or aprons when working with possible biohazard contaminants.
- Keep your hands away from your face.
- Cover all superficial cuts and wounds before starting any work.
- Dispose of contaminated materials according to your laboratory's biohazard control procedures.
- Keep your work area disinfected.
- Disinfect tools and other items that have been near any part of the instrument sample path or waste area with 10% v/v bleach.
- Do not eat, drink, smoke, or apply cosmetics or contact lenses while in the laboratory.
- Do not mouth pipet any liquid, including water.
- Do not place tools or any other items in your mouth.
- Do not use the biohazard sink for personal cleaning such as rinsing coffee cups or washing hands.

To prevent needlestick injuries, needles should not be recapped, purposely bent, cut, broken, removed from disposable syringes, or otherwise manipulated by hand.

## References

1. Centers for Disease Control. 1988. Update: Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus and other bloodborne pathogens in healthcare settings. MMWR, 37:377 – 382, 387, 388.
2. Clinical and Laboratory Standards Institute (formerly NCCLS). *Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline - Third Edition.* CLSI Document M29-A3.[ISBN 1-56238-567-4]. Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2005).
3. Federal Occupational Safety and Health Administration. Bloodborne Pathogens Standard. 29 CFR 1910. 1030.

## Precautions Table

Operational precautions are included throughout this manual. The table below provides a comprehensive list of all the precautions to take for optimal instrument operation.

| Category | Precaution |
|---|---|
| Specimen Tubes | Barcode labels on specimen tubes must face out when in a Sample Rack.<br>Do not use specimen tubes that exceed 100 mm in height or are less than 12 mm in diameter. |
| Bead Packs | Do not use a Bead Pack if the barcode label was damaged or removed. |
| Reagents | Use only IMMULITE 2000 system reagents with the IMMULITE 2000 systems, and IMMULITE 2500 system reagents with the IMMULITE 2500.<br>Do not reuse IMMULITE 2000 or IMMULITE 2500 Reagent Wedges.<br>Do not use a reagent wedge if the barcode label was damaged or removed. |
| Kits | Read and carefully follow the package insert instructions supplied with each kit prior to use. |
| Water | Water used in the water bottle must be alkaline phosphatase-free. The chemiluminescent substrate used in the instrument is very sensitive to alkaline phosphatase. |
| Reaction Tubes | Use only the specially designed IMMULITE 2000 systems and IMMULITE 2500 system reaction tubes. The reaction tubes must be disposed of after single use. |
| Dilutions | Diluents should not be used beyond the indicated expiration date.<br>To prevent damage to the dilution well, the polypropylene dilution well insert must be in place before performing dilutions. |
| Ventilation | Do not block the fan vents on the sides and back panel of the instrument. |
| Electrical | The instrument must be connected to a dedicated 220V power service. |
| Priming | The water and substrate probes must be removed from their stations before priming. |
| Microsampling | Do not use a microsample tube holder with a damaged or dirty barcode label. |
| Solid and Liquid Waste | Solid and liquid waste may contain biohazardous material. Follow Universal Precautions when handling. |

# Appendix B: Service, Ordering, and Warranty

This section provides the following information:

- address of the Siemens authorized representative, which is the Siemens contact within the European community
- addresses for obtaining service and technical information and for ordering supplies
- system warranty and service delivery policy information

## Siemens Authorized Representative

Siemens Healthcare Diagnostics Inc.
Flanders, NJ 07836-9657 USA

### Limited Warranty

LIMITED WARRANTY. Siemens warrants that the software will substantially conform to specifications and to the documentation, provided that it is used on the computer hardware and with the operating system for which it is designed. Siemens also warrants the disks on which the software is recorded to be free from defects in material and workmanship under normal use for a period of ninety (90) days from the date of purchase.

Siemens warrants that the items delivered hereunder are of good material and workmanship, and are free from defects in design and manufacture. Siemens' responsibility is limited to repairing or replacing any item or part, for a period of one (1) year after delivery to the original purchaser. Defects caused by improper operating conditions, misuse, negligence, or alteration of the product void this warranty. Siemens shall not be liable for any direct, indirect, incidental, or consequential damages arising out of possession or use of the items. Consumables, as defined in the appropriate Siemens Price List for Instrument-Related Parts. Racks and Consumables, are not covered by this Warranty.

CUSTOMER REMEDIES. Siemens' entire liability and your exclusive remedy shall be replacement of the software that does not meet Siemens Limited Warranty and which is returned to Siemens. The Limited Warranty is void if failure of the software has resulted from accident, abuse, or misapplication.

NO OTHER WARRANTIES. Because software is inherently complex and may not be completely free of errors, you are advised to verify your work. The software and related documentation are provided "as is." Siemens disclaims all other warranties, either express or implied, including but not limited to implied warranties of merchantability and fitness for a particular purpose, with respect to the software and the accompanying written materials. Siemens shall not be liable for any direct, indirect, incidental, or consequential damages arising out of possession or use of this product.

# Contacts

This section provides the following information:

- the address of the Siemens authorized representative, which is the Siemens contact within the European community
- the Siemens addresses for obtaining service and technical information and for ordering supplies

## Addresses

For technical assistance, contact your local technical support provider. For customer service or additional information, contact your local technical support distributor.

www.siemens.com/diagnostics

Siemens Healthcare Diagnostics Inc.
Flanders, NJ 07836-9657 USA

EC REP

Siemens Healthcare Diagnostics Ltd.
Sir William Siemens Sq.
Frimley, Camberley, UK GU16 8QD

Siemens Healthcare
Diagnostics Pty Ltd
885 Mountain Highway
Bayswater Victoria 3153
Australia

シーメンスヘルスケア・
ダイアグノスティクス株式会社
東京都品川区東五反田 3－20－14
Siemens Healthcare Diagnostics
輸入

# Appendix C: Reagents and System Fluids

The IMMULITE 2000 systems and IMMULITE 2500 system water system is an automated filling device for the onboard distilled water bottle. It consists of a valve assembly, which connects the laboratory's purified water system to the instrument. The instrument's onboard water bottle is filled automatically as the water is utilized by the instrument.

The laboratory is responsible for providing the purified water to the valves at proper pressure (not to exceed 20 psi). A shut-off valve in the supply line near the instrument is recommended. This will provide a way to interrupt the water supply during service.

## Instrument Water System

The IMMULITE 2000 systems and IMMULITE 2500 system water system is self-contained and requires minimal maintenance by the operator. It is recommended that a minimum of 300 tests per day be processed on an instrument using the automated water system.

### Operation of the Instrument Water System

The IMMULITE 2000 systems and IMMULITE 2500 system water system functions by detecting the level of water in the water bottle and refilling it by activating a set of valves. These valves control the flow of water from the laboratory's water system into the water bottle.

The level of water in the water bottle is measured utilizing the instrument load cell. The load cell sits underneath the water bottle and measures its weight. As water is used by the instrument, the water bottle becomes lighter. This signals control valves in the water system manifold to open, filling the water bottle until the weight returns to the full/maximum value.

There is also a float switch located inside the water bottle, which prevents overfilling. Water will not be allowed to flow into the water bottle unless the float switch is below the preset open position. This is important in situations where the water bottle is removed from the load cell for any length of time or the load cell is damaged or malfunctions.

For more information about maintaining the water system, refer to the following sections:

- *Decontaminating the Bottles and Lines*, page 5-27
- *Water System Routine Maintenance*, page 5-31

## Bypassing the IMMULITE 2000 Water System

The water system may be bypassed if it fails, or it becomes necessary to return the instrument to the standard water bottle. Contact Technical Service prior to bypass the Water System.

To fill the water bottle, refer to *Checking and Filling the Water Bottle*, page 5-7.

Turn off the direct water feed power switch located behind the sample carousel. Look for the label marked water supply.

## *Troubleshooting and Frequently Asked Questions*

The following are some common troubleshooting scenarios and frequently asked questions.

| Situation | Possible Cause | Solution |
|---|---|---|
| Water Bottle does not fill | Water supply is turned off. | Turn water supply on. |
| | Connections to the water bottle are not attached, such as tubings and sensor wire. | Properly attach tubing or wire. |
| | The load cell is not working properly. | Check the consumables graph on the Home screen of the instrument. If it displays full and the bottle is empty, call technical service. |
| Water Bottle overfills | Water supply pressure is too high. | Adjust supply pressure to less than 20 PSI. |
| | Float valve not properly seated. | Check and re-seat the float valve. |
| | Water bottle not seated properly on the load cell. | Assure the bottle is fully seated on the load cell and the tubings and wires are not impinged. |
| | Water source is contaminated. | Contact water supplier for correction. |
| | Less than 300 tests are run per day. | Empty water bottle and allow it to refill before use. |
| | Instrument has been idle for greater than 48 hours. | Empty water bottle and allow it to refill before use. |
| | Water system valve is contaminated. | Contact technical service for service. Bypass the water system to continue running. Refer to *Bypassing the IMMULITE 2000 Water System*, page C-2. |

# Appendix D: Supplies

## Consumables and Accessories

IMMULITE 2000 Systems and 2500 System consumables and accessories are listed in the table below. To place an order, contact Siemens or a distributor.

**NOTE:** Those outside the United States should contact a National Distributor to place an order.

| Part Number | Description | Quantity |
|---|---|---|
| L2ATC | Allergen Tube Caps* | 1000 |
| L2ATS2 | Allergen Tube Septa* | 250 |
| L2AW1 | Allergen Wedge Set | 33 |
| 400920 | Allergy Imaging Scanner Training Guide | 1 |
| 901863 | Barcode Label Printer Ribbon | 1 |
| 901864 | Barcode Label Stock | 1 |
| 400790 | Barcode Printer Kit | 1 |
| 400925-01 | Barcode Scanner (Standard) | 1 |
| 400925-02 | Barcode Scanner (Wedge Allergy Assay) | 1 |
| 10-901807 | Biohazard Bags* | 20 |
| 422023 | CO2 Scrubber Kit | 1 |
| CON6 | Con6 Multivalent Control Module | 2 |
| 400763 | Decontamination Bottle | 1 |
| 500912 | Dilution Well Insert (2) | 2 |
| 501705 | Distilled Water Bottle (6L) | 1 |
| 901689 | Extension Cable for Monitor | 1 |
| 901801 | Fan Filter | 1 |
| 902666 | Image Drum (OKI 14E) | 1<br>Not available for IMMULITE 2000 XPi. |
| 902934 | Image Drum (OKI B4200) | 1<br>Not available for IMMULITE 2000 XPi. |

| Part Number | Description | Quantity |
|---|---|---|
| 901824 | Ink cartridge - black ink (710C printer) | 1<br>Not available for IMMULITE 2000 XPi. |
| 902058 | Ink cartridge - black ink (810C printer) | 1<br>Not available for IMMULITE 2000 XPi. |
| 902058-02 | Ink cartridge - black ink (970C printer) | 1<br>Not available for IMMULITE 2000 XPi. |
| 902057-02 | Ink cartridge - color ink (970C printer) | 1<br>Not available for IMMULITE 2000 XPi. |
| 901825 | Ink cartridge - color ink (710C printer) | 1<br>Not available for IMMULITE 2000 XPi. |
| 902057 | Ink cartridge - color ink (810C printer) | 1<br>Not available for IMMULITE 2000 XPi. |
| 901205 | In-Line Filters* | 6 |
| 400753-54 | Keyboard (English - U.K.) | 1 |
| 400753-53 | Keyboard (English - U.S.) | 1 |
| 400753-58 | Keyboard (French) | 1 |
| 400753-55 | Keyboard (German) | 1 |
| 400753-57 | Keyboard (Italian) | 1 |
| 400753-56 | Keyboard (Spanish) | 1 |
| 400753-59 | Keyboard (Swedish) | 1 |
| 901728 | Keyboard Cover | 1 |
| 400271 | LIS ASTM Specifications | 1 |
| 422013 | LIS Comm Program | 1 |
| 501706 | Liquid Waste Bottle (6L) | 1 |
| LMH5 | Microsample Inserts - set of 5 | 5 |
| LMH15 | Microsample Inserts - set of 15 | 15 |
| LSMC | Microsample Tube Caps* | 1000 |
| LMST | Microsample Tubes* | 1000 |
| 400755 | Monitor Power Cable | 1 |
| 901729 | Paper (1 ream) | 1 |
| 400767 | Power Cord (US) | 1 |

| Part Number | Description | Quantity |
|---|---|---|
| 901836-01 | Power Cord (Argentina, Austria, Brazil, Finland, France, Germany, Netherlands, Norway, Sweden) | 1 |
| 901836-02 | Power Cord (Hong Kong, Singapore, United Kingdom) | 1 |
| 901836-03 | Power Cord (Australian, New Zealand) | 1 |
| 901836-04 | Power Cord (Denmark) | 1 |
| 901836-05 | Power Cord (Switzerland) | 1 |
| 901836-06 | Power Cord (Chile, Italy) | 1 |
| 901836-07 | Power Cord (Israel) | 1 |
| 901836-08 | Power Cord (South Africa) | 1 |
| 901835 | Primary Tube Sample Guide | 1 |
| 400537 | Probe Assembly | 2 |
| L2KPM | Probe Cleaning Kit | 1 |
| L2PWSM | Probe Wash (2 Bottles) | 1 |
| 400706 | Probe Wash Bottle (2L) | 1000 |
| 422223 | Printer: Okidata 4250 | 1<br>Not available for IMMULITE 2000 XPi. |
| LRXT | Reaction Tubes | 26 (A-Z) |
| 400726-01 | Reagent Bottle Assembly (substrate) | 1 |
| 650104 | Sample Rack Letters | 1 |
| 400756 | Sample Racks | 1 |
| 901519 | Scanner Cable | 1 |
| 400749 | Side Tray | 1 |
| 472021 | Software Barcode Label Printer | 20 |
| 400634 | Solid Waste Container | 2 |
| 10-901807 | Solid Waste Container Biohazard Bags | 1 |
| 400794 | Substrate (2 Bottles) | 1 |
| 400726-01 | Substrate Reservoir (250 mL) | 1 |
| 901865 | Thermal Cleaning Kit | 1 |

| Part Number | Description | Quantity |
|---|---|---|
| 902665 | Toner Cartridge (OKI 14E) | 1<br>Not available for IMMULITE 2000 XPi. |
| 902933 | Toner Cartridge (OKI B4200) | 1<br>Not available for IMMULITE 2000 XPi. |
| 901427 | Touchscreen Monitor | 1 |
| 400754 | Trackball | 1 |
| 403034 | Tube Top Sample Rack | 2<br>Only available for IMMULITE 2000 XPi. |
| 901720 | UPS 1400 VA Output (Approx. 20 minutes) | 1 |
| 901721 | UPS 1800 VA Output (Approx. 25 minutes) | 1 |
| 901722 | UPS 2200 VA Output (Approx. 30 minutes) | 1 |
| 400918 | Waste Chute Clean Out Tool | 1 |
| 400909-01 | Water Feed Control System | 1 |
| 501705 | Water Supply Bottle | 1 |
| 905288<br>REF 0374178 | Tube Top Sample Cups | 1000 |
| 905289<br>REF 10374179 | Tube Top Sample Cups | 1000 |

* For single use only. Do not reuse.

# Appendix E: System Specifications

## Specifications Tables

This section includes the following IMMULITE 2000 systems and IMMULITE 2500 system specification tables.

- Output Specifications
- Fluid Usage Specifications
- Computer System Specifications
- Dilution Volumes

### Output Specifications

The Output Specifications Table below displays the expected outputs for the IMMULITE 2000 systems and IMMULITE 2500 system.

| Output Specification | Quantity |
|---|---|
| Throughput | Up to 200 tests per hour |
| Time to first result | IMMULITE 2000 systems: 35 minutes<br>IMMULITE 2500 system: 15 minutes |
| Tests per sample | Unlimited |

### Fluid Usage Specifications

The fluid specifications are listed in the table below:

| Fluid | Volume Used Per Test‡ | Volume of Full Container | Approx. Number of Tests Per Container† |
|---|---|---|---|
| Water | 7.5 mL | 6000 mL | 800 |
| Probe Wash | 2.0 mL | 2000 mL | 1000 |
| Substrate | 0.2 mL | 205 mL | 1025 |

†Number of Tests Per Full Container may vary depending upon amount of priming performed.
‡Volume Used Per Test is based upon a one-cycle, undiluted assay. Add 3 mL for a two-cycle (sequential) assay. If an assay is diluted onboard, add an additional 1 ml.

## Computer Specifications

The current specifications for the computer supplied with the IMMULITE 2000 systems and IMMULITE 2500 system display in the table below. These specifications are subject to change without notice.

**WARNING**

The computer supplied with the instrument was designed to run the included software. The installation of third-party software programs may adversely affect the proper operation of the instrument software or analyzer and may void the product warranty. Refer to *Limited Warranty* for more information.

***For IMMULITE 2000 and IMMULITE 2500 Systems***

| Specification | Description |
|---|---|
| Processor | Pentium II with a minimum 800 Mhz |
| RAM | 256 megabyte |
| Hard Drives (3) | • 40-gigabyte user<br>• 40-gigabyte back-up<br>• 40-gigabyte control |
| Monitor | 19-inch flat screen monitor with Surface Acoustic Wave touchscreen |

***For IMMULITE 2000 XPi Systems***

| Specification | Description |
|---|---|
| Processor | Integrate Core 2 Duo, 2.13 GHz |
| RAM | 2 GB |
| Hard Drives (3) | • SATA hard drive user<br>• DVD-RW drive backup |
| External Port | USB |
| Monitor | 19-inch flat screen monitor with Surface Acoustic Wave touch-screen |

## Dilution Volume Specifications

The Dilution Volumes Specification Table below displays the amount of sample, water, and diluent used for onboard dilutions.

| Dilution | Sample Volume (µL) | Water Volume (µL) | Diluent Volume (µL) |
|---|---|---|---|
| 3X | 67 | 80 | 53 |
| 5X | 40 | 96 | 64 |
| 10X | 20 | 108 | 72 |

| Dilution | Sample Volume (µL) | Water Volume (µL) | Diluent Volume (µL) |
|---|---|---|---|
| 20X | 10 | 114 | 76 |
| 40X | 5 | 117 | 78 |
| 100X | 5 | 297 | 198 |

## Sample Volume and Tube Sizes

**WARNING**

Sample cups placed in the tops of primary collection tubes are not approved for use on the IMMULITE 2000 and IMMULITE 2500 systems. Placing sample or nesting cups in a primary tube may cause the system to use an inaccurate sample volume during testing. The principle risk is undetected short sampling from the cup, creating a risk of erroneous results.

Only the IMMULITE 2000 XPi instrument supports this type of testing on the tube top rack with the approved tube top sample cups / nesting cups.

**WARNING**

Ensure that you use only these tube sizes, and that the tubes are firmly seated in the Sample Racks. Otherwise, sampling problems or incorrect results may occur.

**WARNING**

Ensure that you use only 16 x 100 mm tubes for diluents. Using narrower or shorter tubes can cause short-sampling of the diluent under certain conditions.

To determine the correct primary tube sample volume, see the Sample Tube Guide (Part Number 901835). The following primary and secondary round bottom tube sizes may be used.

| Approved Tube Sizes | |
|---|---|
| 12 x 75 mm | 12 x 100 mm |
| 13 x 75 mm | 13 x 100 mm |
| 16 x 75 mm | 16 x 100 mm |

To process small sample volumes, use only the microsample tubes and tube holders available with the IMMULITE 2000 and IMMULITE 2500 instruments. Refer to *Loading Microsamples*, page 2-5.

The Sample Racks are labeled alphabetically: A, B, C, D, E, F, etc.

**NOTE:** Sample rack labels are available from A-Z.

Do not use two or more Sample Racks with the same letter – the instrument will not run.

The sample volume required varies with the assay to be run and the number of replicates requested on that sample.

The exact sample volume required for each test can be found in the corresponding package insert. An additional 250 µl of sample is required for proper instrument operation.

If there is insufficient volume, an error message displays and "Sample Error" displays on the Display Worklist screen.

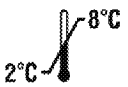
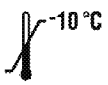
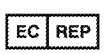
# Appendix F: Instrument Symbols

## Icon Glossary

IVD Symbols are International representations of information and/or instructions on the Instrument's labeling. The following table displays the International symbols that display on the Instrument's labeling and their definitions.

| Symbol | Description |
|---|---|
|  | Consult instructions for use |
|  | Do not re-use |
|  | Fragile, handle with care. |
|  | Caution, refer to accompanying documents |
|  | Batch code |
| REF | Catalog number |
| SN | Serial number |
|  | Use by (expiration date) |
|  | Sterile |
|  | Sterilized using aseptic processing techniques |
|  | Sterilized using radiation |
|  | Sterilized using ethylene oxide |
|  | Sterilized using steam or dry heat |
|  | Biological risk |
|  | Non-sterile |
|  | Do not re-sterilize |

601005-0004 Rev. A

| Symbol | Description |
|---|---|
|  | Keep away from heat |
|  | Keep dry |
|  | Protect from heat and radioactive source |
|   | Lower limit of temperature |
|   | Temperature limitation |
|   | Upper limit of temperature |
|   | Control |
|   | Negative control |
|   | Positive control |
|  | Date of manufacture |
|  | Do not use if package is damaged |
|   | *In vitro* diagnostic medical device |
|  | Manufactured by |
|   | Contains sufficient for <X> tests |
|   | For Performance Evaluation only |
|   | Representative in European Community |

# Appendix G: Installation and Relocation

## Overview - Installation Preparation

The IMMULITE 2000 systems and IMMULITE 2500 system must be installed by an authorized Siemens Diagnostics Service Representative. Before the Service Representative's arrival, make a few simple preparations to expedite the installation process.

Upon receipt of the instrument and computer, inspect the shipping container. If there is any external damage to the container, notify your shipping department and call Technical Service.

Next, select a suitable location for the system based on the power, space, and temperature requirements described in this section.

## Choosing a Location

Select a suitable location for the instrument in the laboratory, based on power, space, and temperature requirements.

## Power Requirements

Keep the following requirements in mind when choosing a location for the system.

Use one of the following dedicated voltage power supply services.

- 200
- 208
- 220
- 230
- 240

**CAUTION**

Do not place the system near centrifuges, ultrasound or X-ray machinery, NMR scanners, or other sources of magnetic fields.

## Space Requirements

Keep the following space requirements in mind when choosing a location for the system:

- The instrument must be on a level floor.
- For proper airflow, leave at least 4 inches of space around the sides and back of the instrument.
- The IMMULITE 2000 system and IMMULITE 2500 system dimensions are 59.7 inches wide, 29.7 inches deep, and 79 inches high.
- The IMMULITE 2000 XPi system dimensions are 63 inches wide, 36 inches deep, and 72 inches high.

## Temperature Requirements

Keep the following temperature requirements in mind when choosing a location for the system:

- The temperature should be between 18° and 32° Celsius.
- The relative humidity should be less than 80% for a temperature up to 32° Celsius.
- The IMMULITE 2000 systems and IMMULITE 2500 system generates 3,413 BTU/hr.

## Water Requirements

Distilled or de-ionized water of consistent quality is required. Water used should meet NCCLS Type 1 reagent water standards at the time of preparation. Prior to using any water, it should be tested for alkaline phosphatase contamination.

For detailed instructions, including how to evaluate the results, refer to *Water Test Procedure (IMMULITE 2000 System)*, page 5-32 or *Water Test Procedure (IMMULITE 2500 System)*, page 5-33.

IMMULITE systems are sensitive to the presence of alkaline phosphatase resulting from microbial contamination of the water or the containers used.

Properly maintained commercial water treatment systems commonly used in laboratories generally produce reagent water that meets the requirements of Type 1 water standards at the time of preparation.

Often, high quality reagent water becomes contaminated during storage and transport. To ensure water quality on the system:

- Keep commercial water systems appropriately maintained.
- Do not use water from a commercial water system while maintenance is being performed. After maintenance, verify water system cleanliness and test the water for alkaline phosphatase contamination.
- Maintain cleanliness of storage containers, transfer containers, spigots, hoses or other plumbing used to transfer water from its source to the instrument.
- Limit the length of plumbing between the source and the instrument. Long plumbing lines increase the likelihood of introducing contamination.

  **NOTE:** On rare occasions, non-alkaline phosphatase water contaminants may interfere with individual assays. The Water Testing Procedure used to detect alkaline phosphatase will not detect these contaminants. For assistance, call Technical Service.

# Appendix H: Error Messages

When the Instrument encounters an error, two messages are generally reported; one from the Control Side computer and one from the User Side computer.

- Control Side Computer

  Controls the motion of all instrument motors. Messages from this computer include raw data about events, such as bad bead pack. These messages indicate what is wrong but are not specific.

- User Side Computer:
- Displays instrument screens and performs result management functions. This computer receives messages from the control side computer and provides more specific information, such as, Rerunning test HCG marked as bad by bead pack error.

Reading both messages allows the operator to better understand what event occurred and why. This section discusses error message severities and priorities, explains some of the common errors and solutions, covers flags associated with results, and lists common errors and solutions.

## Error Message Severity and Priority

Error messages display on-screen within either white or red boxes, or are written to the daily error log without displaying on the screen. For error messages that are displayed, the box color indicates the severity of the message - white boxes contain informative messages and instrument status, while red boxes contain important warnings and errors.

- **WARNING** – indicates the Instrument requires attention soon. It does not affect the patient results or the operation of the Instrument.
- **ERROR** – requires the operator's attention but does not stop the entire Instrument from running. Typically, only one compartment is stopped.
- **SEVERE** – may stop the Instrument and requires the operator's immediate attention.

Within each severity level (white or red box) are several priority levels. The higher the priority, the greater the importance of the error message. In addition, priorities within a specific severity level are differentiated by the color text used or the accompanying icon. For example, a message about a low luminometer temperature displays in a white box with black print and has a low priority (1), while a message about an instrument status that needs attention displays in a white box with red print and has a higher priority (3).

The following table describes the types of messages that are displayed:

| Priority | Severity | Description |
|---|---|---|
| 0 | Daily Error Log | Information messages that become apparent on result printouts and appropriate screens, such as no reagent on board. |
| 1 | White box black print | Informative messages indicating instrument has taken an automatic action, such as reordering a test. |
| 2 | White box blue print | Messages indicating Instrument status that will result in a problem if left unattended, such as substrate low. |
| 3 | White box red print | Messages indicating Instrument status that needs attention and will imminently result in a problem, such as substrate is empty. |
| 11 | Red box warning icon | Circumstances not addressed by priorities 12 and 13 that require immediate attention. |
| 12 | Red box error icon | Instrument has entered Pause mode and is no longer processing new samples. |
| 13 | Red box severe icon | Instrument shut down; only the Luminometer is active. |

## Common Errors and Solutions

Following is a list of some of the more common errors and how they may be resolved. For more detailed information on error messages, causes, and solutions, refer to *List of Error Messages*, page H-4.

- (237) Sample Pipettor Did Not Level Sense

This usually indicates an insufficient (i.e., short) sample amount. Add additional sample and repeat.

- (287, 302, 392) Sample, Reagent, or Bead Carousel has Jammed While Homing

  Reseat the sample rack, reagent wedge, or bead pack as necessary.

- (380) Errors Have Shutdown the MCP Routine

  Check for sample, bead, and reagent carousel jams and re-run the IMMULITE 2000 program.

- (524) Sample Door or Main Cover is Open

  Close the appropriate doors or covers; IMMULITE 2000 will continue to initialize.

- (534) Tip Jam Reagent Pipettor

  This message indicates that the pipetting probe has physically contacted something solid. Check to see that the reagent wedge is properly seated and the reagent wedge glide is properly attached and moves freely.

- (547) Reagent Probe False Level Sensed at top or above wedge

  Remove the reagent wedge and open the glide (lid). Dry the top of the reagent wedge with a clean, lint free wiper and re-install the glide.

- (555) No Reaction Tube Detected Going into Bead Pause

  Refill the tube hopper as needed and check for jams in the orientation chute.

- (594) Marking Sample Tube as Bad

  This usually indicates an insufficient (i.e., short) sample amount. Add additional sample and repeat.

- (595) Marking Reagent Pack as Bad

- Check the associated error message, such as Reagent False Level Sense, to correct the situation.

- (12400) Substrate Low (or Empty)

  Refill the substrate reservoir.

- (12406) Probe Wash Low (or Empty)

  Refill the probe wash bottle.

- (12408) Water Supply Low (or Empty)

- Refill the distilled/de-ionized water bottle.

- (12506) Substrate Temperature Low

- If this message continues for more than 10 minutes, it may indicate a failure with the substrate probe heater. In this situation, contact your local service provider or distributor.

# Flags Associated with Results

The following flags may appear with results. For more detailed information on error messages, causes, and solutions, *List of Error Messages*, page H-4.

| Flag | Description |
|---|---|
| QC | One or more controls have failed for this assay. |
| HIGH | Result is greater than the operator-specified normal range (i.e., above the first line of the test range).<br>Refer to *Defining Test Ranges*, page 8-12 for more information about defining test ranges. |
| LOW | Result is less than the operator-specified normal range (i.e., below the first line of the test range).<br>Refer to *Defining Test Ranges*, page 8-12 for more information about defining test ranges. |
| ADJ | • Adjustment for this assay failed due to slope limits<br>• Adjustment for this assay is overdue for readjustment by more than 24 hours<br>• The assay was never adjusted.<br>• The kit was overwritten. |
| ERROR | Unable to calculate the result. The result should be verified. |
| EXP | The Kit expired. |
| TMP | The Substrate, Luminometer, and/or Incubator temperature was out of range when this result was calculated. |
| Review Low | Result is less than the operator-specified review range.<br>Refer to *Defining Test Ranges*, page 8-12 for more information about defining test ranges. |
| Review High | Result is greater than the operator-specified review range.<br>Refer to *Defining Test Ranges*, page 8-12 for more information about defining test ranges. |

# List of Error Messages

The IMMULITE 2000/2500 error messages are listed in numerical order:

0-100

**Programming Errors**

Occurs when underlying hardware errors cause software communication issues.

§If the message persists, call Technical Service.

| | |
|---|---|
| 101 | **Z8 and MCP not communicating**<br>Communication Error between Control PC and Slave card.<br>§Call Technical Service. |
| 102 | **Programmer error**<br>Communication Error between Control PC and Slave card.<br>§Call Technical Service. |
| 103 | **Cannot locate the POSITION.IML file**<br>The missing file was either deleted or moved to another directory.<br>§Call Technical Service. |
| 104 | **Cannot locate the current version of POSITION.IML file**<br>The file is corrupt and contains invalid information.<br>§Call Technical Service. |
| 105 | **POSITION.IML is corrupt**<br>The file is corrupt and contains invalid information.<br>§Call Technical Service. |
| 106 | **LmiMoveMotor has taken longer than 18 seconds.**<br>A MoveMotor motion to a configured position has taken longer than 18 seconds.<br>§Call Technical Service. |
| 108 | **LmiMoveSensor has taken longer than 18 seconds.**<br>A MoveMotor motion to a sensor position has taken longer than 18 seconds.<br>§Call Technical Service. |

111

**LmiMoveHome has taken longer than 18 seconds.**

A Motor move to a HOME sensor position has taken longer than 18 seconds have.

§Call Technical Service.

114

**LmiReadPMT has taken longer than 18 seconds.**

The PMT read has taken longer than 18 seconds.

§Call Technical Service.

115

**LmiMoveEnc cannot move more than 65535 motor steps.**

The MoveEncoder has calculated that it must take more than 65,535 steps to reach a configured encoder position.

§Call Technical Service.

116

**LmiDrawDiluter has taken longer than 18 seconds.**

A DRD/Aspiration motion to a configured position has taken longer than 18 seconds.

§Call Technical Service.

118

**LmiDispenseDilutor has taken longer than 18 seconds.**

A DRD/Dispense motion to a configured position has taken longer than 18 seconds.

§Call Technical Service.

120

**LmiDrawBiphasic has taken longer than 18 seconds.**

A DRD Aspiration Probe Wash motion to a configured position has taken longer than 18 seconds.

§Call Technical Service.

122

**LmiDispenseBiPhasic has taken longer than 18 seconds.**

A DRD/Dispense (Probe Wash) motion to a configured position has taken longer than 18 seconds.

§Call Technical Service.

124

**LmiMoveDilutorEnc cannot move than 65535 motor steps.**

The DRD MoveEncoder has calculated that it must take more than 65,535 steps to reach a configured encoder position.

§Call Technical Service.

125

**LmiMoveBiPhasic cannot move more than 65535 motor steps.**

A Timed Tube Spinner motion has taken longer than 18 seconds.

§Call Technical Service.

126

**Tube spinner exceeded the 18 seconds**

A Timed Tube Spinner motion has taken longer than 18 seconds.

§Call Technical Service.

127

**LmiTimedDilutionWell has taken longer than 18 seconds.**

A Timed Dilution Well motion has taken longer than 18 seconds.

§Call Technical Service.

128

**Sample Pipettor jammed in the X direction**

Sample Pipettor has jammed while moving in the horizontal direction.

§Check that the sample tube or diluent tube is seated correctly.
§Check the movement of Pipettor is not obstructed.
§Check for unauthorized tube tops (sample cups sitting on top of tubes).
§Check that the Sample Probe is not bent.
§If the message persists, call Technical Service.

129

**Sample Pipettor exceeded 18 seconds in the X direction**

Sample Pipettor horizontal movement to a configured position has taken longer than 18 seconds.

§Call Technical Service.

130

**Sample Pipettor movement exceeded 65535 steps in the X direction**

Sample Pipettor has calculated that it must take more than 65535 steps to reach a configured encoder position.

§Call Technical Service.

132

**Sample Pipettor jammed in the Z direction**

Sample Pipettor has jammed while moving in the vertical direction.

§Check that the sample tube or diluent tube is seated correctly.
§Check the movement of Pipettor is not obstructed.
§Check for caps on sample tubes.
§Check for unauthorized tube tops (sample cups sitting on top of tubes).
§Check that the Sample Probe is not bent.
§If the message persists, call Technical Service.

133

**Sample Pipettor exceeded 18 seconds in the Z direction**

Sample Pipettor vertical movement to a configured position has taken longer than 18 seconds.

§Call Technical Service.

134

**Sample Pipettor movement exceeded 65535 steps in the Z direction**

Sample Pipettor has calculated that it must take more than 65535 steps to reach a configured encoder position.

§Call Technical Service.

136

**Sample Pipettor jammed in the Z direction**

Sample Pipettor has jammed while moving in the vertical or Z out direction.

§Check that the sample tube or diluent tube is seated correctly.
§Check the movement of Pipettor is not obstructed.
§Check for caps on sample tubes.
§Check for unauthorized tube tops (sample cups sitting on top of tubes).
§Check that the Sample Probe is not bent.
§If the message persists, call Technical Service.

137

**Sample Pipettor exceeded 18 seconds in the Z direction**

A single Sample Pipettor's Z out movement to a configured position has taken longer than 18 seconds.

§Call Technical Service.

139

**Sample valve jammed**

The Sample Valve has jammed.

§Call Technical Service.

140

**Sample valve exceeded 18 seconds**

A single Sample Valve movement to a configured position has taken longer than 18 seconds.

§Call Technical Service.

141

**Sample valve movement exceeded 65535 steps**

Sample Valve has calculated that it must take more than 65535 steps to reach a configured encoder position.

§Call Technical Service.

143

**Reagent Pipettor jammed in the X direction**

The Reagent Pipettor has jammed while moving in the horizontal direction.

§Check that the Reagent Wedge is seated correctly.
§Movement of Pipettor is obstructed.
§If the message persists, call Technical Service.

144

**Reagent Pipettor exceeded 18 seconds in the X direction**

A single Reagent Pipettor movement to a configured position in the X (horizontal) direction has taken longer than 18 seconds.

§Call Technical Service.

145

**Reagent Pipettor movement exceeded 65535 steps in the X direction**

Reagent Pipettor has calculated that it must take more than 65535 steps to reach a configured encoder position in the X (horizontal) direction.

§Call Technical Service.

147

**Reagent Pipettor jammed in the Z direction**

Reagent Pipettor has jammed while moving in the vertical direction.

§Check that the Glide is on correctly.
§Check that the Wedge is seated correctly.
§If the message persists, call Technical Service.

148

**Reagent Pipettor exceeded 18 seconds in the Z direction**

A single Reagent Pipettor movement to a configured position in the Z (vertical) direction has taken longer than 18 seconds.

§Call Technical Service.

149

**Reagent Pipettor movement exceeded 65535 steps in the Z direction**

Reagent Pipettor has calculated that it must take more than 65535 steps to reach a configured encoder position in the Z (vertical) direction.

§Call Technical Service.

151

**Reagent Pipettor jammed in the Z direction**

The Reagent Pipettor has jammed while moving in the vertical or Z-out direction.

§Check that the Glide is on correctly.
§Wedge is not seated correctly.
§If the message persists, call Technical Service.

152

**Reagent Pipettor exceeded 18 second in the Z direction**

A single Reagent valve movement to a configured position has taken longer than 18 seconds.

§Call Technical Service.

154

**Reagent valve jammed**

Reagent Valve has jammed.

§Call Technical Service.

155

**Reagent valve exceeded 18 seconds**

A single Reagent valve movement to a configured position has taken longer than 18 seconds.

§Call Technical Service.

156

**Reagent valve movement exceeded 65535 steps**

Reagent Valve has calculated that it must take more than 65535 steps to reach a configured encoder position.

§Call Technical Service.

158

**Tube indexer jammed**

Tube Indexer has jammed.

§Verify correct Reaction Tube is used.
§Check for a malformed tube.
§Check for obstructions.
§If the message persists, call Technical Service.

159

**Tube indexer exceeded 18 seconds**

A single Tube Indexer movement to a configured position has taken longer than 18 seconds.

§Call Technical Service.

160

**Tube indexer movement exceeded 65535 steps**

Tube Indexer has calculated that it must take more than 65535 steps to reach a configured encoder position.

§Call Technical Service.

162

**Tube transport jammed**

Tube Transport Chain has jammed.

§Verify correct tubes are used.
§Check for malformed tube.
§Visually inspect chain for any kind of interference.
§If the message persists, call Technical Service.

163

**Tube transport exceeded 18 seconds timer**

A single Tube Transport chain movement to a configured position has taken longer than 18 seconds.

§Call Technical Service.

164

**Tube transport movement exceeded 65535 steps**

Tube Transport Chain has calculated that it must take more than 65535 steps to reach a configured encoder position.

§Call Technical Service.

166

**Tube Transport cannot find home flag**

Tube Transport chain cannot find home.

§Call Technical Service.

167

**Processor shuttle has jammed**

Processor Shuttle has jammed a second time while trying to move a fixed number of steps.

§Remove mispositioned Reaction Tube.
§If the message persists, call Technical Service.

168

**Processor shuttle movement has exceeded 18 second timer**

A single Processor shuttle movement to a configured position has taken longer than 18 seconds.

§Call Technical Service.

169

**Processor shuttle movement exceeded 65535 steps**

The Processor Shuttle has calculated that it must take more than 65535 steps to reach a configured encoder Position.

§Call Technical Service.

171

**Incubator chain jammed**

Incubator chain has jammed.

§Check for obstruction at the pipetting area. Remove tube.
§If the message persists, call Technical Service.

172

**Incubator chain exceeded 18 second timer**

A single Incubator Chain movement to a configured position has taken longer than 18 seconds.

§Call Technical Service.

173

**Home sensor missed Incubator chain flag**

Incubator chain cannot find home.

§Call Technical Service.

175

**Luminometer shuttle has jammed**

Luminometer shuttle has jammed.

§Check for overfilled or incorrectly seated solid waste container.
§Check for correct Biohazard Bags.
§Clear the Exit Chute using the Waste Chute Clean Out tool and check for Reaction Tubes obstructing the chute.
§Check Reaction Tubes in the Tube Hopper for any abnormalities.
§Check for clear plastic protruding from the upper trap opening and for plastic pieces in the Solid Waste Container.
§If the message persists, call Technical Service.

176

**Luminometer shuttle exceeded 18 second timer**

A single Luminometer Shuttle movement to a configured position has taken longer than 18 seconds.

§Call Technical Service.

178

**Tube lifter has jammed**

Tube Lifter has jammed.

§Call Technical Service.

179

**Tube lifter exceeded 18 second timer**

A single Tube Lifter movement to a configured position has taken longer than 18 seconds.

§Call Technical Service.

180

**Tube lifter movement exceeded 65535 steps**

A single Tube Lifter movement to a configured position has taken longer than 18 seconds.

§Call Technical Service.

182

**Luminometer chain has jammed**

Luminometer Chain has jammed.

§Check for overfilled or incorrectly seated Solid Waste container.
§Check for correct Biohazard Bags.
§Clear the Exit Chute and check for Reaction Tubes obstructing the chute.
§Check Reaction Tubes in the Tube Hopper for any abnormalities.
§Call Technical Service.

183

**Luminometer chain exceeded 18 second timer**

A single Luminometer Chain movement to a configured position has taken longer than 18 seconds.

§Call Technical Service.

185

**PMT shutter has jammed**

An error was detected in the vertical movement of the PMT shutter. The Instrument tries to correct itself and continue processing assays. If the error cannot be corrected, the Instrument stops processing tubes and another error message appears. The results for tubes following this second error message are lost.

§Call Technical Service.

186

**PMT shutter exceeded 18 second timer**

A single PMT Shutter movement to a configured position has taken longer than 18 seconds.

§Call Technical Service.

187

**PMT shutter movement exceeded 65535 steps**

The PMT shutter has calculated that it must take more than 65535 steps to reach a configured encoder Position.

§Call Technical Service.

189

**Attenuator disk has jammed**

Attenuator Disk has jammed.

§Call Technical Service.

190

**Attenuator disk exceeded 18 second timer**

A single Attenuator Disk movement to a configured position has taken longer than 18 seconds.

§Call Technical Service.

191

**Attenuator disk movement exceeded 65535 steps**

The Attenuator Disk has calculated that it must take more than 65535 steps to reach a configured encoder Position.

§Call Technical Service.

193

**Dilution well exceeded 18 second timer**

The dilution well has taken longer than 18 seconds to process a command.

§Call Technical Service.

194

**Sample dilutor has jammed aspirating sample**

Sample DRD has jammed while aspirating.

§Check for physical obstruction preventing the DRD from moving.
§Check for Sample Probe obstruction.
§If the message persists, call Technical Service.

195

**Sample dilutor exceeded 18 second timer**

A single one-speed Sample DRD draw motion, such as draw air slug, has taken longer than 18 seconds.

§Call Technical Service.

197

**Sample dilutor has jammed aspirating probe wash**

Sample DRD has jammed a second time while aspirating probe wash.

§Check for physical obstruction preventing the DRD from moving.
§Check for Sample Probe obstruction.
§If the message persists, call Technical Service

198

**Sample dilutor exceeded 18 second timer**

A single two-speed Sample DRD draw motion (e.g., draw probe wash) has taken longer than 18 seconds.

§Call Technical Service.

200

**Sample dilutor has jammed dispensing sample**

Sample DRD has jammed a second time while dispensing.

§Check for physical obstruction preventing the DRD from moving.
§Check for Sample Probe obstruction.
§If the message persists, call Technical Service

201

**Sample dilutor exceeded 18 second timer**

A single two-speed Sample DRD draw motion (e.g., draw probe wash) has taken longer than 18 seconds.

§Call Technical Service.

203

**Sample dilutor has jammed during biphasic dispense**

Sample DRD has jammed a second time while dispensing.

§Check for physical obstruction preventing the DRD from moving.
§Check for Sample Probe obstruction.
§If the message persists, call Technical Service.

204

**Sample dilutor exceeded 18 second timer**

A single two-speed Sample DRD dispense motion has taken longer than 18 seconds.

§Call Technical Service.

206

**Sample dilutor has jammed dispensing into blind hole**

Sample DRD has jammed.

§Check for physical obstruction preventing the DRD from moving
§Check for physical obstruction of pipettor movements.
§If the message persists, call Technical Service.

207

**Sample dilutor exceeded 18 second timer**

A Sample DRD motion to a configured position has taken longer than 18 seconds.

§Call Technical Service.

208

**Sample dilutor movement exceeded 65535 steps**

The Sample DRD has calculated that it must take more than 65,535 steps to reach a configured encoder position.

§Call Technical Service.

210

**Sample dilutor has jammed**

Sample DRD has jammed a second time while moving to a configured position and performing a two-speed move.

§Check for physical obstruction preventing the DRD from moving.
§Check for physical obstruction of pipettor movements.
§Call Technical Service.

211

**Sample dilutor exceeded 18 second timer**

A Sample DRD motion to a configured position using a two-speed move has taken longer than 18 seconds.

§Call Technical Service.

212

**Sample dilutor movement exceeded 65535 steps**

The Sample DRD has calculated that it must take more than 65,535 steps to reach a configured encoder position using a two-speed move.

§Call Technical Service.

214

**Reagent dilutor has jammed aspirating reagent**

Reagent DRD has jammed a second time while performing a one-speed draw motion (air slug, sample, etc).

§Check for physical obstruction preventing the DRD from moving.
§If the message persists, call Technical Service.

215

**Reagent dilutor exceeded 18 second timer**

A single one-speed Reagent DRD draw motion, such as draw air slug, has taken longer than 18 seconds.

§Call Technical Service.

217

**Reagent dilutor has jammed aspirating probe wash**

Reagent DRD has jammed a second time while performing a two-speed draw motion (probe wash aspiration).

§Check for physical obstruction preventing the DRD from moving.
§If the message persists, call Technical Service.

218

**Reagent dilutor exceeded 18 second timer**

A single two-speed Reagent DRD draw motion (e.g., draw probe wash) has taken longer than 18 seconds.

§Call Technical Service.

220

**Reagent dilutor has jammed dispensing reagent**

Reagent DRD has jammed.

§Check for physical obstruction preventing the DRD from moving.
§If the message persists, call Technical Service.

221

**Reagent dilutor exceeded 18 second timer**

A single one-speed Reagent DRD dispense motion has taken longer than 18 seconds.

§Call Technical Service.

223

**Reagent dilutor has jammed during biphasic dispense**

Reagent DRD has jammed.

§Check for physical obstruction preventing the DRD from moving.
§If the message persists, call Technical Service.

224

**Reagent dilutor exceeded 18 second timer**

A single two-speed Reagent DRD dispense motion has taken longer than 18 seconds.

§Call Technical Service.

226

**Reagent dilutor has jammed dispensing into blind hole**

Reagent DRD has jammed.

?Check for physical obstruction preventing the DRD from moving.
§If the message persists, call Technical Service.

227

**Reagent dilutor exceeded 18 second timer**

A Reagent DRD motion to a configured position has taken longer than 18 seconds.

§Call Technical Service.

228

**Reagent dilutor movement exceeded 65535 steps**

The Reagent DRD has calculated that it must take more than 65,535 steps to reach a configured encoder position.

§Call Technical Service.

230

**Reagent dilutor has jammed**

Reagent DRD has jammed a second time while moving to a configured position and performing a two-speed move.

§Call Technical Service.

231

**Reagent dilutor exceeded 18 second timer**

A Reagent DRD motion to a configured position using a two-speed move has taken longer than 18 seconds.

§Call Technical Service.

232

**Reagent dilutor movement exceeded 65535 steps**

The Reagent DRD has calculated that it must take more than 65,535 steps to reach a configured encoder position using a two-speed move.

§Call Technical Service.

234

**Sample pipettor Z direction has jammed during level sense**

Something interfered with the vertical movement of the pipettor arm. The Instrument tries to correct itself and continue processing assays. If the error

cannot be corrected, the pipetting stops. If the Sample Pipettor caused the error, the tests on-board continue to process.

§Check that the sample tube or diluent tube is seated correctly.
§Check the movement of Pipettor is not obstructed.
§Check for caps on sample tubes.
§Check for unauthorized tube tops (sample cups sitting on top of tubes).
§Check that the Sample Probe is not bent.
§If the message persists, call Technical Service.

---

236

**Sample pipettor Z direction exceeded 18 second timer**

A Sample Pipettor motion to a configured position using a two-speed move has taken longer than 18 seconds.

§Call Technical Service.

---

237

**Sample pipettor did not level sense**

Sample Pipettor has reached the tube bottom, diluent bottom or dilution well bottom position and has not level sensed.

§Check for insufficient sample.
§Check for bubble on sample.
§Check for unauthorized tube tops (sample cups sitting on top of tubes).
§Verify a tube is present in the position.
§If the message persists, call Technical Service.

---

238

**Reagent pipettor Z direction has jammed during level sense**

Something interfered with the vertical movement of the pipettor arm. The Instrument tries to correct itself and continue processing assays. If the error cannot be corrected, the pipetting stops. If the Reagent Pipettor caused the error, the tests on-board continue to process.

§Check that the sample tube or diluent tube is seated correctly.
§Check the movement of Pipettor is not obstructed.
§Check that the Reagent Probe is not bent.
§If the message persists, call Technical Service.

---

240

**Reagent pipettor Z direction exceeded 18 second timer**

A Reagent Pipettor motion to a configured position using a two-speed move has taken longer than 18 seconds.

§Call Technical Service.

241

**Reagent pipettor did not level sense**

Reagent Pipettor has reached the reagent bottom position and has not level sensed.

§Check to see if the Glide is on correctly.
§Check to see if the Wedge is seated correctly.
§If the message persists, call Technical Service.

258

**Rack transfer error during homing. Remove rack if present and retry**

Rack transfer error during homing.

§Remove rack if present and retry.

260

**Rack transfer jammed while moving to home position. Remove rack if present and retry**

§Rack transfer jammed while moving to home position.
§Remove rack if present and retry.

261

**Rack transfer timed out during homing. Contact Technical Service**

§Contact Technical Service.

262

**Rack transfer has not found home. Contact Technical Service.**

§Contact Technical Service.

263

**Rack transfer communication error during homing. Contact Technical Service.**

§Contact Technical Service.

265

**Rack transfer has jammed. Remove rack if present and retry.**

Rack transfer has jammed.

§Remove rack if present and retry.

| | |
|---|---|
| 266 | **Rack transfer timed out. Contact Technical Service.**<br>§Contact Technical Service. |
| 267 | **Rack transfer movement exceeded maximum steps. Contact Technical Service.**<br>§Contact Technical Service. |
| 268 | **Rack transfer communication error. Contact Technical Service.**<br>§Contact Technical Service. |
| 269 | **Rack gripper error during homing. Remove rack if present and retry.**<br>Rack gripper error during homing.<br>§Remove rack if present and retry. |
| 271 | **Rack gripper has jammed while moving to home position. Remove rack if present and press Run button to attempt recovery.**<br>Rack gripper has jammed while moving to home position.<br>§Remove rack if present and press Run button to attempt recovery. |
| 272 | **Rack gripper timed out during homing. Contact Technical Service.**<br>§Contact Technical Service. |
| 273 | **Rack gripper has not found home. Contact Technical Service.**<br>§Contact Technical Service. |
| 274 | **Rack gripper communication error during homing. Contact Technical Service.**<br>§Contact Technical Service |

275

**Sample pipettor X direction has jammed looking for home**

Something interfered with the horizontal movement of the pipettor arm.

The Instrument tries to correct itself and continue processing assays. If the Instrument cannot correct the error, the pipetting stops. If the Sample Pipettor caused the error, the tests on-board continue to process.

§Check that the sample tube or diluent tube is seated correctly.
§Check the movement of Pipettor is not obstructed.
§Check for caps on sample tubes.
§Check for unauthorized tube tops (sample cups sitting on top of tubes).
§Check that the Sample Probe is not bent.
§If the message persists, call Technical Service.

276

**Sample pipettor X direction exceeded 18 second timer**

A Sample Pipettor X-direction (horizontal) movement to Home has taken longer than 18 seconds.

§Call Technical Service.

277

**Sample pipettor did not find HOME in the X direction**

While attempting to return to the home position, the Sample Pipettor did not find the home sensor in the X direction (horizontal).

§Call Technical Service.

278

**Sample pipettor Z direction has jammed looking for home.**

The Sample Pipettor jammed a second time while attempting to do a homing routine in the Z direction (vertical). This may also occur if one of the sample devices has jammed and the Instrument is homing all the sample devices.

§Check that the sample tube or diluent tube is seated correctly.
§Check the movement of the pipettor is not obstructed.
§Check for caps on the sample tubes.
§Check that the Sample Probe is not bent.
§If the message persists, call Technical Service.

279

**Sample pipettor Z direction exceeded 18 second timer**

A Sample Pipettor Z-direction (vertical) motion to Home has taken longer than 18 seconds.

§Call Technical Service.

280

**Sample pipettor did not find HOME in the Z direction**

While attempting to return to the home position, the Sample Pipettor did not find the home sensor in the vertical direction.

§Check that the sample tube or diluent tube is seated correctly.
§Check the movement of Pipettor is not obstructed.
§Check for caps on sample tubes.
§Check for unauthorized tube tops (sample cups sitting on top of tubes).
§Check that the Sample Probe is not bent.
§If the message persists, call Technical Service.

281

**Sample valve has jammed while homing**

The Sample Valve jammed.

§Call Technical Service.

282

**Sample valve exceeded the 18 second timer**

A Sample Valve motion to Home has taken longer than 18 seconds. This error should never occur in normal operation.

§Call Technical Service.

283

**Sample valve did not find HOME**

While attempting to return to the home position, the Sample Valve did not find the home sensor.

§Call Technical Service.

284

**Sample dilutor has jammed while homing**

The Sample Diluter jammed.

§Check for physical obstruction preventing the DRD from moving.
§Check for clotted probe.
§If the message persists, call Technical Service.

285

**Sample dilutor exceeded the 18 second timer**

A Sample Dilutor motion to Home has taken longer than 18 seconds.

§Call Technical Service.

286

**Sample dilutor did not find HOME**

While attempting to return to the home position, the Sample Dilutor did not find the home sensor.

§Check for physical obstruction preventing the DRD from moving.
§If the message persists, call Technical Service.

287

**Sample carousel has jammed while homing**

The Sample Carousel jammed.

§Check the placement of the Sample Racks, ensuring the racks are properly attached to the Instrument.
§Ensure that the tubes are positioned correctly in the Sample Racks and that none of the tubes are too tall.
§If the message persists, call Technical Service.

288

**Sample carousel exceeded the 18 second timer**

A Sample Carousel motion to Home has taken longer than 18 seconds.

§Call Technical Service.

289

**Sample carousel did not find HOME**

While attempting to return to the home position, the Sample Carousel did not find the home sensor.

§Check the placement of the Sample Racks, ensuring the racks are properly attached to the Instrument.
§Ensure that the tubes are positioned correctly in the Sample Racks and that none of the tubes is too tall.
§If the message persists, call Technical Service.

290

**Reagent pipettor X direction has jammed**

Something interfered with the horizontal movement of the pipettor arm.

The Instrument tries to correct itself and continue processing assays. If the Instrument cannot correct the error, the pipetting stops.

§Reagent Wedge may not be seated correctly.
§Movement of Pipettor is obstructed.
§If the message persists, call Technical Service.

291

**Reagent pipettor exceeded the 18 second timer in the X direction**

A Reagent Pipettor X-direction motion to Home has taken longer than 18 seconds.

§Call Technical Service.

292

**Reagent pipettor did not find HOME in the X direction**

While attempting to return to the home position, the Reagent Pipettor did not find the home sensor.

§Reagent Wedge may not be seated correctly.
§Movement of Pipettor is obstructed.
§If the message persists, call Technical Service.

293

**Reagent pipettor Z direction has jammed**

Something interfered with the vertical movement of the pipettor arm. The Instrument tries to correct itself and continue processing assays. If the error cannot be corrected, the pipetting stops.

§Check to see if the Glide is on correctly.
§Check to see if the Wedge is seated correctly.
§If the message persists, call Technical Service.

294

**Reagent pipettor exceeded the 18 second timer in the Z direction**

A Reagent Pipettor motion to Home has taken longer than 18 seconds.

§Call Technical Service.

295

**Reagent pipettor did not find HOME in the Z direction**

While attempting to return to the home position, the Reagent Pipettor did not find the home sensor.

§Check to see if there are any obstructions around the reagent Pipettor.
§If the message persists, call Technical Service.

296

**Reagent valve has jammed**

The Reagent Valve jammed.

§Call Technical Service.

297

**Reagent valve exceeded the 18 second timer**

A Reagent Valve motion to Home has taken longer than 18 seconds.

§Call Technical Service.

298

**Reagent valve did not find HOME**

While attempting to return to the home position, the Reagent Valve did not find the home sensor.

§Call Technical Service.

299

**Reagent dilutor has jammed**

The Reagent Dilutor jammed.

§Check for physical obstruction preventing the DRD from moving.
§If the message persists, call Technical Service.

300

**Reagent dilutor exceeded the 18 second timer**

A Reagent Dilutor motion to Home has taken longer than 18 seconds.

§Call Technical Service.

301

**Reagent dilutor did not find HOME**

While attempting to return to the home position, the Reagent Dilutor did not find the home sensor.

§Check for physical obstruction preventing the DRD from moving.
§If the message persists, call Technical Service.

302

**Reagent carousel has jammed**

The Reagent Carousel jammed.

§Reseat Wedge or carousel tray.
§Check the Wedge Glide is properly installed.
§If message persists, call Technical Service.

303

**Reagent carousel exceeded the 18 second timer**

A Reagent Carousel motion to Home has taken longer than 18 seconds.

§Call Technical Service.

304

**Reagent carousel did not find HOME**

While attempting to return to the home position, the Reagent Carousel did not find the home sensor.

§Reseat Wedge or carousel tray.
§Check Wedge Glide for proper installation.
§If the message persists, call Technical Service.

305

**Tube Indexer has jammed**

At initialization and while returning to run from All Pause, Bead Pause, or Stop, the Tube Indexer jammed a second time while attempting to do a homing routine.

§Check for obstructions.
§Check that the proper Reaction Tube is used.
§Check for a malformed Reaction Tube.
§If the message persists, call Technical Service.

306

**Tube Indexer exceeded the 18 second timer**

A Tube Indexer motion to Home has taken longer than 18 seconds.

§Call Technical Service.

307

**Tube Indexer did not find HOME**

While attempting to return to the home position, the tube Indexer did not find the home sensor.

§Check for obstructions.
§If the message persists, call Technical Service.

308

**Tube Transport has jammed**

The Tube Transport Chain jammed.

§Verify correct Reaction Tube is used.
§Check for a malformed tube.
§Visually inspect chain for any kind of interference.
§If the message persists, call Technical Service.

309

**Tube Transport exceeded the 18 second timer**

A Tube Transport chain motion to Home has taken longer than 18 seconds.

§Call Technical Service.

310

**Tube Transport did not find HOME**

While attempting to return to the home position, the tube transport chain did not find the home sensor.

§Verify correct Reaction Tube is used.
§Check for a malformed tube.
§Visually inspect chain for any kind of interference.
§If the message persists, call Technical Service.

311

**Processor Shuttle has jammed**

The Processor Shuttle jammed.

§Check for mispositioned Reaction Tube.
§If the message persists, call Technical Service.

312

**Processor Shuttle exceeded the 18 second timer**

A Processor shuttle motion to Home has taken longer than 18 seconds.

§Call Technical Service.

313

**Processor Shuttle did not find HOME**

While attempting to return to the home position, the processor shuttle did not find the home sensor.

§Check for mispositioned Reaction Tube.
§If the message persists, call Technical Service.

314

**PMT Shutter has jammed looking for home.**

An error was detected in the vertical movement of the PMT shutter.

The Instrument tries to correct itself and continue processing assays. If the error can not be corrected, the Instrument stops processing tubes, and another error message appears. The results for tubes following this second error message are lost.

§Call Technical Service.

315

**PMT Shutter exceeded the 18 second timer.**

A PMT Shutter motion to Home has taken longer than 18 seconds.

§Call Technical Service.

316

**PMT Shutter did not find HOME.**

While attempting to return to the home position, the PMT shutter did not find the home sensor.

§Call Technical Service.

317

**Luminometer Chain has jammed**

The Luminometer chain jammed.

§Check for overfilled or incorrectly seated solid waste container.
§Check for correct Biohazard Bags.
§Check the Exit Chute for Reaction Tubes and clear it.
§Check Reaction Tubes in the Tube Hopper for any abnormalities.
§Call Technical Service.

318

**Luminometer Chain exceeded the 18 second timer**

A Luminometer Chain motion to Home has taken longer than 18 seconds.

§Call Technical Service.

319

**Luminometer Chain did not find HOME**

While attempting to return to the home position, the Luminometer Chain did not find the home sensor.

§Check for overfilled or incorrectly seated solid waste container.
§Check for correct Biohazard Bags.
§Check the Exit Chute for Reaction Tubes and clear it.
§Check Reaction Tubes in the Tube Hopper for any abnormalities.
§If the message persists, call Technical Service.

320

**Luminometer Shuttle has jammed**

The Luminometer Shuttle jammed.

§Check for overfilled or incorrectly seated solid waste container.
§Check for correct Biohazard Bags.
§Correct and clear the Exit Chute.
§Check Reaction Tubes in the Tube Hopper for any abnormalities.
§Call Technical Service.

321

**Luminometer Shuttle exceeded the 18 second timer**

A Luminometer Shuttle motion to Home has taken longer than 18 seconds.

§Call Technical Service.

322

**Luminometer Shuttle did not find HOME**

While attempting to return to the home position, the Luminometer Shuttle did not find the home sensor.

§Check for overfilled or incorrectly seated solid waste container.
§Check for correct Biohazard Bags.
§Correct and clear the Exit Chute.
§Check Reaction Tubes in the Tube Hopper for any abnormalities.
§If the message persists, call Technical Service.

323

**Tube Lifter has jammed**

At initialization and while returning to run from Stop, the Tube Lifter jammed a second time while attempting to do a homing routine.

§Call Technical Service.

| | |
|---|---|
| 324 | **Tube Lifter exceeded the 18 second timer**<br>A Tube Lifter motion to Home has taken longer than 18 seconds.<br>§Call Technical Service. |
| 325 | **Tube Lifter did not find HOME**<br>While attempting to return to the home position, the Tube Lifter did not find the home sensor.<br>§Call Technical Service. |
| 326 | **Incubator Chain has jammed**<br>Incubator Chain has jammed.<br>§Call Technical Service. |
| 327 | **Incubator Chain exceeded the 18 second timer**<br>An Incubator Chain motion to Home has taken longer than 18 seconds.<br>§Call Technical Service |
| 328 | **Incubator Chain did not find HOME**<br>While attempting to return to the home position, the Incubator Chain did not find the home sensor.<br>§Call Technical Service. |
| 329 | **Attenuator Disk has jammed**<br>The PMT Attenuator was unable to reach the correct position.<br>§Call Technical Service. |
| 330 | **Attenuator Disk exceeded the 18 second timer**<br>An Attenuator Disk motion to Home has taken longer than 18 seconds.<br>§Call Technical Service. |

331

**Attenuator Disk did not find HOME**

While attempting to return to the home position, the Attenuator Disk did not find the home sensor.

§Call Technical Service.

332

**Rack Loader sensor did not detect ejected rack. Remove rack if present and retry.**

§Remove rack if present and retry.

333

**Unexpected error. Contact Technical Service.**

§Contact Technical Service.

334

**Unexpected error. Contact Technical Service.**

§Contact Technical Service.

338

**Error opening configuration file RLCfg.IMR. Contact Technical Service.**

§Contact Technical Service.

339

**Error reading configuration file RLCfg.IMR. Contact Technical Service.**

§Contact Technical Service.

340

**Unexpected error. Contact Technical Service.**

§Contact Technical Service.

363

**Rack gripper has jammed. Press Run button to attempt recovery.**

Rack gripper has jammed.

§Press Run button to attempt recovery.

364

**Rack gripper timed out. Contact Technical Service.**

Rack gripper timed out.

§Contact Technical Service.

| | |
|---|---|
| 365 | **Rack gripper movement exceeded maximum steps. Contact Technical Service.**<br>§Contact Technical Service. |
| 366 | **Rack gripper communication error. Contact Technical Service.**<br>§Contact Technical Service. |
| 367 | **Inner rack door error during homing. Remove rack if present and retry.**<br>Inner rack door error during homing.<br>§Remove rack if present and retry. |
| 369 | **Inner rack door has jammed while moving to home position. Remove rack if present and retry.**<br>Inner rack door has jammed while moving to home position.<br>§Remove rack if present and retry. |
| 370 | **Inner rack door timed out during homing. Contact Technical Service.**<br>§Contact Technical Service. |
| 371 | **Inner rack door has not found home. Contact Technical Service.**<br>§Contact Technical Service. |
| 372 | **Inner rack door communication error during homing. Contact Technical Service.**<br>§Contact Technical Service. |
| 374 | **Inner rack door has jammed. Remove rack if present and retry.**<br>Inner rack door has jammed.<br>§Remove rack if present and retry. |

375

**Bar Code and Encoder position do not match**

Instrument has failed to read a reagent barcode.

§Call Technical Service.

376

**Partial reagent bar code read**

Instrument has failed to read a reagent barcode.

§Check the integrity of the Wedge label.
§Clean label and re-interrogate.
§If the message persists, call Technical Service.

377-379

**Programming Errors**

Occurs when underlying hardware errors cause software communication issues.

§Check error log for hardware errors and resolve them.
§If the message persists, call Technical Service.

380

**Errors have shut down the MCP routine**

Errors at start-up have shut down the MCP routine. More specific error messages will be generated.

§Check Event Log for associated mechanical jams. Correct and reinitialize.
§If unsuccessful, call Technical Service.

381

**Large Reagent Door is open during start-up. Close door to continue.**

The Large Reagent Door is open.

§Ensure that the Reagent door is fully closed before start up.
§If error persists, call Technical Service.

392

**Bead Carousel has jammed.**

Bead Carousel has jammed a second time while trying to move to a configured position.

§Ensure that the Bead Packs are positioned correctly in the Bead Carousel.
§If the message persists, call Technical Service.

393

**Bead Carousel has exceeded 18 second cycle shutting down instrument.**

A Bead Carousel movement to home has taken longer than 18 seconds.

§Call Technical Service.

394

**Bead Carousel has not detected home sensor**

While attempting to return to the home position, the Bead Carousel did not find the home sensor.

§Call Technical Service.

401

**Allergen not found/rerun test**

The required Allergen was not found on the Reagent Carousel, assay(s) cannot be processed.

§Check inventory and verify that the allergen is in the allergen wedge.
§If the problem persists, call Technical Service.

402

**No reaction tube detected at the tube indexer.**

Sensor does not see a tube at the indexer.

§Check for Reaction Tubes in the Tube Hopper.
§Fill Hopper.
§Verify correct Reaction Tube is used.
§Check for a malformed tube.
§Check for jam in the Orientation Chute.
§If the message persists, call Technical Service.

403

**No bead dispensed rerunning test**

No bead detected in tube after dispense.

§Check if the bead pack is seated properly, and ensure beads are moving freely.
§If error persists, call Technical Service.

405

**Luminometer Shuttle pushed again**

Luminometer Shuttle attempted to push tube from the Wash Station into the luminometer a second time and failed. The sensor detected that the tube was still at the Wash Station after the push.

§Call Technical Service.

406

**Tube Lifter not in the up position rerunning test**

At the beginning of the wash cycle, the tube lifter detected that the tube was not in the Up position.

§If the message persists, call Technical Service.

407

**Extra bead detected rerunning test**

Instrument detects a bead prior to the bead dispense.

§If the message persists, call Technical Service.

408

**Two beads detected rerunning test**

Instrument detects two beads in the tube after the bead dispense.

§If the message persists, call Technical Service.

409

**Clot detection has timed out. Call Technical Service.**

Clot detection board did not respond in the allowable time. Control Software is locked, and all tests on board will be lost.

§Call Technical Service.

410

**Sample Pipettor has jammed in the X direction**

Sample Pipettor has jammed a second time while trying to move a fixed number of steps in the X direction (horizontal).

§Check that the sample tube or diluent tube is seated correctly.
§Check that the movement of the Pipettor is not obstructed.
§Check for caps on sample tubes.
§Check for unauthorized tube tops (i.e., sample cups sitting on top of tubes).
§Check that the Sample Probe is not bent.
§If the message persists, call Technical Service.

412

**Sample Pipettor exceeded the 18 second timer in the X direction**

Sample Pipettor has taken longer than 18 seconds moving to a configured position in the X direction (horizontal).

§Call Technical Service.

413

**Sample Pipettor has jammed in the Z direction**

Sample Pipettor has jammed a second time while trying to move a fixed number of steps in the Z direction (vertical).

§Check that the sample tube or diluent tube is seated correctly.
§Check that the movement of the Pipettor is not obstructed.
§Check for caps on sample tubes.
§Check for unauthorized tube tops (i.e., sample cups sitting on top of tubes).
§Check that the Sample Probe is not bent.
§If the message persists, call Technical Service.

415

**Sample Pipettor exceeded the 18 second timer in the Z direction**

Sample Pipettor has taken longer than 18 seconds moving to a configured position in the Z direction (vertical).

§Call Technical Service.

416

**Sample Valve has jammed**

Sample Valve has jammed a second time while trying to move a fixed number of steps.

§Call Technical Service.

418

**Sample Valve exceeded the 18 second timer**

Sample Valve has taken longer than 18 seconds to move a fixed number of steps.

§Call Technical Service.

419

**Sample Carousel has jammed**

Sample Carousel has jammed a second time while trying to move a fixed number of steps.

§Check the placement of the Sample Racks, ensuring the racks are properly attached to the Instrument.
§Ensure that the tubes are positioned correctly in the Sample Racks and that none of the tubes are too tall.
§If the message persists, call Technical Service.

421

**Sample Carousel exceeded the 18 second timer**

Sample Carousel movement to a configured position has taken longer than 18 seconds.

§Call Technical Service.

422

**Reagent Pipettor has jammed in the X direction**

Reagent Pipettor has jammed a second time in the X direction (horizontal) while trying to move a fixed number of steps.

§Check to see if the Reagent Wedge is seated correctly.
§Check to see if the Movement of the Pipettor is obstructed.

424

**Reagent Pipettor exceeded the 18 second timer in the X direction**

Reagent Pipettor has taken longer than 18 seconds moving to a configured position in the X direction (horizontal).

§Call Technical Service.

425

**Reagent Pipettor had jammed in the Z direction**

Reagent Pipettor has jammed a second time while trying to move a fixed number of steps in the Z direction (vertical).

§Check to see if the Glide is on correctly.
§Check to see if the Wedge is positioned properly.

427

**Reagent Pipettor exceeded the 18 second timer in the Z direction**

Reagent Pipettor movement to a configured position has taken longer than 18 seconds.

§Call Technical Service.

428

**Reagent Valve has jammed**

Reagent Valve has jammed a second time while trying to move a fixed number of steps.

§Call Technical Service.

430

**Reagent Valve exceeded the 18 second timer**

Reagent Valve movement to a configured position has taken longer than 18 seconds.

§Call Technical Service.

431

**Reagent Carousel has jammed**

Reagent Carousel has jammed a second time while trying to move a fixed number of steps.

§Check for mispositioned Wedge or carousel tray.
§Check Wedge glide for proper installation

433

**Reagent Carousel exceeded the 18 second timer**

Reagent Carousel motion to a configured position has taken longer than 18 seconds.

§Call Technical Service.

434

**Bead Carousel has jammed**

Bead Carousel has jammed a second time while trying to move to a configured position.

§Ensure that the Bead Packs are positioned correctly in the Bead Carousel.
§If the message persists, call Technical Service.

436

**Bead carousel exceeded the 18 second timer**

Bead Carousel movement to a configured position has taken longer than 18 seconds.

§Call Technical Service.

437

**Tube Transport has jammed**

Tube Transport Chain has jammed a second time while trying to move a fixed number of steps.

§Verify correct Reaction Tube is used.
§Check for a malformed tube.
§Visually inspect chain for any kind of interference.

439

**Tube Transport exceeded the 18 second timer**

Tube Transport Chain movement to a configured position has taken longer than 18 seconds.

§Call Technical Service

440

**Incubator Chain has jammed**

Incubator Chain has jammed a second time while trying to move a fixed number of steps.

§Check for obstruction at the Reagent Pipetting area. Remove tube.
§Call Technical Service.

442

**Incubator Chain exceeded the 18 second timer**

Incubator Chain movement to a configured position has taken longer than 18 seconds.

§Call Technical Service.

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**443**

**Luminometer Shuttle has jammed**

Luminometer Shuttle has jammed a second time while trying to move a fixed number of steps.

§Check for overfilled or incorrectly seated solid waste container.
§Check for correct biohazard bags.
§Correct and clear the Exit Chute.
§Check the Reaction Tubes in the Tube Hopper for abnormalities, extra flashing, etc.
§Call Technical Service.

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**445**

**Luminometer Shuttle exceeded the 18 second timer**

Luminometer Shuttle movement to a configured position has taken longer than 18 seconds.

§Call Technical Service.

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**446**

**Tube Lifter has jammed**

Tube Lifter has jammed a second time while trying to move a fixed number of steps.

§Call Technical Service.

---

**448**

**Tube Lifter exceeded the 18 second timer**

Tube Lifter movement to a configured position has taken longer than 18 seconds.

§Call Technical Service.

---

**449**

**Luminometer Chain has jammed**

Luminometer Chain has jammed.

§Check for overfilled or incorrectly seated solid waste container.
§Check for correct biohazard bags.
§Correct and clear the Exit Chute.
§Check the Reaction Tubes in the Tube Hopper for abnormalities, extra flashing, etc.
§Call Technical Service.

451

**Luminometer Chain exceeded the 18 second timer**

Luminometer Chain movement to a configured position has taken longer than 18 seconds.

§Call Technical Service.

452

**Luminometer Shutter has jammed**

An error was detected in the vertical movement of the PMT shutter.

The Instrument tries to correct itself and continue processing assays. If the error can not be corrected, the Instrument stops processing tubes, and another error message appears. The results for tubes following this second error message are lost.

§Call Technical Service.

454

**Luminometer Shutter exceeded the 18 second timer**

Luminometer Shutter movement to a configured position has taken longer than 18 seconds.

§Call Technical Service.

455

**Attenuator Disk has jammed**

Attenuator Disk has jammed a second time while trying to move a fixed number of steps.

§Call Technical Service.

457

**Attenuator Disk exceeded the 18 second timer**

Attenuator Disk movement to a configured position has taken longer than 18 seconds.

§Call Technical Service.

458

**Processor Shuttle has jammed**

Processor Shuttle has jammed a second time while trying to move a fixed number of steps.

§Remove mispositioned Reaction Tube.
§If the message persists, call Technical Service.

460

**Processor Shuttle exceeded the 18 second timer**

Processor Shuttle movement to a configured position has taken longer than 18 seconds.

§Call Technical Service.

461

**Sample Carousel has jammed**

The Sample Carousel jammed.

§Check the placement of the Sample Racks, ensuring the racks are properly attached to the Instrument.
§Ensure that the tubes are positioned correctly in the Sample Racks and that none of the tubes is too tall.
§If the message persists, call Technical Service.

462

**Sample Carousel exceeded the 18 second timer**

A single Sample Carousel movement to a configured position has taken longer than 18 seconds.

§Call Technical Service.

463

**Sample Carousel has exceeded the 65535 steps**

The Sample Carousel has calculated that it must take more than 65535 steps to reach a configured encoder position.

§Call Technical Service.

465

**Reagent Carousel has jammed**

Reagent Carousel has jammed a second time while trying to move to a configured position.

§Reseat Wedge or carousel.
§Check Wedge Glide for proper installation.
§If the message persists, call Technical Service.

466

**Reagent Carousel exceeded the 18 second timer**

A single Reagent Carousel movement to a configured position has taken longer than 18 seconds. This error should never occur in normal operation.

§Call Technical Service.

467

**Reagent Carousel has exceeded the 65535 steps**

The Reagent Carousel has calculated that it must take more than 65535 steps to reach a configured encoder position.

§Call Technical Service.

469

**Bead Carousel has jammed**

Bead Carousel has jammed.

§Ensure that the Bead Packs are positioned correctly in the Bead Carousel.
§If the message persists, call Technical Service.

470

**Bead Carousel exceeded the 18 second timer**

A single Bead Carousel movement to a configured position has taken longer than 18 seconds.

§Call Technical Service.

471

**Bead Carousel has exceeded the 65535 steps**

The Bead Carousel has calculated that it must take more than 65535 steps to reach a configured encoder position.

§Call Technical Service.

473

**Reaction Tube is not in the pipetting position**

Instrument does not detect a tube at the pipetting position.

§Check for mispositioned Reaction Tube.
§If the message persists, call Technical Service.

494

**Luminometer Chain has exceeded 65535 steps.**

The Luminometer Chain has calculated that it must take more than 65,535 steps to reach Home.

§Call Technical Service.

495

**Luminometer Shuttle has exceeded 65535 steps**

The Luminometer Shuttle has calculated that it must take more than 65,535 steps to reach Home.

§Call Technical Service.

496

**Sample Pipettor has jammed in the Z direction**

Sample Pipettor Z Motor has jammed.

§Check that the sample tube or diluent tube is seated correctly.
§Check the movement of Pipettor is not obstructed.
§Check for caps on sample tubes.
§Check for unauthorized tube tops (sample cups sitting on top of tubes).
§Check that the Sample Probe is not bent.
§If the message persists, call Technical Service.

498

**Sample Pipettor exceeded the 18 second timer in the Z direction**

Sample Pipettor Z Motor motion to a configured position has taken longer than 18 seconds.

§Call Technical Service.

499

**Sample Pipettor has exceeded 65535 steps**

Sample Pipettor Z Motor has calculated that it must take more than 65535 steps to reach a configured encoder position.

§Call Technical Service

500

**Reagent Pipettor has jammed in the Z direction**

Reagent Pipettor Z Motor has jammed a second time while trying to move to a configured position.

§Check to see if the Glide is on correctly.
§Check to see if the Wedge is seated correctly.

502

**Reagent Pipettor exceeded the 18 second timer**

Reagent Pipettor Z Motor motion to a configured position has taken longer than 18 seconds.

§Call Technical Service.

503

**Reagent Pipettor has exceeded 65535 steps**

Reagent Pipettor Z Motor has calculated that it must take more than 65535 steps to reach a configured encoder position.

§Call Technical Service.

504

**Rerun test designated bad by Initializing Run Mode**

A sequential assay was unable to receive second reagent because the Instrument was initializing the Run Mode from the Pause Mode.

§If the message persists, call Technical Service.

505

**Rerun test designated bad by Pause Mode**

A sequential assay was unable to receive second reagent because the Instrument was in Pause Mode.

§If the message persists, call Technical Service.

506

**Rerun test designated bad by In-Cycle Prime Mode**

A sequential assay was unable to receive second reagent because the Instrument was performing an In-cycle prime.

§Call Technical Service.

507

**Rerun test designated bad by Sample Tube**

A problem was detected with a sample tube during sample pipetting.

§Check sample.

508

**Rerun test designated bad by Reagent Pack**

A problem was detected with a reagent pack during reagent pipetting.

§Check reagent pack.
§If the message persists, call Technical Service.

509

**Rerun test designated bad by Bead Pack**

A problem was detected with a Bead Pack while attempting to dispense a bead.

§Check Bead Pack for static. Tap gently and return it to the Bead Carousel.
§Check for empty pack.
§Manually dispense bead.
§Rerun.

510

**Rerun test designated bad by Running Error**

Jam in a reagent or sampling device preventing the pipetting of reagent for a sequential assay or further processing of B12 and Folate.

§Check Error Log for associated errors.
§Correct the errors if possible.
§If the message persists, call Technical Service.

511

**Rerun test designated bad by Sample 1 Not Found**

The required Sample1 was not found on the Sample Carousel. Assay(s) can not be processed.

§Call Technical Service.

512

**Rerun test designated bad by Sample 2 Not Found**

The required Sample2 was not found on the Sample Carousel. Assay(s) can not be processed.

§Call Technical Service.

513

**Rerun test designated bad by No Diluent**

The appropriate, required onboard diluent was not found when an onboard dilution had been requested.

§Put diluent on board.
§If the message persists, call Technical Service.

514

**Rerun test designated bad by Reagent 1 Not Found**

The required Reagent 1 was not found on the Reagent Carousel. Assay(s) can not be processed.

§Call Technical Service.

515

**Rerun test designated bad by Reagent 2 Not Found**

The required Reagent 2 was not found on the Reagent Carousel. Assay(s) can not be processed.

§Call Technical Service.

516

**Rerun test designated bad by No Bead**

The required Bead Pack was not found on the Bead Carousel. Assay(s) can not be processed.

§Check Bead Pack for obstructions to dispense.
§Manually dispense bead.
§Reseat Bead Pack and try again.
§Rerun.

517

**Rerun test designated bad by Motor Jam**

A Motor Jam error has occurred preventing the sampling and/or continued processing of an assay(s).

§Call Technical Service.

518

**Rerun test designated bad**

An unknown error has prevented a sample or reagent from being pipetted. This should not occur in normal operation.

§Call Technical Service.

519

**IMMULITE 2000 doors must be closed for operation**

A door, or doors, are not properly closed, or there is a failure of door sensor(s).

§Close the door.

520

**Processor Shuttle has jammed**

The Processor Shuttle has jammed a second time while moving to the BACK position.

§Remove mispositioned Reaction Tube.
§If the message persists, call Technical Service.

521

**Processor Shuttle exceeded the 18 second timer**

Processor shuttle motion has taken longer than 18 seconds.

§Call Technical Service.

522

**Processor Shuttle has exceeded 65535 steps**

The Processor Shuttle has calculated that it must take more than 65,535 steps to reach a configured encoder position.

§Call Technical Service.

524

**Sample Door or Main Cover is open**

The Sample Door or the Instrument cover was not closed before RUN was selected.

§Close the door or cover.

525

**Reagent Door is open**

Reagent Access Door or Reagent Cover is open.

§Close the door.

526

**Bead Door is open**

Bead Chamber Door is open.

§Close the door.

530

**Tip Jam**

The probe has not found liquid.

§Check that the sample tube or diluent tube is seated correctly.
§Check the movement of Pipettor is not obstructed.
§Check for caps on sample tubes.
§Check for unauthorized tube tops (sample cups sitting on top of tubes).
§Check that the Sample Probe is not bent.
§If the message persists, call Technical Service.

531

**Tip Jam Sample Pipettor**

Sample Pipettor has not found liquid.

§Check that the sample tube or diluent tube is seated correctly.
§Check the movement of Pipettor is not obstructed.
§Check for caps on sample tubes.
§Check for unauthorized tube tops (sample cups sitting on top of tubes).
§Check that the Sample Probe is not bent.
§If the message persists, call Technical Service.

532

**Tip Jam Sample Pipettor**

Sample Pipettor has not found liquid.

§Check that the sample tube or diluent tube is seated correctly.
§Check the movement of Pipettor is not obstructed.
§Check for caps on sample tubes.
§Check for unauthorized tube tops (sample cups sitting on top of tubes).
§Check that the Sample Probe is not bent.
§If the message persists, call Technical Service.

533

**Tip Jam Sample Pipettor**

Sample Pipettor has not found liquid.

§Check that the sample tube or diluent tube is seated correctly.
§Check the movement of Pipettor is not obstructed.
§Check for caps on sample tubes.
§Check for unauthorized tube tops (sample cups sitting on top of tubes).
§Check that the Sample Probe is not bent.
§If the message persists, call Technical Service.

534

**Tip Jam Reagent Pipettor**

Reagent Pipettor has not found liquid.

§Ensure that the Glide is seated correctly on the Reagent Wedge.
§Ensure that Reagent Wedge is seated correctly.
§Ensure the pack lid opener is retracted.
§If the message persists, call Technical Service.

535

**Tip Jam Reagent Pipettor**

A Reagent Z pipettor motion for a fixed number of steps has encountered a Tip Jam.

§Ensure that the Glide is seated correctly on the Reagent Wedge.
§Ensure that Reagent Wedge is seated correctly.
§Ensure the pack lid opener is retracted.
§If the message persists, call Technical Service.

536

**Tip Jam Reagent Pipettor**

A Reagent Z pipettor motion to a configured position has encountered a Tip Jam.

§Ensure that the Glide is seated correctly on the Reagent Wedge.
§Ensure that Reagent Wedge is seated correctly.
§Ensure the pack lid opener is retracted.
§If the message persists, call Technical Service.

537

**Tip Jam Reagent Pipettor**

A Reagent Z level sense motion has encountered a tip jam. This can only occur when going into the Reagent Wedge.

§Ensure that the Glide is seated correctly on the Reagent Wedge.
§Ensure that Reagent Wedge is seated correctly.
§Ensure the pack lid opener is retracted.
§If the message persists, call Technical Service.

538

**Bead Dispenser jammed - motor does not move**

The Bead Dispenser has been unsuccessful in dispensing a bead.

§Be sure Bead Pack is seated correctly.
§Remove the Bead Pack, invert it, and then re-install it.
§Manually dispense a bead.
§If the message persists, call Technical Service.

539

**Bead Dispenser jammed - cannot find bead dispense sensor**

The Bead Dispenser has been unsuccessful in dispensing a bead.

§Be sure Bead Pack is seated correctly.
§Remove the Bead Pack, invert it, and then re-install it.
§Manually dispense a bead.
§If the message persists, call Technical Service.

540

**Bead Dispenser jammed - in dispense position**

The Bead Dispenser has been unsuccessful in dispensing a bead.

§Be sure Bead Pack is seated correctly.
§Remove the Bead Pack, invert it, and then re-install it.
§Manually dispense a bead.
§If the message persists, call Technical Service.

541

**Bead Dispenser jammed - cannot find home**

The Bead Dispenser has been unsuccessful in dispensing a bead.

§Be sure Bead Pack is seated correctly.
§Remove the Bead Pack, invert it, and then re-install it.
§Manually dispense a bead.
§If the message persists, call Technical Service.

542

**Reagent Lid Opener jammed - pack lid opener not extending**

The Reagent Lid Opener has tried to open a Wedge unsuccessfully.

§Call Technical Service.

543

**Reagent Lid Opener jammed - cannot find reagent open**

The Reagent Lid Opener has tried to open a Wedge unsuccessfully.

§Call Technical Service.

544

**Reagent Lid Opener jammed - cannot find home**

The Reagent Lid Opener has tried to retract unsuccessfully.

§Call Technical Service.

546

**Sample False Level Sensed**

A sample z-pipettor level sense motion has level sensed higher than expected.

§Check the position of the tube in the Sample Rack
§Ensure there is sufficient sample in the tube.
§Check for and eliminate any bubbles in the tube.
§Check for splashing near the pipettor.
§Check that approved tube size was used.
§Confirm that an unapproved tube insert was not used.
§If the message persists, call Technical Service.

547

**Reagent Probe False Level Sensed at top or above wedge**

A Reagent z-Pipettor level sense motion has level sensed higher than expected

§Check the position of the Reagent Wedge in the Reagent Carousel.
§Make sure the Reagent Wedge lid is positioned correctly and that it moves freely.
§Ensure there are not bubbles in the reagent.
§Check for a reagent fluid film under the Wedge Glide.
§Check for splashing on or near the probe.
§If the message persists, call Technical Service.

548

**Bad Bead Pack**

A Bead Pack has failed to dispense three beads in a row.

§Remove Bead Pack from carousel and invert.
§Reseat the Bead Pack.

549

**Wash Station spinner exceeded the 18 second timer**

The Wash Station motor has taken longer than 18 seconds to complete a spin.

§Call Technical Service.

550

**Bad spin at Wash Station**

The Wash Station motor has spun at an incorrect speed.

§Call Technical Service

551

**Dilution Well exceeded the 18 second timer**

The Dilution Well motor has taken longer than 18 seconds to complete a spin.

§Call Technical Service.

552

**Bad spin at Dilution Well**

The Dilution Well motor has spun at an incorrect speed.

§Call Technical Service

553

**Incubator Shaker has stopped**

The Incubator Shaker motor is not moving.

§Call Technical Service

554

**Tube Escalator has jammed or Hopper left open**

The sensor indicates that the Tube Escalator belt is not moving. This may be caused by a jam, or by the Hopper being left open.

§Close the Hopper.
§Clear out Orientation chute.
§Check for obstruction in the Hopper or Escalator.
§Check for obstruction preventing closure of Hopper.
§If the message persists, call Technical Service.

555

**No reaction tube detected going into bead pause**

No Reaction tube detected in at the Tube Indexer.

§Check for Reaction Tubes in the Tube Hopper.
§Fill Hopper.
§Check for jam in the Orientation Chute.
§Verify correct Reaction Tube is used.
§Check for a malformed tube.
§If the message persists, call Technical Service.

556

**Substrate Probe missing - Is probe fully seated?**

Error is generated during Start-Up or Initialization if the Substrate Probe is not detected.

§Ensure the Substrate probe is seated correctly.
§If the message persists, call Technical Service.

557

**Water Probe missing - Is probe fully seated?**

Error is generated during Start-Up or Initialization if the Water Probe is not detected.

§Ensure the Water Probe is seated correctly.
§If the message persists, call Technical Service.

558

**Trigger Probe missing - Is probe fully seated?**

Error is generated during Start-Up or Initialization if the Trigger Flag is not detected.

§Call Technical Service.

559

**Marked bad and rerunning test - water dispense error**

A tube needs to be spun during the current cycle and the water probe was not detected.

§If the message persists, call Technical Service.

560

**Marked bad and rerunning test - substrate dispense error**

A tube needs to receive substrate during the current cycle and the substrate probe was not detected.

§If the message persists, call Technical Service.

561

**Marked bad and rerunning test - trigger reagent dispense error**

A tube needs to receive the trigger reagents during the current cycle and the trigger flag was not detected.

§Call Technical Service.

562

**Clot detected in sample tube - sample will not be run**

The Instrument has determined that a clot has been detected in the sample tube, but is not clinging to the outside of the probe.

§Check sample. Spin down tube to remove clot.
§Rerun sample.

563

**Clot detected in sample tube. Clean exterior of sample probe before resuming operation.**

The Instrument has determined that a clot has been detected in the sample tube and is clinging to the outside of the probe.

§Remove Clinging clot.
§Look in the mirror by the Sample Probe for air bubbles; if air is detected run Clot Prime diagnostics.
§If Sample Probe has entered gel barrier, change the probe.
§If the message persists, call Technical Service.

564-568

**Programmer Error**

§Call Technical Service.

569

**Bar Code was read but tube in place sensor did not see tube**

Bar Code was read but tube in place sensor did not see tube

§Call Technical Service.

570

**Programmer Error**

Position from reading the bead carousel is outside the valid range.

§Call Technical Service.

571

**Unrecognized port**

Instrument does not recognize port for sample/reagent barcode reader

§Call Technical Service.

572

**Unrecognized port**

Instrument does not recognize port for Bead Pack barcode reader

§Call Technical Service.

573

**Instrument jammed**
**Please Reboot System**

Instrument has recognized an error in the system but cannot identify error. This error should not occur in normal operation.

§Call Technical Service.

575

**Sample Pipettor jammed inside incubator only luminometer working**

Sample Pipettor is jammed inside the incubator. All attempts to clear jam errors have failed. Only the Luminometer is active.

§Ensure nothing is blocking the sample pipettor at the reagent/sample pipetting area.
§Check for misalignment of the Sample Probe at the pipetting area.
§Check the Sample Probe is not bent.
§If the message persists, call Technical Service.

576

**Sample Pipettor jammed above Pipettor position - front end shut down**

Sample Pipettor jammed above Reaction Tube. All attempts to clear jam errors have failed.

§Check the movement of Pipettor is not obstructed.

578

**Sample Pipettor is clogged due to clot**

The sample pipettor or sample DRD jammed during the clinging clot test.

§Remove Clinging clot.
§Look in the mirror by the Sample Probe for air bubbles; if air is detected run Clot Prime diagnostics.
§If Sample Probe has entered gel barrier, change the probe.
§If the message persists, call Technical Service.

579

**Corrective Jam Actions has also jammed going into Pause Mode**

The system tried to clear a sample device jam unsuccessfully.

§See associated error message to determine cause of jam.
§If the message persists, call Technical Service.

580

**Sample Carousel has jammed during bar code read going into pause**

Sample Carousel has jammed.

§Check that the sample tube or diluent tube is seated correctly.
§Check that the Sample Racks are seated correctly.
§If the message persists, call Technical Service.

581

**Homing sample devices resulted in a jam returning to Pause Mode**

Homing routines have failed during re-initialization, following Error 579.

§Check for associated error messages and resolve them.
§If the message persists, call Technical Service.

582

**Reagent Pipettor has jammed only the luminometer is active**

Reagent Pipettor is jammed inside the incubator. All attempts to clear jam errors have failed. Only the Luminometer is active.

§Ensure nothing is blocking the Reagent pipettor at the reagent/sample pipetting area.
§Check for misalignment of the Reagent probe at the pipetting area.
§Check the Reagent probe is not bent.
§If the message persists, call Technical Service.

583

**Reagent Pipettor has jammed shutting down sample-reagent pipettors**

Reagent Pipettor jammed above Reaction Tube. All attempts to clear jam errors have failed.

§Ensure nothing is blocking the Reagent pipettor at the reagent/sample pipetting area.
§Check for misalignment of the Reagent probe at the pipetting area.
§Check the Reagent probe is not bent.
§If the message persists, call Technical Service.

585

**Homing reagent devices resulted in a jam going into pause mode**

To clear a Reagent device jam (Error 584) the Instrument attempted to home all reagent devices. However, the homing routine encountered an error.

§See associated error message to determine the cause of the jam.
§If the message persists, call Technical Service.

586

**Homing reagent devices has resulted in a jam returning to pause mode**

Homing routines have failed during re-initialization after Error 585.

§Check for related error messages and resolve them.
§If the message persists, call Technical Service.

587

**Reagent Carousel has jammed during bar code read going into Pause**

Reagent Carousel has jammed during barcode read.

§Reseat Wedge or carousel tray.
§Check Wedge Glide for proper installation.

589

**Homing sample tube devices resulted in a jam going into pause mode**

The system tried to clear a tube/bead device jam unsuccessfully.

§See associated error message to determine the cause of the jam.
§If the message persists, call Technical Service.

590

**Homing tube loading devices resulted in a jam. Returning to Pause mode.**

Homing routines have failed during re-initialization after Error 589.

§Check for related error messages and resolve them.
§If the message persists, call Technical Service.

591

**Bead Carousel has jammed during bar code read going into pause**

Bead Carousel has jammed.

§Check for mispositioned Bead Pack.
§If the message persists, call Technical Service.

592

**INSTRUMENT ENTERED FRONT END SHUTDOWN**

Device in incubator has jammed.

§See associated error message to determine cause of the jam.
§If the message persists, call Technical Service.

593

**INSTRUMENT ENTERED STOP MODE**

Device in the Luminometer has jammed or semaphore errors have shut down instrument.

§See associated error message to determine cause of the jam.
§If the message persists, call Technical Service.

594

**Marking sample tube as bad**

Result of physical error on sample tube (e.g., clot detected, empty tube)

§See associated error message.
§Check sample volume.
§Check sample for clot.
§Check that Sample Probe is not bent.

595

**Marking reagent pack as bad**

Result of physical error on reagent pack (e.g., empty pack)

§Check position of Reagent Wedge.
§Check that Glide is on correctly.
§Check for sufficient amount of reagent.
§Check for bubbles on the Wedge.
§If the message persists, contact Technical Service

596

**Marking bead pack as bad**

Result of physical error on Bead Pack (e.g., failure to dispense three beads)

§Check for empty Bead Pack.
§Invert and reseat Bead Pack in Bead Carousel and try again.
§Visually inspect plunger for obstruction.
§Manually dispense a bead.
§If the message persists, call Technical Service

597

**Marking sample tube empty**

Insufficient sample

§Check sample volume.

598

**Marking reagent pack empty**

Insufficient reagent.

§Check reagent volume.

599

**Attempting to use a NULL RAMP TABLE. Switching to default speed**

Unrecognizable data was passed to the control side.

§Call Technical Service.

600

**Jammed while washing the dilution well. Returning to pause mode.**

While cleaning the dilution well, a device jammed.

§Call Technical Service.

603

**Cannot enter run with the bulk exit chute blocked**

Sensor(s) indicate that the solid waste chute is blocked.

§Check for overfilled or incorrectly seated solid waste container.
§Check for correct biohazard bags.
§Check the Waste chute for blockage.
§Check for clear plastic protruding from the upper trap opening and for plastic pieces in the Solid Waste Container.
§If the message persists, call Technical Service.

604

**Bulk Exit Chute is blocked. Entering pause mode**

Sensor(s) indicate that the solid waste chute is blocked.

§Check for overfilled or incorrectly seated solid waste container.
§Check for correct biohazard bags.
§Clear the Exit Chute.
§Check for clear plastic protruding from the upper trap opening and for plastic pieces in the Solid Waste Container.
§If the message persists, call Technical Service.

605

**Tube Transport is not in position. Tube might be on component deck**

Occurs after the Instrument experiences unusual stop mode and a tube may have been left on the transport chain. The tube will fall on the component deck during initialization.

§Check for associated error message to determine the cause.
§If the message persists, call Technical Service.

606

**Processor Shuttle has jammed**

Processor Shuttle has jammed.

§Remove mis-positioned Reaction Tube.
§If the message persists, call Technical Service.

611

**Homing Bead Carousel has resulted in a jam. In pause mode now**

Bead Carousel has jammed for a third time as it has attempted to clear jams.

§If the message persists, call Technical Service.

612

**Homing Bead Dispenser has resulted in a jam. In pause mode now.**

Bead Dispenser has jammed for a third time as it has attempted to clear jams.

§If the message persists, call Technical Service.

613

**Homing Tube Indexer has resulted in a jam. In pause mode now**

Tube Indexer has jammed for a third time as it has attempted to clear jams.

§Verify correct Reaction Tube is used.
§Check for malformed tube or tube abnormalities.
§Visually inspect chain for any tube abnormality.
§If the message persists, call Technical Service.

614

**Homing Tube Transport has resulted in a jam. In pause mode now**

Tube Transport has jammed for a third time as it has attempted to clear jams.

§Verify correct Reaction Tube is used.
§Check for malformed tube or tube abnormalities.
§Visually inspect chain for any tube abnormality.
§If the message persists, call Technical Service.

615

**In pause now. Remove reaction tube in front of the processor shuttle**

Processor shuttle has jammed and not recovered.

§Check for obstruction near the Reagent/Sample pipetting area.
§If the message persists, call Technical Service.

618

**Sample Probe level sense error in Dilution Well. Entering Sample Pause mode.**

Instrument did not level sense in the dilution well.

§Check for a bent probe.
§Check probe angle.
§Check that the dilution well insert is seated correctly.
§If the message persists, call Technical Service.

619

**Third bead pack marked bad in a row. Entering Bead Pause Mode.**

Third Bead Pack marked bad in a row. Entering Bead Pause Mode

§Reseat Bead Pack in Bead Carousel and try again
§Visually inspect plunger for obstruction
§Manually dispense a bead if first two steps do not correct.
§If the message persists, call Technical Service.

620

**Unknown ucMode detected. Entering Stop Mode.**

User side has sent unrecognizable instrument status mode.

§Call Technical Service.

621

**Barcode queue has overflowed.**

While reading the sample carousel, more than 99 barcodes were detected.

§Instrument will re-interrogate the sample carousel.
§If unsuccessful, error 646 will be posted.

622

**Inner rack door movement exceeded maximum steps. Contact Technical Service.**

§Contact Technical Service.

623

**Tube queue has overflowed.**

Encoder queue has overflowed.

§Instrument will re-interrogate the sample carousel.
§If unsuccessful, error 646 will be posted.
§If the message persists, call Technical Service.

624

**Attention!! - water probe is out.**

Water Probe sensor is not detecting the probe

§Reseat Water Probe.
§If the message persists, call Technical Service.

625

**Attention!! - substrate probe is out.**

Substrate Probe sensor is not detecting the probe

§Reseat Substrate Probe.
§If the message persists, call Technical Service.

626

**Attention!! - trigger probe is out.**

The plug that is used in place of the trigger probe is not detected by the sensor.

§Call Technical Service.

627

**Reaction Tube is missing at bead drop position. Rerunning test.**

The sensor at the bead drop position is not detecting a tube.

§Check Tube Hopper for Reaction tubes.
§Check for obstruction in the Orientation chute.
§If the message persists, call Technical Service.

628

**Tube at indexer disk sensor is struck high.**

Sensor at the bottom of the tube chute continues to see a tube when none can be there.

§Check for mispositioned tube in front of sensor.
§If the message persists, call Technical Service.

629

**Tube shaker sensor is stuck high.**

Sensor at Tube Shaker continues to see a tube when none should be there.

§Call Technical Service.

630

**Tube ladder sensor is stuck high.**

Sensor at ladder continues to see a tube when none should be there.

§Ensure the front and side panel doors are closed.
§Select the **Diagnostics** icon located on the desktop.
§Select the Hopper Elevator Test.
§Manually move reaction cups away from escalator.
§Once the hopper elevator advances, stop the diagnostic.
§Exit Diagnostics and select **RUN IMMULITE**.
§If the message persists, call Technical Service.

631

**Reaction tube at pipette position sensor is stuck high.**

Sensor at pipette position continues to see a tube when none should be there.

§Call Technical Service.

632

**Bulk Exit chute is blocked. Entering Stop mode.**

The solid waste chute is blocked.

§Check for overfilled or incorrectly seated solid waste container.
§Check for correct biohazard bags.
§Check the Waste chute for blockage.
§Check for clear plastic protruding from the upper trap opening and for plastic pieces in the Solid Waste Container.
§If the message persists, call Technical Service.

633

**Clean Dilution Well Fail-Safe triggered.**

A sample error resulted in the need to clean the dilution well or the dilution well insert is not fully seated.

§Check for associated bead, reagent, or sample errors.
§If the message persists, call Technical Service.

637

**DPRAM semaphore locked up for longer than 18 sec. Entering STOP mode.**

Communication between the User and Control sides has been interrupted.

§Call Technical Service.

640

**Wash spinner is not operating correctly. Rerunning test.**

Wash Spinner has failed to reach appropriate speed while processing test.

§Call Technical Service

641

**Cannot enter RUN because wash spinner is not operating correctly.**

Wash Spinner has failed to reach appropriate speed during initialization from Stop to Run.

§Call Technical Service.

642

**Inner rack door communication error. Contact Technical Service.**

§Contact Technical Service.

646

**Fatal Sample Carousel position mismatch, carousel was not read. Please Call Technical Service immediately.**

Sample carousel reread triggered by Error 642, 643, 644, 645 or 655 has resulted in another carousel reading error.

§Check integrity of barcode labels.
§Manually assign sample identification.
§If message persists, call Technical Service.

650

**Fatal Reagent Carousel position mismatch, carousel was not read. Please Call Technical Service immediately.**

Reagent carousel reread triggered by Error 647, 648, 649 or 656 has resulted in another carousel reading error.

§Check integrity of label.
§Check position of reagent wedge.
§If message persists, call Technical Service.

655

**Rack detected in rack loader after load operation complete. Check Rack Loader area.**

A rack was still detected in the rack loader after a load operation completed. Causes include, but are not limited to: Debris in front of rack in place sensor.

§Check Rack Loader area.

658

**Sample Barcode misread during carousel read.**

§The barcode reader returned two different strings for the same accession number on a sample tube.
§Check integrity of barcode labels.
§Manually assign sample identification.
§If the message persists, call Technical Service.

659

**Mismatch between first and second read of accession number.**

After the second carousel read, there is a mismatch between the accession numbers for a sample tube.

§Check integrity of barcode labels.
§Manually assign sample identification.
§If the message persists, call Technical Service.

660

**Mismatch between first and second read of the rack ID.**

After the second carousel read, there is a mismatch between the rack identifiers for the sample carousel.

§Check integrity of barcode label.
§Ensure the rack is seated correctly.
§If the message persists, call Technical Service.

661

**Mismatch between first and second read of the Reagent Pack barcode.**

After the second carousel read, there is a mismatch between the Reagent pack barcodes.

§Check integrity of barcode label.
§Ensure wedges are seated correctly.
§If the message persists, call Technical Service.

662

**Mismatch between first and second read of the Bead Pack barcode.**

After the second carousel read, there is a mismatch between the Bead pack barcodes.

§Check integrity of barcode label.
§Ensure Bead Packs are seated correctly.
§If the message persists, call Technical Service.

670

**RGT_BKLS.iml file is missing**

File could not be found.

§Call Technical Service.

671

**DilWelLS.IML file is missing**

File could not be found.

§Call Technical Service.

672

**PRIMECNT.IML file is missing**

File could not be found.

§Call Technical Service.

673

**Bad mix at Dilution Well**

Sample and diluent were not properly mixed in the Sample Dilution Well.

§Call Technical Service.

676

**ReagFLS.IML file is missing.**

File could not be found.

§Call Technical Service.

677

**Reagent Probe False Level Sensed out of tolerance.**

A Reagent z-Pipettor level sense motion has level sensed higher than expected

§ Check the position of the Reagent Wedge in the Reagent Carousel.
§Make sure the Reagent Wedge lid is positioned correctly and that it moves freely.
§Ensure there are no bubbles in the reagent.
§Check for a reagent fluid film under the Wedge Glide.
§Check for splashing on or near the Reagent Probe.
§Replace the Reagent Wedge with a new one and try again.
§If the message persists, call Technical Service.

679

**Clot detection mechanism failure entering front end shutdown. Contact Technical Service.**

Peak clot feedback is less than minimum

§Call Technical Service.

680

**Tube size discrepancy detected scanning Rack 1, rescanning all sample racks.**

Instrument has detected a change on the sample rack that was not being rescanned.

§If the message persists, call Technical Service.

735

**Sample Transfer Status message was received before REINIT1.**

Analyzer was unable to properly communicate with the SMS.

§On the SMS, select the **STOP** button.
§Select the **LOGOFF** button and log off the SMS.
§Restart the SMS.
§If the message persists, call Technical Service.

736

**Query Analyzer Status message has the wrong length.**

SMS query message has wrong length.

§Call Technical Service.

737

**Sequence number error in Query Analyzer Status message.**

Sequence number error in Query Analyzer Status message.

§Call Technical Service.

738

**Query Analyzer Status message was received before REINIT 1**

Analyzer was unable to properly communicate with the SMS.

§On the SMS, select the **STOP** button.
§Select the **LOGOFF** button and log off the SMS.
§Restart the SMS.
§If the message persists, call Technical Service.

739

**Reinitialize Communications message has unknown Recovery Type.**

SMS used unknown protocol

§If the message persists, call Technical Service.

740

**Reinitialize Communications message has the wrong length.**

SMS message has the wrong length

§If the message persists, call Technical Service.

741

**Unknown message ID.**

SMS sent unknown message

§If the message persists, call Technical Service.

742

**ACK has wrong length.**

SMS ACK message has a length that does not follow protocol

§If the message persists, call Technical Service.

743

**Sequence number in ACK doesn't match last sent message.**

The sequence number in the ACK (acknowledgement between the SMS and the analyzer) does not match the sequence number of any message sent and was therefore not acknowledged by the Control computer.

§Call Technical Service.

744

**ACK was not expected.**

All messages sent by the Control computer have been acknowledged; this ACK (acknowledgement between the SMS and the analyzer) is invalid.

§Call Technical Service.

745

**Cannot match ACK to a sent message.**

An ACK (acknowledgement between the SMS and the analyzer) could not be matched to the message sent between the analyzer and the SMS.

§Call Technical Service.

746

**NAK has the wrong length.**

SMS sends NAK that does not follow the length protocol

§Call Technical Service.

747

**Sequence number in NAK doesn't match last sent message.**

SMS sends NAK in response to the wrong message

§Call Technical Service.

748

**Cannot match NAK to a sent message.**

SMS sends NAK in response to the message that was never sent

§Call Technical Service.

749

**Message has an invalid message type.**

SMS sends a message other than ACK, NAK, or data.

§Call Technical Service.

750

**AutoSendQueue has overflowed.**

The serial communication is broken

§Call Technical Service.

751

**Accession number to be sent is longer than 20 char.**

Programming error

§Call Technical Service.

752

**Cannot switch into INTEGRATED mode when not in STOP.**

The Control computer received a command to switch to Integration mode while the analyzer was running or paused.

§On the analyzer, select the **STOP** button.
§From the IMMULITE 2000 Home screen, select **Configure** from the **Configurations** menu.
§Select the **Instrument Mode** button.
§Select the Integrated option and select the **Save** button.
§Select the **Save** button.
§Select the **RUN** button to begin processing samples.
§If the message persists, call Technical Service.

753

**Cannot switch into STAND ALONE mode when not in STOP.**

The Control computer received a command to switch to Non-Integrated mode while the analyzer was running or paused.

§On the analyzer, select the **STOP** button.
§From the IMMULITE 2000 Home screen, select **Configure** from the **Configurations** menu.
§Select the **Instrument Mode** button.
§Select the Non-Integrated option and select the **Save** button.
§Select the **Save** button.
§Select the **RUN** button to begin processing samples.
§If the message persists, call Technical Service.

754

**Switching to PAUSE due to timeout. Automation may be active!!!**

Attempting to switch to Pause mode after communication timeout with SMS

§Press Run to continue processing samples.

755

**Switching to STOP due to timeout. Automation may be active!!!**

Attempting to switch to stop mode after communication timeout with SMS

§Press Run to continue processing samples.

756

**Test made bad by Reinitialize 1 command.**

Re-initialize message was received while a sample was waiting to be pipette.

§This message is for informational purposes only. No action is required.

757

**Please clear the IMMULITE 2000 of automation tubes.**

A fault was detected when the Sample Carousel was interrogated at start up.

§On the analyzer, open the Top Cover and remove the sample tubes from Automation Rack on the Sample Carousel.
§On the analyzer, select the **RUN** button.
§If the sample tubes were not run, place them on the SMS and rerun them.

759

**Received Reinitialize 1**

SMS is trying to reset the communications

§This message is for informational purposes only. No action is required.

760

**Automation tube appears to have been misplaced. Going to sample pause.**

A sample tube was improperly placed on the analyzer.

§On the analyzer, open the Top Cover and remove the sample tubes from Automation Rack on the Sample Carousel.
§Select the **RUN** button.
§If the sample tubes were not run, place them on the SMS and rerun them.

762

**IMMULITE time out waiting for Place - Sample SMS Transfer Reply. Going to sample pause.**

Sample tube was not placed within the allotted time. The analyzer timed out waiting for a reply from the SMS.

§On the analyzer, open the Top Cover and remove the sample tubes from Automation Rack on the Sample Carousel.
§On the analyzer, select the **RUN** button.
§If the sample tubes were not run, place them on the SMS and rerun them.

763

**IMMULITE time out waiting for Pick - Sample Transfer Reply. Going to sample pause.**

Sample tube was not picked up by the SMS within the allotted time. The analyzer timed out waiting for a reply from the SMS.

§On the analyzer, open the Top Cover and remove the sample tubes from Automation Rack on the Sample Carousel.
§On the analyzer, select the **RUN** button.
§If the sample tubes were not run, place them on the SMS and rerun them.

764

**Please clear the IMMULITE 2000 of automation tubes. Going to sample pause.**

A fault was detected when the Sample Carousel was interrogated.

§On the analyzer, open the Top Cover and remove the sample tubes from Automation Rack on the Sample Carousel.
§On the analyzer, select the **RUN** button.
§If the sample tubes were not run, place them on the SMS and rerun them.

765

**Please clear the IMMULITE 2000 of automation tubes. Going to sample pause.**

A fault was detected when the Sample Carousel was interrogated.

§On the analyzer, open the Top Cover and remove the sample tubes from Automation Rack on the Sample Carousel.
§On the analyzer, select the **RUN** button.
§If the sample tubes were not run, place them on the SMS and rerun them.

766

**Please clear the IMMULITE 2000 of automation tubes. Going to sample pause.**

A fault was detected when the Sample Carousel was interrogated.

§On the analyzer, open the Top Cover and remove the sample tubes from Automation Rack on the Sample Carousel.
§On the analyzer, select the **RUN** button.
§If the sample tubes were not run, place them on the SMS and rerun them.

767

**Please clear the IMMULITE 2000 of automation tubes. Going to sample pause.**

A fault was detected when the Sample Carousel was interrogated.

§On the analyzer, open the Top Cover and remove the sample tubes from Automation Rack on the Sample Carousel.
§On the analyzer, select the **RUN** button.
§If the sample tubes were not run, place them on the SMS and rerun them.

768

**Please clear the IMMULITE 2000 of automation tubes. Going to sample pause.**

A fault was detected when the Sample Carousel was interrogated.

§On the analyzer, open the Top Cover and remove the sample tubes from Automation Rack on the Sample Carousel.
§On the analyzer, select the **RUN** button.
§If the sample tubes were not run, place them on the SMS and rerun them.

769

**Please clear the IMMULITE 2000 of automation tubes. Going to sample pause.**

A fault was detected when the Sample Carousel was interrogated.

§On the analyzer, open the Top Cover and remove the sample tubes from Automation Rack on the Sample Carousel.
§On the analyzer, select the **RUN** button.
§If the sample tubes were not run, place them on the SMS and rerun them.

770

**Please clear the IMMULITE 2000 of automation tubes. Going to sample pause.**

A fault was detected when the Sample Carousel was interrogated.

§On the analyzer, open the Top Cover and remove the sample tubes from Automation Rack on the Sample Carousel.
§On the analyzer, select the **RUN** button.
§If the sample tubes were not run, place them on the SMS and rerun them.

771

**Robot Status message has the wrong length.**

SMS status message does not follow length protocol

§This message is for informational purposes only. No action is required.

772

**Sequence number error in Robot Status message.**

SMS status message does not match any sent message

§This message is for informational purposes only. No action is required.

773

**Robot Status message was received before REINIT1.**

Analyzer was unable to properly communicate with the SMS.

§On the SMS, select the **STOP** button.
§Select the **LOGOFF** button and log off the SMS.
§Restart the SMS.
§If the message persists, call Technical Service.

774

**Logoff message has the wrong length.**

The log off message does not follow the length protocol

§This message is for informational purposes only. No action is required.

775

**Data Error on UART3.**

Hardware problem in serial card

§Call Technical Service.

800

**Test reordered - Instrument power failure.**

The software detected a PMT power glitch after reading PMT results.

801

**A request mutex call timed out. Contact Technical Service.**

Unexpected Error. On 2000 - The sample Pipettor timed out waiting to gain exclusive access to enter the incubator.

§Contact Technical Service.

802

**A request mutex call timed out. Contact Technical Service.**

Unexpected Error. On 2000 - The sample Pipettor timed out waiting to gain exclusive access to enter the incubator.

§Contact Technical Service.

803

**A request mutex call timed out. Contact Technical Service.**

Unexpected Error. On 2000 - The sample Pipettor timed out waiting to gain exclusive access to enter the incubator.

§Contact Technical Service.

804

**A request mutex call timed out. Contact Technical Service.**

Unexpected Error. On 2000 - The sample Pipettor timed out waiting to gain exclusive access to enter the incubator.

§Contact Technical Service.

805

**A request mutex call timed out. Contact Technical Service.**

Unexpected Error. On 2000 - The sample Pipettor timed out waiting to gain exclusive access to enter the incubator.

§Contact Technical Service.

806

**A request mutex call timed out. Contact Technical Service.**

Unexpected Error. On 2000 - The sample Pipettor timed out waiting to gain exclusive access to enter the incubator.

808

**Instrument power failure, entering Stop mode. Contact Technical Service.**

The PMT power failed signal is detected for 3 consecutive cycles in Run or Pause mode.

§Contact Technical Service.

810

**Bead Carousel error. Going to Bead Pause Mode. Check that Bead Packs are properly inserted.**

An unrecoverable jam occurred on the Bead carousel.

§Check for improperly inserted Bead pack.

811

**Bead Dispenser error. Going to Bead Pause Mode. Check that Bead Packs are properly inserted.**

An unrecoverable jam occurred on the bead dispenser.

§Check for improperly inserted Bead pack.
§This error could also indicate a hardware failure.

812

**Tube Indexer error. Going to Bead Pause Mode. Check Tube Indexer.**

An unrecoverable jam occurred on the tube indexer.

§Check the tube indexer and tube queue.
§The indexer may have a deformed tube jamming it.

814

**Error reading configuration file TubeTop.IML. Contact Technical Service.**

§Contact Technical Service.

815

**Failed to detect bottom of Tube Top Sample Cup.**

Tube Top Sample Cup was not detected during the bottom finding routine.

§Check that you placed the tube top cup in sample tube.

816

**Unexpected error. Contact Technical Service.**

§Contact Technical Service.

817

**Unable to load rack. Eject a rack if the sample carousel is full, or press Run to scan the carousel.**

Either the Sample Carousel is full, or there is no known empty position to load a rack into. If there are any empty Positions, they were set to "Unknown".

818

**Close the sample door to eject rack.**

An eject was ordered, but the external sample door is open.

§Remove any rack in the loader area, and close the external sample door.

819

**Remove rack from loader to allow rack to eject.**

An eject was ordered, but there's a rack in the loader area.

§Remove any rack in the loader area, and close the external sample door.
§If there is no rack present, this may indicate a rack in place sensor failure.

820

**Unexpected error. Contact Technical Service.**

§Contact Technical Service.

821

**Error reading configuration file AutoStrt.IML. System will continue. Contact Technical Service.**

§Contact Technical Service.

822

**Probe clean tube not found for AutoStart. Probe clean was not performed.**

AutoStart Probe clean tube not found in Sample Carousel.

823

**Level sense error in probe clean tube. Probe clean was not performed.**

AutoStart Sample Probe clean Level Sense Failure.

§Make sure enough probe clean solution within the tube.

824

**False level sense error in probe clean tube. Probe clean was not performed.**

False Level sense error. The sample probe level-sensed above the probe clean tube during AutoStart.

§Check if there is a (wet) cap on the probe clean tube.
§Otherwise someone must have touched the probe, or the level sense hardware is oversensitive

825

**Failed to load reaction tube. AutoStart not performed.**

AutoStart Probe clean Fail to get Reaction Tube. Tube was not detected at the incubator pipette position.

§Check inventory of Tube Hopper.
§Make sure Hopper is closed.
Make sure tubes lined-up in the Tube Chute canal.

826

**Failed to load reaction tube at Tube Indexer.**

While getting a tube for Autostart (probe clean, wash prime, or substrate dispense), the Tube indexer did not see a tube. Either the tube queue is clogged, or the hopper is completely empty.

§Check the fill of the tube hopper. Check for jammed tubes in reaction tube chute.

§Otherwise it may be a failure to get the sensor signal.

827

**Reaction tube not found at Incubator pipette position. Aborting AutoStart routine.**

While getting a tube for Autostart (probe clean, wash prime), the tube was not seen in the Incubator after the processor shuttle push. Possibly a sensor error, or the tube did not push in far enough for the sensor to see.

§If it persists, have the Inc0 sensor checked.

831

**Unexpected error. AutoStart not performed. Contact Technical Service.**

§Contact Technical Service.

832

**Unexpected error. AutoStart not performed. Contact Technical Service.**

§Contact Technical Service.

| | |
|---|---|
| 833 | **Unexpected error. AutoStart not performed. Contact Technical Service.**<br>§Contact Technical Service. |
| 834 | **Unexpected error. AutoStart not performed. Contact Technical Service.**<br>§Contact Technical Service. |
| 835 | **Unexpected error. AutoStart not performed. Contact Technical Service.**<br>§Contact Technical Service. |
| 836 | **Unexpected error. AutoStart not performed. Contact Technical Service.**<br>§Contact Technical Service. |
| 837 | **Unexpected error. AutoStart not performed. Contact Technical Service.**<br>§Contact Technical Service. |
| 838 | **Unexpected error. AutoStart not performed. Contact Technical Service.**<br>§Contact Technical Service. |
| 839 | **Unexpected error. AutoStart not performed. Contact Technical Service.**<br>§Contact Technical Service. |
| 840 | **Unexpected error. AutoStart not performed. Contact Technical Service.**<br>§Contact Technical Service. |
| 841 | **Unexpected error. AutoStart not performed. Contact Technical Service.**<br>§Contact Technical Service. |

| | |
|---|---|
| 842 | **Unexpected error. AutoStart not performed. Contact Technical Service.**<br>§Contact Technical Service. |
| 843 | **Unexpected error. AutoStart not performed. Contact Technical Service.**<br>§Contact Technical Service. |
| 844 | **Unexpected error. AutoStart not performed. Contact Technical Service.**<br>§Contact Technical Service. |
| 845 | **Unexpected error. AutoStart not performed. Contact Technical Service.**<br>§Contact Technical Service. |
| 846 | **Unexpected error. AutoStart not performed. Contact Technical Service.**<br>§Contact Technical Service. |
| 847 | **Invalid tube or rack for probe clean. Probe clean will not be performed.**<br>Probe clean tube was wrongly placed into a dedicated rack, within micro-sample tube, or other unknown tube type is assigned. |
| 848 | **Failed to home all motors during AutoStart. AutoStart will not be performed.**<br>Home all motors failed at the beginning of AutoStart.<br>§If repeated attempts fail, contact Technical Service. |
| 849 | **Failed to scan Sample Carousel. AutoStart will not be performed.**<br>Scan of Sample carousel failed prior to AutoStart. May have been a jam. If repeated attempts fail it is likely a configuration, mechanical, or hardware issue<br>§If repeated attempts fail, contact Technical Service. |

850

**Auto Substrate Dispense parameter is out of range. Auto Substrate Dispense will not be performed. Contact Technical Service.**

§Contact Technical Service.

851

**Tube not found at Incubator pipette position. Aborting Auto Substrate Dispense routine. Manually prime the substrate.**

While getting a tube for Substrate Dispense, the tube was not seen in the Incubator after the processor shuttle push. Possibly a sensor error, or the tube did not push in far enough for the sensor to see.

§If it persists, have the Inc0 sensor checked.

852

**Unexpected error during Auto Substrate Dispense routine. Auto Substrate Dispense will not be performed. Contact Technical Service.**

§Contact Technical Service.

853

**Substrate Probe is not in place. Aborting Auto Substrate Dispense routine. Manually prime the substrate.**

Error during Auto Substrate Dispense. The Substrate probe was not in place at the time of dispense of substrate.

§Please put the substrate probe back in place.

854

**Failed to load reaction tube. AutoStart not performed.**

Error during AutoStart. Tube did not physically reach the Incubator pipette position.

§Check tube load area.
§Check that tube hopper is not empty.
§Retry AutoStart.

855

**Tube Lifter error.**

Error during AutoStart. Possibly tube lifter jammed. Wash Station tube lifter may have jammed.

§Check tube lifter.
§Retry AutoStart.

856

**Wash Station spinner failed.**

Error during AutoStart. Error with the Wash Station spinner motor. Wash Station Spinner failed.

§Retry AutoStart

857

**Water Probe is not in place.**

The Water probe is not in place. Error occurred during AutoStart.

§Please put the water probe back in place.
§Retry AutoStart.

860

**Failed to home all motors. Auto Substrate Dispense will not be performed. Contact Technical Service.**

§Contact Technical Service.

861

**Unexpected error during Auto Substrate Dispense. Auto Substrate Dispense will not be performed. Contact Technical Service.**

§Contact Technical Service.

862

**Unexpected error during Auto Substrate Dispense. Auto Substrate Dispense will not be performed. Contact Technical Service.**

§Contact Technical Service.

863

**Unexpected error during Auto Substrate Dispense. Auto Substrate Dispense will not be performed. Contact Technical Service.**

§Contact Technical Service.

864

**Unexpected error during Auto Substrate Dispense. Auto Substrate Dispense will not be performed. Contact Technical Service.**

§Contact Technical Service.

867

**Unexpected error. Contact Technical Service.**

§Contact Technical Service.

| | |
|---|---|
| 868 | **Unexpected error. Contact Technical Service.**<br>§Contact Technical Service. |
| 869 | **Unexpected error. Contact Technical Service.**<br>§Contact Technical Service. |
| 870 | **Unexpected error. Contact Technical Service.**<br>§Contact Technical Service. |
| 871 | **Unexpected error. Contact Technical Service.**<br>§Contact Technical Service. |
| 872 | **Unexpected error. Contact Technical Service.**<br>§Contact Technical Service. |
| 873 | **Unexpected error. Contact Technical Service.**<br>§Contact Technical Service. |
| 874 | **Unexpected error. Contact Technical Service.**<br>§Contact Technical Service. |
| 875 | **Unexpected error. Contact Technical Service.**<br>§Contact Technical Service. |
| 876 | **Unexpected error. Contact Technical Service.**<br>§Contact Technical Service. |
| 877 | **Unexpected error. Contact Technical Service.**<br>§Contact Technical Service. |
| 878 | **Unexpected error. Contact Technical Service.**<br>§Contact Technical Service. |

879

**Unexpected error. Contact Technical Service.**

§Contact Technical Service.

880

**An empty sample rack was detected. Rack will be ejected.**

A sample rack with no tubes was inserted, or a rack with tubes was inserted, but the tubes were not detected by the tube height sensors or the barcode reader.

881

**Unexpected error. Contact Technical Service.**

§Contact Technical Service.

882

**Unexpected error. Contact Technical Service.**

§Contact Technical Service.

883

**Unexpected error. Contact Technical Service.**

§Contact Technical Service.

884

**Unexpected error. Contact Technical Service.**

§Contact Technical Service.

885

**Unexpected error. Contact Technical Service.**

§Contact Technical Service.

886

**Unexpected error. Contact Technical Service.**

§Contact Technical Service.

887

**Inner rack door will not open. Close all covers. Reopen main cover.**

Normally, when opening the cover, the rack transfer door opens automatically. If you have the external rack loader door opened, this will be skipped.

§Closing the rack loader door prior to popping the hood will prevent this.

888

**Unexpected error. Contact Technical Service.**

§Contact Technical Service.

889

**Rack Loader door is open.**

The rack loader door is open during initialization.

§Close the door to continue.
Occurs if the rack loader door is opened. May also occur if sensor fails or becomes disconnected

890

**Unexpected error. Contact Technical Service.**

§Contact Technical Service.

891

**Unexpected error. Contact Technical Service.**

§Contact Technical Service.

892

**Unexpected error. Contact Technical Service.**

§Contact Technical Service.

893

**Error reading configuration file RLCfg.IMR. Contact Technical Service.**

§Contact Technical Service.

894

**Unexpected error. Contact Technical Service.**

§Contact Technical Service.

895

**Rack Loader unavailable. Close door.**

The rack loader door was opened while the rack loader is busy. This is hazardous and not advised. Alternatively, the rack loader door sensor assembly may be malfunctioning.

§Take care to not open rack loader door when red light is lit.

896

**Unexpected error. Contact Technical Service.**

§Contact Technical Service.

897

**Unexpected error. Contact Technical Service.**

§Contact Technical Service.

898

**Rack Loader device jammed while homing. Returning to Pause Mode. Check Rack Loader area.**

The Rack Gripper, Rack Transfer, or Rack Transfer Door jammed during the transition from Pause mode to Run.

§Check Rack Loader area.

899

**Unexpected error. Contact Technical Service.**

§Contact Technical Service.

901

**Automation Rack cannot be ejected.**

The instrument is configured in nonintegrated mode, detects a tube in the auto rack, operator attempts to eject it.

902

**Main cover is open.**

The Main Cover door is opened during Initialization.

§Close the door to continue.
May also occur if the sensor fails or becomes disconnected. This error is reported one time if the door is open.

903

**Sample pipettor door is open.**

The sample pipettor (Top) Door (aka Clot Door) is open during initialization.

§Close the door to continue.
May also occur if the sensor fails or becomes disconnected.

904

**Main cover is open. AutoStart will not be performed.**

The Main Cover was open when AutoStart began.

§Close the door and re-run the operation.
May also occur if the sensor fails or becomes disconnected.

905

**Sample pipettor door is open. AutoStart will not be performed.**

The sample pipettor (Top) Door (aka Clot Door) was open when AutoStart began.

§Close the door and re-run the operation.
May also occur if the sensor fails or becomes disconnected.

906

**Sample rack loader door is open. AutoStart will not be performed.**

The Rack Loader External Door was open when AutoStart began.

§Close the door and re-run the operation.
May also occur if the sensor fails or becomes disconnected.

907

**Main cover is open. Automatic Substrate Dispense will not be performed.**

The Main Cover was open when Auto substrate dispense began.

§Close the cover and re-run the operation.
May also occur if the sensor fails or becomes disconnected.

908

**Sample pipettor door is open. Automatic Substrate Dispense will not be performed.**

The sample pipettor (Top) door (aka Clot Door) was open when Auto substrate dispense began.

§Close the door and re-run the operation.
May also occur if the sensor fails or becomes disconnected.

909

**Sample rack loader door is open. Automatic Substrate Dispense will not be performed.**

The Rack Loader External Door was open when Auto substrate dispense began.

Close the door and re-run the operation.

May also occur if the sensor fails or becomes disconnected.

910

**Main cover is open. AutoStart is running. Close cover.**

The Main Cover was open while AutoStart operation was active.

§Close the door.
May also occur if the sensor fails or becomes disconnected.

911

**Sample pipettor door is open. AutoStart is running. Close door.**

Sample pipettor (Top) Door (aka Clot Door) was open while AutoStart operation was active.

§Close the door.
May also occur if the sensor fails or becomes disconnected.

912

**Unexpected error. Contact Technical Service.**

§Contact Technical Service.

913

**Main cover is open. Automatic Substrate Dispense is running. Close cover.**

The Main Cover was open while Automatic substrate dispense operation was active.

§Close the door.
May also occur if the sensor fails or becomes disconnected.

914

**Sample pipettor door is open. Automatic Substrate Dispense is running. Close door.**

The sample pipettor (Top) Door (aka Clot Door) was open while Automatic substrate dispense was active.

§Close the door.
May also occur if the sensor fails or becomes disconnected.

917

**Empty unbarcoded rack detected. Rack will be ejected.**

A rack that has no detectable tubes on it, and no rack barcode (or an unreadable barcode) has been detected on the system. Because the instrument suspects the rack was loaded but cannot be seen, it will be ejected.

918

**Rack transfer has jammed during retract. Remove rack if present and retry.**

A retract motion jammed or failed. Some Causes may be an obstruction restricting motion, improper configuration, failure due to a electrical issue, etc.

§Remove rack if present and retry.

919

**A sample rack changed status unexpectedly. Sample carousel must be rescanned. Retry the operation to rescan the carousel.**

A rack either disappeared or appeared since the last scan when the rack has never been accessed via the rack loader or the main cover is open.

§Retry the operation to rescan the carousel.

920

**Sample rack status cleared. After closing main cover, press Run prior to resuming use of Rack Loader.**

Opening the main cover (on XPi systems) causes the instrument to consider all sample carousel positions as unknown because the operator may now insert/ remove racks directly from the sample carousel without the instrument's knowledge.

921

**Aborting transition to Run Mode due to errors. Returning to Stop Mode.**

An error (specified via a different error code) has caused the MCP to abort the transition to run mode from stop mode. The instrument is returning to pause mode.

§Resolve the accompanying errors.

922

**Aborting transition to Run Mode due to errors. Returning to Pause Mode.**

An error (specified via a different error code) has caused the MCP to abort the transition to run mode from pause mode. The instrument is returning to pause mode.

§Resolve the accompanying errors.

923

**The Results Buffer has overflowed. Test Rerun.**

The results Buffer has overflowed. The control side cannot put the result in the full buffer, so the data is lost. (actually it is saved in "results.dat" which is in the control side c:\bin directory).

1002

**Bead Dispenser fatal timeout.**

Bead Dispenser has failed to respond to a command in the allowable time. Instrument shut down. All tests on board are lost.

§Call Technical Service.

1003

**Test designated bad - Pretreatment transfer scheduling issue - Test Rerun.**

Unable to transfer pre-treatment tube. Test will be reordered.

§No action required. If this problem, persists, call Technical Service.

1004

**Error has forced Error Pause Mode. RUN Button is deactivated until STOP mode is entered.**

Incubator 1, Incubator 2, Wash Station 1 or Wash Station 2 has shut down. Instrument is in Error Pause mode and will not enter RUN mode.

§Wait until all tests on the system complete, then enter STOP mode.

---

1005

**IMMULITE 2500 doors must be closed for operation.**

A door, or doors are not properly closed.

§Verify that the Bead Carousel, Large Reagent, Small Reagent, Main Cover and Sample Loading doors are closed. If all doors are fully closed, a sensor may be malfunctioning.
§Call Technical Service.

---

1006

**Please clear the $IM2K$ of automation tubes.**

When SMS messages to the IMMULITE serious enough error with the pick or place of a Sample Tube that the operator needs to clear the error

§Open the top cover and remove the sample tubes from the automation rack on the Sample Carousel.
§Select the **RUN** button. If sample tubes were not run, place them on the SMS and rerun them.

---

1007

**Please clear the $IM2K$ of automation tubes. Going into sample pause.**

SCAS Error - Tube On board

§Open the top cover and remove the sample tubes from the automation rack on the Sample Carousel.
§Select the **RUN** button. If sample tubes were not run, place them on the SMS and rerun them.

---

1008

**Please clear the $IM2K$ of automation tubes. Going into sample pause.**

Three tubes on AR.

§Open the top cover and remove the sample tubes from the automation rack on the Sample Carousel.
§Select the **RUN** button. If sample tubes were not run, place them on the SMS and rerun them.

1009

**Please clear the $IM2K$ of automation tubes. Going into sample pause.**

Auto A - DPR Mismatch #1

§Open the top cover and remove the sample tubes from the automation rack on the Sample Carousel.
§Select the **RUN** button. If sample tubes were not run, place them on the SMS and rerun them.

1010

**Please clear the $IM2K$ of automation tubes. Going into sample pause.**

Auto B - DPR Mismatch #1

§Open the top cover and remove the sample tubes from the automation rack on the Sample Carousel.
§Select the **RUN** button. If sample tubes were not run, place them on the SMS and rerun them.

1011

**Please clear the $IM2K$ of automation tubes. Going into sample pause.**

Auto C - DPR Mismatch #1

§Open the top cover and remove the sample tubes from the automation rack on the Sample Carousel.
§Select the **RUN** button. If sample tubes were not run, place them on the SMS and rerun them.

1025

**Event 1 has fatally timed out.**

An earlier error has caused a timeout in a portion of the Instrument. This portion will be shutdown.

§Allow the Instrument to complete tests in progress.
§Call Technical Service.

1026

**Event 2 has fatally timed out.**

An earlier error has caused a timeout in a portion of the instrument. This portion will be shutdown.

§Allow the Instrument to complete tests in progress.
§Call Technical Service.

1027

**Event 3 has fatally timed out.**

An earlier error has caused a timeout in a portion of the instrument. This portion will be shutdown

§Allow the Instrument to complete tests in progress.
§Call Technical Service.

1031

**Luminometer Belt calculated an excessive time for a move.**

Unexpected error. An internal timing error for the Luminometer Belt has caused the Instrument to shut down. All tests on board are lost.

§Call Technical Service.

1032

**Luminometer Belt calculated an excessive distance for a move.**

Unexpected error. An internal timing error for the Luminometer Belt has caused the Instrument to shut down. All tests on board are lost.

§Call Technical Service.

1033

**Incubator 1 Belt calculated an excessive time for a move.**

Unexpected error. An internal timing error for Incubator 1 has caused the Instrument to shut down. No new tests will be loaded.

§Allow the Instrument to complete tests in progress.
§Call Technical Service.

1034

**Incubator 1 Belt calculated an excessive distance for a move.**

Unexpected Error. An internal timing error for Incubator Belt 1 has caused Incubator 1 to shut down. No new tests will be loaded.

§Allow the Instrument to complete tests in progress.
§Call Technical Service.

1035

**Incubator 2 Belt calculated an excessive time for a move.**

Unexpected Error. An internal timing error for Incubator Belt 2 has caused both Incubators to shut down. Instrument will attempt to complete tests in the Luminometer. No new tests will be loaded.

§Allow the Instrument to complete tests in progress.
§Call Technical Service.

1036

**Incubator 2 Belt calculated an excessive distance for a move.**

Unexpected Error. An internal timing error for Incubator Belt 2 has caused both Incubators to shut down. Instrument will attempt to complete tests in the Luminometer. No new tests will be loaded.

§Allow the Instrument to complete tests in progress.
§Call Technical Service.

1037

**Incubator 1 Belt movement timeout. Incubator 1 will shut down.**

Unexpected Error. An internal timing error for Incubator Belt 2 has caused Incubator 1 to shut down. Instrument will attempt to complete tests in the Luminometer. No new tests will be loaded.

§Allow the Instrument to complete tests in progress.
§Call Technical Service.

1038

**Incubator 2 Belt movement timeout. Incubator 2 will shut down.**

Unexpected Error. An internal timing error for Incubator Belt 2 has caused both incubators to shut down. Instrument will attempt to complete tests in the Luminometer. No new tests will be loaded.

§Allow the Instrument to complete tests in progress.
§Call Technical Service.

1039

**Luminometer Belt movement timeout. Luminometer will shut down.**

Unexpected Error. The Luminometer Belt has been asked to move for a longer time than permitted. The Instrument will shut down. All tests on board are lost.

§Call Technical Service.

1040

**A single motor attempted two simultaneous motor moves.**

Unexpected error. Sample Arm X motor attempted two simultaneous moves. Instrument will attempt to enter Sample Pause.

§Allow the Instrument to complete tests in progress.
§Call Technical Service.

1041

**A single motor attempted two simultaneous motor moves.**

Unexpected error. Sample Arm Z motor attempted two simultaneous moves. Instrument will attempt to enter Sample Pause.

§Allow Instrument to complete tests in progress.
§Call Technical Service.

1042

**A single motor attempted two simultaneous motor moves.**

Unexpected error. Sample Valve motor attempted two simultaneous moves. Instrument will attempt to enter Sample Pause.

§Allow Instrument to complete tests in progress.
§Call Technical Service.

1043

**A single motor attempted two simultaneous motor moves.**

Unexpected error. Sample Dilutor motor attempted two simultaneous moves. Instrument will attempt to enter Sample Pause.

§Allow Instrument to complete tests in progress.
§Call Technical Service.

1044

**A single motor attempted two simultaneous motor moves.**

Unexpected error. Sample Carousel motor attempted two simultaneous moves. Instrument will attempt to enter Sample Pause.

§Allow Instrument to complete tests in progress.
§Call Technical Service.

1045

**A single motor attempted two simultaneous motor moves.**

Unexpected error. Reagent Arm Z motor attempted two simultaneous moves. Instrument will attempt to enter Reagent Pause.

§Allow Instrument to complete tests in progress.
§Call Technical Service.

1046

**A single motor attempted two simultaneous motor moves.**

Unexpected error Reagent Arm X motor attempted two simultaneous moves. Instrument will attempt to enter Reagent Pause.

§Allow the Instrument to complete tests in progress.
§Call Technical Service.

1047

**A single motor attempted two simultaneous motor moves.**

Unexpected error. Reagent Valve motor attempted two simultaneous moves. Instrument will attempt to enter Reagent Pause.

§Allow Instrument to complete tests in progress.
§Call Technical Service.

1048

**A single motor attempted two simultaneous motor moves.**

Unexpected error. Reagent Dilutor motor attempted two simultaneous moves. Instrument will attempt to enter Reagent Pause.

§Allow Instrument to complete tests in progress.
§Call Technical Service.

1049

**A single motor attempted two simultaneous motor moves.**

Unexpected error. Reagent Carousel or Pack Lid Opener motor attempted two simultaneous moves. Instrument will attempt to enter Reagent Pause.

§Allow Instrument to complete tests in progress.
§Call Technical Service.

1050

**A single motor attempted two simultaneous motor moves.**

Unexpected error. Bead Carousel or Bead Dispenser motor attempted two simultaneous moves. Instrument will attempt to enter Bead Pause.

§Allow Instrument to complete tests in progress.
§Call Technical Service.

1051

**A single motor attempted two simultaneous motor moves.**

Unexpected error. Tube Indexer motor attempted two simultaneous moves. Instrument will attempt to enter Bead Pause.

§Allow Instrument to complete tests in progress.
§Call Technical Service.

1052

**A single motor attempted two simultaneous motor moves.**

Unexpected error. Tube Transport motor attempted two simultaneous moves. Instrument will attempt to enter Bead Pause.

§Allow Instrument to complete tests in progress.
§Call Technical Service.

1053

**A single motor attempted two simultaneous motor moves.**

Unexpected error. Incubator Belt 1 motor attempted two simultaneous moves. Instrument will attempt to shut down Incubator 1

§Allow Instrument to complete tests in progress.
§Call Technical Service.

1054

**A single motor attempted two simultaneous motor moves.**

Unexpected error. Incubator Belt 2 motor attempted two simultaneous moves. Instrument will attempt to shut down Incubator 1 and 2.

§Allow Instrument to complete tests in progress.
§Call Technical Service.

1055

**A single motor attempted two simultaneous motor moves.**

Unexpected error. Luminometer Belt motor attempted two simultaneous moves. Instrument will attempt to shut down.

§Allow Instrument to complete tests in progress.
§Call Technical Service.

1069

**Substrate probe not fully seated.**

Substrate probe is not fully seated.

§Ensure that the Substrate probe is in place and fully seated
§If the error persists, call Technical Service.

1070

**A beaded tube is marked bad due to a problem with a pre-treatment tube.**

A beaded tube is marked bad due to a problem with a pre-treatment tube.

§If the error persists, call Technical Service.

1073

**Test Designated bad - the inter-cycle sample movements timed out - Rerun Test**

The Sample Diluter did not finish the move within a certain amount of time.

§If the error persists, call Technical Service.

1074

**Test Designated bad - the inter-cycle reagent movements timed out - Rerun Test**

The Reagent Diluter did not finish the move within a certain amount of time.

§If the error persists, call Technical Service.

1077

**Pretreatment aborted due to pause mode or error condition.**

A pretreatment tube was marked bad because the Instrument is in Pause Mode due to a prior error condition.

§Test will be re-run.
§If the error persists, call Technical Service.

1078

**Dilution aborted due to pause mode or error condition.**

The first dilution replicate was marked bad because the Instrument is in Pause Mode due to a prior error condition.

§Test will be re-run.
§If the error persists, call Technical Service.

1079

**Scheduler Error**

A Wash was scheduled while the test was on Incubator 1.

§If the error persists, call Technical Service

1086

**Missing the file SAMPSCAN.IML. Sample access monitoring will be turned off.**

The program can not find the Sampscan.iml file, and the feature will be turned off.

§Call Technical Service.

1087

**Missing the file LAUNCHSP.IML. Launch Spacing is turned OFF.**

The launch spacing .iml file is missing.

§Call Technical Service.

1088

**SampleZ move to fixed position has failed. Test marked bad and reordered.**

The Sample Pipettor could not aspirate a pretreatment test.

§Test will be rerun. If error continues, call Technical Service

1175

**Wash 1 Transfer jammed during recovery.**

Wash Transfer 1 jammed. Tests in Incubator 1 are lost. No new tests will be loaded. Instrument will attempt to complete tests in Incubator 2 and Luminometer. If jam blocks Incubator 2, all tests in Incubator 2 will also be lost.

§Allow Instrument to complete tests in progress.
§Call Technical Service.

1176

**Wash 1 Transfer fatal timeout.**

Wash Transfer 1 did not respond to a move command within 18 seconds.

§Call Technical Service.

1178

**Tube Lifter 1 jammed during recovery.**

Tube Lifter 1 jammed. Tests in Incubator 1 are lost. No new tests will be loaded. Instrument will attempt to complete tests in Incubator 2 and Luminometer.

§Allow Instrument to complete tests in progress.
§Call Technical Service.

1179

**Tube Lifter 1 fatal timeout.**

Tube Lifter 1 did not respond to a move command within 18 seconds.

§Call Technical Service.

1180

**Tube Lifter 1 exceeded maximum steps**

Tube Lifter exceeded maximum steps.

§Call Technical Service.

1185

**Incubator Belt Transfer jammed during recovery.**

The Belt Transfer jammed while attempting to recover from a jam. No new tests will be loaded. Instrument will attempt to complete tests in Luminometer.

§Allow Instrument to complete tests in progress.
§Call Technical Service.

1186

**Incubator Belt Transfer fatal timeout.**

The Belt Transfer did not respond to a move command in the allowable time.

§Call Technical Service.

1187

**Incubator Belt Transfer exceeded maximum steps.**

Unexpected Error. Belt Transfer has been asked to move more than the allowable number of steps.

§Call Technical Service.

1244

**Luminometer Disk jammed during recovery.**

The Luminometer Disk has jammed. Instrument Shutdown. All tests on board lost.

§Call Technical Service.

1246

**PMT Transfer jammed during recovery.**

The PMT Transfer has jammed. Instrument shutdown. All tests on board lost.

§Call Technical Service.

1248

**PMT Transfer fatal timeout.**

The PMT transfer did not respond to a command in the allowable time. Instrument shutdown. All tests on board are lost.

§Call Technical Service.

1249

**PMT Transfer exceeded maximum steps.**

Unexpected Error. PMT Transfer has been asked to move more than the allowable number of steps.

§Call Technical Service.

1250

**PMT Transfer home not found.**

The PMT Transfer has jammed looking for Home.

§Call Technical Service.

1252

**Wash 1 cycle exceeded time limit.**

The wash thread for Wash Station 1 ran longer than permitted. Tests on Incubator 1 Belt and Incubator 2 Belt are lost. No new tests will be loaded. Instrument will attempt to complete tests in Luminometer.

§Allow Instrument to complete tests in progress.
§Call Technical Service.

1253

**Processor Shuttle move timed out.**

Incubator 1 was waiting or the Processor Shuttle and was unable to move in the allowable time. Tests in Incubator 1 are lost. No new tests will be loaded. Instrument will attempt to complete tests in Incubator 2 and Luminometer.

§Allow Instrument to complete tests in progress.
§Call Technical Service.

1254

**Incubator 1 Belt Transfer timed out.**

Incubator Chain 1 timed out waiting for the Belt Transfer to finish. Tests in Incubator 1 are lost. No new tests will be loaded. Instrument will attempt to complete tests in Incubator 2 and Luminometer.

§Allow Instrument to complete tests in progress.
§Call Technical Service.

1255

**Wash 1 Transfer timed out at Incubator 2.**

Incubator Chain 2 timed out waiting for wash Transfer 1 to finish.

§Call Technical Service.

1256

**Wash 2 Transfer timed out at Incubator 2.**

Incubator 2 was waiting for Wash Transfer 2 and was unable to move in the allowable time. Tests in both Incubators are lost. No new tests will be loaded. Instrument will attempt to complete tests in the Luminometer.

§Call Technical Service.

1257

**Reagent dispense timed out at Incubator 1.**

Incubator 1 was waiting for the Reagent Arm and was unable to move in the allowable time. Tests in Incubator 1 are lost. No new tests will be loaded. Instrument will attempt to complete tests in Incubator 2 and Luminometer.

§Allow Instrument to complete tests in progress.
§Call Technical Service.

1258

**Sample Pipettor timed out at Incubator 1.**

Incubator 1 was waiting for the Sample Arm and was unable to move in the allowable time. Tests in Incubator 1 are lost. No new tests will be loaded. Instrument will attempt to complete tests in Incubator 2 and Luminometer.

§Allow Instrument to complete tests in progress.
§Call Technical Service.

1266

**Luminometer Disk initialization step jammed during recovery.**

The Luminometer Disk has jammed. Instrument shutdown. All tests on board lost.

§Call Technical Service.

1267

**Luminometer Disk initialization step fatal timeout.**

Luminometer Disk has not responded in the allowable time. Instrument shutdown. All tests on board are lost.

§Call Technical Service.

1270

**Luminometer Belt timed out at Luminometer Disk.**

The Luminometer Disk was waiting for the Luminometer Chain and was unable to move in the allowable time. Instrument shutdown. All tests on board are lost.

§Call Technical Service.

1271

**Substrate dispense timed out.**

The Substrate Dispense consumed more time than was allotted.

§Call Technical Service.

1272

**Time in the Luminometer out of range.**

Tests in the Luminometer exceeded allowable time. Tests will be marked bad and reordered.

§Call Technical Service.

1273

**Luminometer Disk timed out at Luminometer Belt.**

The Luminometer Chain was waiting for the Luminometer Disk and was unable to move in the allowable time. Instrument shutdown. All tests on board are lost.

§Call Technical Service.

1274

**A Wash Station shut down. Some tests may not complete.**

The Wash Station experienced mechanical problems.

§Allow Instrument to complete tests in progress.
§Call Technical Service.

1314

**Incubator 2 Belt step jammed during recovery.**

Incubator 2 jammed. Tests in both Incubators are lost. No new tests will be loaded. Instrument will attempt to complete tests in Luminometer.

§Allow Instrument to complete tests in progress.
§Call Technical Service.

1316

**Incubator 2 Belt step fatal timeout.**

Incubator Chain 2 has not responded in the allowable time.

§Call Technical Service.

1320

**Wash 1 Transfer home jammed during recovery.**

Wash Transfer 1 has jammed while homing. Instrument will not run until this condition is corrected.

§Call Technical Service.

1321

**Wash 1 Transfer home fatal timeout.**

Wash Transfer 1 has not responded in the allowable time. Instrument will not run until this condition is corrected.

§Call Technical Service.

1322

**Wash 1 Transfer home not found.**

Wash 1 Transfer has jammed looking for Home. Instrument will not run until this condition is corrected.

§Call Technical Service.

1323

**Tube Lifter 1 has jammed.**

The Tube Lifter 1 Home has jammed while attempting to recover from a jam. The Instrument will not run until the condition is corrected.

§Call Technical Service.

1324

**Tube Lifter 1 exceeded the 18 second timer.**

Tube Lifter 1 has timed out during homing. The Instrument will not run until the condition is corrected.

§Call Technical Service.

1325

**Tube Lifter 1 did not find Home.**

Tube Lifter 1 has jammed looking for Home. The Instrument will not run until the condition is corrected.

§Call Technical Service.

1330

**Attenuator Disk home fatal timeout.**

Attenuator Disk has not responded in the allowable time. The Instrument will not run until the condition is corrected.

§Call Technical Service.

1331

**Control side computation error - Call Technical Service.**

Unexpected Error – the Instrument has shut down.

§Call Technical Service.

1332

**Luminometer Disk fatal timeout.**

Luminometer Disk has not responded in the allowable time. Instrument shutdown.

§Call Technical Service.

1333

**Luminometer Disk exceeded maximum steps.**

Luminometer Disk has been asked to move more than the allowable number of steps. Instrument shutdown. All tests on board are lost.

§Call Technical Service.

1334

**Luminometer Disk home not found.**

Luminometer Disk has jammed looking for Home. Instrument will not run until this condition is corrected.

§Call Technical Service.

1335

**Exit Transfer home not found.**

Exit Transfer has jammed looking for home. Instrument will not run until this condition is corrected.

§Call Technical Service

1338

**Exit Transfer jammed during recovery.**

The Exit Transfer has jammed while trying to recover from a jam. If running, the Instrument will immediately enter STOP mode. The Instrument cannot run until the jam is corrected.

§Call Technical Service.

1339

**Exit Transfer fatal timeout.**

The Exit Transfer has not responded in the allowable time. Instrument shutdown. All tests on board are lost.

§Call Technical Service.

1340

**Exit Transfer exceeded maximum steps.**

The Exit Transfer has been asked to move more than the allowable number of steps. Instrument will not run until this condition is corrected.

§Call Technical Service.

1342

**Exit Transfer Home jammed during recovery.**

The Exit Transfer has jammed looking for Home. The Instrument will not run until this condition is corrected.

§Call Technical Service.

1343

**Exit Transfer fatal timeout.**

The Exit Transfer failed to find its home sensor.

§Call Technical Service.

1347

**Reagent Dispense timed out at Incubator 2.**

Incubator Chain 2 was waiting for the Reagent dispense and was unable to move in the allowable time. Tests in both Incubators are lost. No new tests will be added. Instrument will attempt to complete tests in the Luminometer.

§Allow Instrument to complete tests in progress.
§Call Technical Service.

1348

**Wash 2 timed out.**

Wash Station 2 has not responded in the allowable time. Instrument shutdown. All tests on board are lost.

§Call Technical Service.

1349

**Incubator 2 Belt Transfer timed out.**

The Incubator Chain 2 was waiting for the Belt Transfer and was unable to move in the allowable time. All tests in Incubator 1 are lost. No new tests will be added. Instrument will attempt to complete tests in Incubator 2 and Luminometer.

§Allow Instrument to complete tests in progress.
§Call Technical Service.

1350

**Wash 1 Transfer timed out at Luminometer.**

The Luminometer Chain was waiting for Wash Transfer 1 and was unable to move in the allowable time. Instrument shutdown. All tests on board are lost.

§Call Technical Service.

1351

**Wash 2 Transfer timed out at Luminometer.**

The Luminometer Chain was waiting for Wash Transfer 2 and was unable to move in the allowable time. Instrument shutdown. All tests on board are lost.

§Call Technical Service.

1352

**Incubator 2 Belt home not found.**

Incubator Chain 2 has jammed looking for Home.

§Call Technical Service.

1353

**Belt home jammed during recovery.**

Incubator Belt 2 has jammed. Both incubator belts will shut down. Instrument will attempt to complete tests in Luminometer. All other tests on board will be lost.

§Allow Instrument to complete tests in progress.
§Call Technical Service.

1354

**Incubator 2 Belt home fatal timeout.**

Incubator Chain 2 has not responded in the allowable time. Instrument shutdown.

§Call Technical Service.

1359

**Wash 2 Transfer jammed during recovery.**

The Wash 2 Transfer has jammed while attempting to recover from a jam. No new tests will be loaded. The Instrument will attempt to complete tests in progress.

§Call Technical Service.

1361

**TIMECYCL.IML is corrupt. Exiting MCP.**

The file TIMECYCL.IML was unable to be opened

§Call Technical Service.

1362

**Wash 2 Transfer fatal timeout.**

Wash Transfer 2 has not responded in the allowable time. Instrument shutdown.

§Call Technical Service.

1363

**Wash 2 Transfer home not found.**

Wash Transfer 2 has jammed looking for Home. Instrument will not run until this condition is corrected.

§Call Technical Service.

1364

**Wash 2 Transfer home jammed during recovery.**

The Wash 2 Transfer Home has jammed while attempting to recover from a jam. Instrument will not run until the condition is corrected.

§Call Technical Service.

1365

**Wash 2 Transfer home fatal timeout.**

Wash Transfer 2 has not responded in the allowable time. Instrument will not run until this condition is corrected.

§Call Technical Service.

1366

**TimeCycl.iml is missing or has an incorrect format.**

The TimeCycle.iml file is missing or corrupt.

§Call Technical Service.

1368

**Tube Lifter 2 jammed during recovery.**

Tube Lifter 2 is jammed. Any active test currently in Wash Station 2 will be marked bad. Instrument will continue to run with Wash Station 1.

§Call Technical Service.

1369

**Tube Lifter 2 fatal timeout.**

Tube Lifter 2 failed to respond to respond in the allowable time. Any active test currently in Wash Station 2 will be marked bad. Instrument will continue to run with Wash Station 1.

§Call Technical Service.

1370

**Tube Lifter 2 exceeded maximum steps.**

Unexpected Error. Tube Lifter 2 has been asked to move more than the allowable number of steps. Any active test currently in Wash Station 2 will be marked bad. Instrument will continue to run with Wash Station 1.

§Call Technical Service.

1371

**Tube Lifter 2 home not found.**

Tube Lifter 2 has jammed looking for Home.

§Call Technical Service.

1372

**Tube Lifter 2 home jammed during recovery.**

Tube Lifter 2 home has jammed while attempting to recover from a jam. The Instrument will not run until the condition is corrected.

§Call Technical Service.

1373

**Tube Lifter 2 home fatal timeout.**

Tube Lifter 2 has not responded in the allowable time. Instrument will not run until this condition is corrected.

§Call Technical Service.

1374

**Tube Lifter 1 is not at expected Wash position.**

Tube Lifter 1 is not in its expected position during a wash. This may be due to a previous tube lifter error. Any test at Wash Station 1 will be marked bad and reordered.

§If this error persists, call Technical Service.

1375

**Tube not detected in Luminometer at Wash Station 1.**

A tube was not detected at the Luminometer when expected. The Instrument will not run until this condition is corrected.

§Call Technical Service.

1376

**Tube not detected in Luminometer at Wash Station 2.**

A tube was not detected at the Luminometer when expected. The Instrument will not run until this condition is corrected.

§Call Technical Service.

1377

**Empty all tubes has failed to complete. Entering Stop Mode.**

The Instrument has failed to empty all tubes in the allowable time. The Instrument will not run until this condition is corrected.

§Attempt to enter Run mode again. If this error persists, call Technical Service.

1378

**Wash Station 2 was not primed.**

Due to previous errors, the wash station could not be primed.

§Log off, and then log back on.

1379

**Wash Stations 1 and 2 were not primed.**

Due to previous errors in the wash station, the pumps cannot be primed.

§Log off, and then log back on.

1380

**Programmer Error: HmiAlignIncChain2To Wash was passed invalid parameter value.**

An unexpected error has occurred in the software. Do not attempt to run.

§Call Technical Service.

1381

**No empty baffles found on Incubator 2 while homing Wash Transfer 1.**

Instrument was unable to home properly because it detected that Incubator 2 was full.

§Call Technical Service.

1382

**No empty baffles found on Incubator Belt 2 while homing Wash Transfer 2.**

Instrument was unable to home properly because it detected that Incubator 2 was full.

§Call Technical Service.

1384

**Requested number of primes did not complete due to Wash Spinner 1 failure.**

The Wash 1 Spinner failed during a prime. Attempt to re-prime pumps. If error reoccurs, do not run instrument.

§Call Technical Service.

1385

**Requested number of primes did not complete due to a Wash Spinner 2 failure.**

The Wash 2 Spinner failed during a prime.

§Attempt to re-prime the pumps.
§If the error persists, do not run the Instrument, and call Technical Service.

1386

**Requested number of primes did not complete due to a Wash Pump 1 failure.**

Wash 1 Pump failed during a prime.

§Attempt to re-prime the pumps.
§If the error persists, do not run the Instrument, and call Technical Service.

1387

**Requested number of primes did not complete due to a Wash Pump 2 failure.**

Wash 2 Pump failed during a prime.

§Attempt to re-prime the pumps.
§If the error persists, do not run the Instrument, and call Technical Service.

1388

**Requested number of primes did not complete due to Tube Lifter 1 failure.**

Tube Lifter 1 failed during a prime.

§Attempt to re-prime the pumps.
§If the error persists, do not run the Instrument, and call Technical Service.

1389

**Requested number of primes did not complete due to Tube Lifter 2 failure.**

Tube Lifter 2 failed during a prime.

§Attempt to re-prime the pumps.
§If the error persists, do not run the Instrument, and call Technical Service.

1390

**Wash 2 Spinner has taken longer than 18 seconds.**

Wash 2 Spinner timed out. Instrument will be shut down. All tests on board are lost.

§Call Technical Service.

1391

**Wash 2 Spinner has failed to spin correctly.**

Bad Spin at Wash Station 2. Test will be marked bad and reordered.

§If this error persists, call Technical Service.

1392

**Wash Stations 1 and 2 both failed. Requested number of primes did not complete.**

An error occurred at both wash stations. The instrument cannot run until the errors are corrected.

§Call Technical Service.

1393

**We can not enter RUN because Wash Spinner 1 is not operating correctly.**

Wash Spinner 1 has failed during initialization. The instrument will not run until this error is corrected.

§Call Technical Service.

1394

**We can not enter RUN because Wash Spinner 2 is not operating correctly.**

Wash Spinner 2 has failed during initialization. The instrument will not run until this error is corrected.

§Call Technical Service.

1395

**Instrument is running with only one wash station. Call Technical Service.**

Wash station 1 was shut down as a result of a hardware problem.

§Call Technical Service.

1396

**Instrument is running with only one wash station. Call Technical Service.**

Wash station 1 was shut down as a result of a hardware problem

§Call Technical Service.

1398

**Instrument cannot enter RUN because both wash stations are disabled. Call Technical Service.**

Both wash stations have been shut down due to hardware problems. You can not run tests if none of the wash stations work.

§Call Technical Service.

1401

**Test designated bad - Allergen not found - Test rerun.**

Allergen necessary for ordered test was not found. Test was marked bad and reordered.

§Verify the correct allergen is on board, and rescan the wedge, or replace the allergen, as necessary.

1443

**Wash 1 transfer initialization step jammed during recovery.**

Wash Transfer 1 has jammed during initialization. Instrument will not run until this condition is corrected.

§Call Technical Service.

1445

**Wash 1 Transfer initialization step fatal timeout.**

Wash Transfer 1 has not responded in the allowable time. Instrument will not run until this condition is corrected.

§Call Technical Service.

1453

**Wash 2 Transfer initialization step jammed during recovery.**

Wash 2 Transfer has jammed during initialization. Instrument will not run until this condition is corrected.

§Call Technical Service.

1454

**Wash 2 Transfer step fatal timeout.**

Wash Station 2 has not responded in the allowable time. Instrument shutdown.

§Call Technical Service.

1481

**Exit Resource was not found during wash Station 1 recovery.**

Unexpected Error. Instrument is unable to schedule the removal of a tube marked bad, due to an error at Wash Station 1. Instrument shut down.

§Call Technical Service.

1482

**Exit Resource was not found during Wash Station 2 recovery.**

Unexpected Error. Instrument is unable to schedule the removal of a tube marked bad, due to an error at Wash Station 2. Instrument shut down.

§Call Technical Service.

1483

**Recover Resource Error during Wash Station 1 recovery.**

Unexpected Error. Instrument is unable to reschedule tests marked for Wash Station 1. Incubator 2 is shut down. Instrument will attempt to complete tests in the Luminometer.

§Call Technical Service.

1484

**Recover Resource Error during Wash Station 2 recovery.**

Unexpected Error. Instrument is unable to reschedule tests marked for Wash Station 2. Incubator 2 is shut down. Instrument will attempt to complete tests in the Luminometer.

§Call Technical Service.

1495

**Wash 1 Transfer home exceeded maximum steps.**

Unexpected Error. Wash Transfer 1 has been asked to move more than the allowable number of steps. Instrument will continue to run with Wash Station 1.

§Call Technical Service.

1497

**Requested belt move exceeds limits.**

Unexpected Error. Requested belt move exceeds limits.

§Allow Instrument to complete tests in progress.
§Call Technical Service.

1498

**Wash 2 Transfer home not found.**

Wash Transfer 2 has jammed looking for Home. Instrument will continue to run with Wash Station 1.

§Call Technical Service.

1500 - 1639

**An event semaphore timed out. Contact Technical Service.**

Unexpected Error.

§Call Technical Service.

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1641-1699

**An event semaphore timed out. Contact Technical Service.**

Unexpected Error.

§Call Technical Service.

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1700-1799

**A request mutex call timed out. Contact Technical Service.**

Unexpected Error - Request for a mutex.

§Call Technical Service.

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1877

**Flag not detected at sensor.**

A sensor was not found during a motor move. More specific errors will arise.

§Troubleshoot the additional errors as they arise.
§Call Technical Service.

---

1878

**Flag not detected a sensor due to a jam.**

A motor error has occurred. The Instrument will attempt to correct.

§Troubleshoot the additional errors as they arise.
§Call Technical Service.

---

1879

**Config.iml file is missing.**

The config.iml file is missing, or there are invalid values in config.iml. This file holds value for diagnostic configurations.

§Contact Technical Service

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1880

**Incubator Belt Transfer cannot find home.**

The Belt Transfer could not find its home sensor. This could indicate a bad motor, bad home sensor, or bad board (6)

§Call Technical Service.

1881

**Tube Lifter 1 is not at expected spin position.**

Tube Lifter 1 is in an unexpected position during a spin. This is likely due to a prior error.

§Call Technical Service.

1882

**Tube Lifter 2 is not at expected wash position.**

Tube Lifter 2 is in an unexpected position during a wash. This is likely due to a prior error

§Call Technical Service.

1883

**Tube Lifter 2 is not at expected spin position.**

Tube Lifter 2 is in an unexpected position during a spin. This is likely due to a prior error.

§Call Technical Service.

1884-1904

**Scheduler Error.**

The scheduler was unable to complete a test in progress due to a resource conflict.

§Allow the Instrument to complete tests in progress.
§Call Technical Service.

1905

**Assay time exceeds scheduler limit.**

The assay requires more time than the resource allocator will permit. The scanned kit barcode may contain invalid information.

§Allow instrument to complete tests in progress.
§Call Technical Service.

1906

**Assay cycles exceeds scheduler limit.**

The assay requires more time than the resource allocator will permit. The scanned kit barcode may contain invalid information.

§Allow instrument to complete tests in progress.
§Call Technical Service.

1907

**Tube designated bad - Reagent dispense not performed due to conflicting sample draw - Test Rerun.**

The reagent arm has been scheduled to dispense to Incubator Chain 1 on the same cycle as a sample transfer draw.

§The Instrument will continue to operate, unless other specific errors are raised.
§The test will be re-run.
§Call Technical Service.

1908

**No data available for next reagent dispense.**

A reagent dispense has been scheduled, but there is no data for the carousel or arm to act upon.

§Call Technical Service.

1909

**No data available for next sample pipette.**

A sample action has been scheduled, but there is no data for the carousel or arm to act upon.

§Call Technical Service.

1910

**Incubator 1 Belt shutting down. Incubator 2 Belt continues.**

The Incubator Chain 1 has shut down. Incubator Chain 2 is still attempting to process tests.

§Allow instrument to complete tests in progress.
§Call Technical Service.

1911

**Incubator 1 Belt flag not detected at sensor.**

Incubator 1 has failed to reach its position. The Instrument shut down, and all tests on board are lost.

§Call Technical Service.

1912

**Incubator 2 Belt flag not detected at sensor.**

Incubator 2 has failed to reach its position. The Instrument shut down, and all tests on board are lost.

§Call Technical Service.

1913

**Luminometer Belt flag not detected at sensor.**

The Luminometer Belt flag was not detected at the sensor. The Instrument shutdown, and all tests on board are lost.

§Call Technical Service.

1914

**Wash 1 position sensor can not find an empty baffle on Luminometer Belt.**

The Tube in Place sensor at the Luminometer Chain near Wash Station 1 can not find an empty baffle. This could be due to a bad TIP sensor.

§Call Technical Service.

1915

**Wash 2 position sensor can not find an empty baffle on Luminometer Belt.**

The Tube in Place sensor at the Luminometer Chain near Wash Station 2 can not find an empty baffle. This could be due to a bad TIP sensor.

§Call Technical Service.

1916

**Wash 1 failed. Wash 2 continues.**

Wash Station 1 has shut down. Wash Station 2 will attempt to process some tests.

§Allow instrument to complete tests in progress.
§Call Technical Service.

1917

**Wash 2 failed. Wash 1 continues.**

Wash Station 2 has shut down. Wash Station 1 will attempt to process some tests.

§Call Technical Service.

1918

**The second wash station has had a fatal error**

One of the wash stations had previously shut down. The second wash station just shut down. We will be in front-end shutdown.

§Allow instrument to complete tests in progress.
§Call Technical Service.

1919

**Scheduler Error.**

Unexpected Error – the Instrument will attempt to complete tests in the Luminometer. Incubator 1 and Incubator 2 have shut down.

§Call Technical Service.

1920

**Test designated bad - Wash 1 dispense failed - Test Rerun.**

A test is marked bad due to a bad pump in Wash Station 1. Two bad pumps in a row occurred which suggests a bad Wash 1 Linear Actuator pump.

§The Instrument will re-order a test and attempt to complete tests onboard. This error will be followed by Error 1916.
§Allow the Instrument to complete tests in progress.
§Call Technical Service.

1921

**Test designated bad - Wash 2 dispense failed - Test Rerun.**

A test is marked bad due to a bad pump in Wash Station 2. Two bad pumps in a row occurred which suggests a bad Wash 2 Linear Actuator pump.

§The Instrument will re-order a test and attempt to complete tests onboard. This error will be followed by Error 1917.
§Allow the Instrument to complete tests in progress.
§Call Technical Service.

1922

**Test designated bad - Wash 1 Transfer failed - Test Rerun.**

Wash Transfer 1 failed, and a test is marked bad.

§The Instrument will re-order a test and attempt to complete tests onboard. This error will be followed by Error 1916.
§Allow the Instrument to complete tests in progress.
§Call Technical Service.

1923

**Test designated bad - Wash 2 Transfer failed - Test Rerun.**

Wash Transfer 2 failed, and a test is marked bad.

§The Instrument will re-order a test and attempt to complete tests onboard. This error will be followed by Error 1917.
§Allow the Instrument to complete tests in progress.
§Call Technical Service.

1924

**Test designated bad - Tube Lifter 1 move failed - Test Rerun.**

Tube Lifter 1 failed, and a test is marked bad.

§The Instrument will re-order the test due to a Tube Lifter 1 error.

1925

**Test designated bad - Tube Lifter 2 move failed - Test Rerun.**

Tube Lifter 2 failed, and a test is marked bad.

§The Instrument will re-order the test due to the Wash Station 2 error.

1926

**Test designated bad - Tube Lifter 2 not in the up position - Test Rerun.**

Tube Lifter 2 is not in the expected position, and a test is marked bad.

§The Instrument will re-order the test due to the Tube Lifter 2 error.

1927

**Test designated bad - Wash 2 spin failed - Test Rerun.**

Tube Spinner 2 or Tube Lifter 2 has failed, and a test is marked bad.

§The Instrument will re-order the test lost due to the Wash Station 2 error.

1928

**Test designated bad - Wash 2 Transfer to Luminometer retry failed - Test Rerun.**

Wash Transfer 2 has failed to push a tube into the Luminometer Chain, and a test is marked bad.

§The Instrument will re-order the test lost due to the Wash Station 2 error

1931

**Incubator Belt Transfer home jammed during recovery.**

The Belt Transfer jammed while attempting to recover from a jam during a home. This may indicate a bad home sensor, motor, encoder, or board (6).

§Call Technical Service.

1932

**Incubator Belt Transfer home fatal timeout.**

The Belt Transfer has failed to respond to a home command within 18 seconds. This may indicate a bad backplane or board (6).

§Call Technical Service.

1934

**Tube designated bad - Incorrect substrate dispense - Test Rerun.**

Incorrect substrate dispense during run caused a tube re-order.

§While in Stop mode, examine the end of the substrate probe, and attempt to clean any substrate deposits.
§If this error occurs after cleaning the probe, call Technical Service.

1935

**Incorrect substrate dispense during priming.**

The substrate pump did not dispense the correct amount of fluid. This may be due to a defect in the substrate probe, calcification of substrate at the end of the probe, or a bad Substrate Linear Actuator pump.

§While in Stop mode, examine the end of the substrate probe, and attempt to clean any substrate deposits.
§If this error occurs after cleaning the probe, call Technical Service.

1936

**Substrate Pump has failed. Only tests in the Luminometer will complete.**

The substrate pump did not dispense the correct amount of fluid enough times that we will enter a front-end shutdown.

§Allow the Instrument to complete tests in progress.
§Call Technical Service.

1938

**Attenuator Disk home not found.**

The attenuator disk did not find its home. This may be due to a bad home sensor, motor, or board (3).

§Call Technical Service.

1940

**Rerun test designated bad by reagent pipetting error.**

Reagent arm failed to level sense. This may indicate a reagent pack that was not properly seated, a reagent pack lid that will not open easily, a bad level sensor, on an incorrect configuration of the Reagent Arm.

§While in Reagent Pause mode, check if the reagent marked bad is seated correctly, and verify if the lid allows access to the reagent by lightly pushing it.
§If the error still occurs once the wedge is checked, call Technical Service.

1941

**Scheduler Error**

The scheduler was unable to complete a test in progress due to a resource conflict.

§Allow the Instrument to complete tests in progress.
§Call Technical Service.

1942

**Scheduler Error**

The scheduler was unable to complete a test in progress due to a resource conflict.

§Allow the Instrument to complete tests in progress.
§Call Technical Service.

1943

**Sample data missing for a sample dilution or dispense.**

A sample dilution or dispense was ordered without the sample data. This defect is due to a bad barcode or a software defect.

§Attempt to re-scan the kit.
§If this error persists, call Technical Service.

1944

**Scheduler Error.**

There were 2 tests in a row that need a dilution at the beginning of the test .

§Test will be reordered.

1945

**Incubator Belt Transfer home sensor stuck on.**

The home sensor was found for the belt transfer where it wasn't expected. This could be a home sensor defect, a motor defect, or a board defect (6).

§Call Technical Service.

1946

**Incubator 1 Belt movement timeout. Incubator 1 will shut down.**

Incubator 1 will shut down, since it took too long to move. This could be due to a bad TimeCycl.iml, a motor, or board(2) problem.

§Call Technical Service.

1947

**Incubator 2 Belt movement timeout. Incubator 2 will shut down.**

Incubator 2 will shut down, since it took too long to move. This could be due to a bad TimeCycl.iml, a motor, or board(2) problem

§Allow the Instrument to finish tests in progress.
§Call Technical Service.

1948

**Luminometer Belt movement timeout. Luminometer will shut down.**

Luminometer will shut down, since it took too long to move. This could be due to a bad TimeCycl.iml, or a motor or board(3) problem.

§Allow the Instrument to finish tests in progress.
§Call Technical Service.

1950

**Pack Lid Opener jammed during recovery**

Reagent Opener open jammed during recovery. This could be due to a jammed reagent cover, a misconfigured pack lid opener, a bad sensor, motor, or board (1).

§The Instrument will attempt to clear the error and continue with the next test.
§If unable to clear the error, the Instrument will enter Reagent Pause.
§Call Technical Service.

1951

**Pack Lid Opener fatal timeout.**

Reagent Opener open fatal timeout. This may be due to a problem with a backplane or the board (1).

§Call Technical Service.

1952

**Pack Lid Opener exceeded maximum steps.**

Reagent Opener open did not find the sensor within the step parameters given to it via diagnostics' position.iml. This could be due to a bad sensor, configuration or board (1)

§Call Technical Service.

1954

**Pack Lid Opener home fatal timeout**

Reagent Opener home attempting recovery after jam. This could be due to a misconfigured Reagent Opener or Reagent Carousel, or a pack that is not properly seated, or that has a stuck lid.

§Call Technical Service.

1956-1964

**Scheduler Error**

The scheduler was unable to complete a test in progress due to a resource conflict.

§Allow the Instrument to complete tests in progress.
§Call Technical Service.

1965

**There are too many immortal threads.**

Unexpected software error.

§Place the Instrument in Pause mode to prevent new tests from loading.
§Call Technical Service.

1966

**Tube in Place Sensor error. Entering Stop Mode.**

A tube was detected at the Belt Transfer position on Inc2 when none was expected. This indicates a sensor malfunction. Note that errors 1966-1981 can be turned-off by an .iml file.

§Call Technical Service.

1967

**Tube in Place Sensor error. Entering Stop Mode.**

No tube was detected at the Belt Transfer position on Inc2 when one was expected. This indicates a sensor malfunction. Note that errors 1966-1981 can be turned-off by an .iml file.

§Call Technical Service.

1968

**Tube in Place Sensor error. Entering Stop Mode.**

A tube was detected at the Wash 1 position on Inc2 when none was expected. This indicates a sensor malfunction. Note that errors 1966-1981 can be turned-off by an .iml file.

§Call Technical Service.

1969

**Tube in Place Sensor error. Entering Stop Mode.**

No tube was detected at the Wash 1 position on Inc2 when one was expected. This indicates a sensor malfunction. Note that errors 1966-1981 can be turned-off by an .iml file. A tube was detected at the Wash 1 position on Inc2 when none was expected. This indicates a sensor malfunction. Note that errors 1966-1981 can be turned-off by an .iml file.

§Call Technical Service.

1970

**Tube in Place Sensor error. Entering Stop Mode.**

A tube was detected at the Wash 1 position on Inc2 when none was expected. This indicates a sensor malfunction. Note that errors 1966-1981 can be turned-off by an .iml file.

§Call Technical Service.

1971

**Tube in Place Sensor error. Entering Stop Mode.**

No tube was detected at the Wash 1 position on Inc2 when one was expected. This indicates a sensor malfunction. Note that errors 1966-1981 can be turned-off by an .iml file.

§Call Technical Service.

1972

**Tube in Place Sensor error. Entering Stop Mode.**

A tube was detected at the Wash 1 position on Inc2 when none was expected. This indicates a sensor malfunction. Note that errors 1966-1981 can be turned-off by an .iml file.

§Call Technical Service.

1973

**Tube in Place Sensor error. Entering Stop Mode.**

No tube was detected at the Wash 1 position on Inc2 when one was expected. This indicates a sensor malfunction. Note that errors 1966-1981 can be turned-off by an .iml file

§Call Technical Service.

1974

**Tube in Place Sensor error. Entering Stop Mode.**

A tube was detected at the Wash 1 position on Inc2 when none was expected. This indicates a sensor malfunction. Note that errors 1966-1981 can be turned-off by an .iml file.

§Call Technical Service.

1975

**Tube in Place Sensor error. Entering Stop Mode.**

A tube was detected at the Wash 2 position on Inc2 when none was expected. This indicates a sensor malfunction. Note that errors 1966-1981 can be turned-off by an .iml file.

§Call Technical Service.

1976

**Tube in Place Sensor error. Entering Stop Mode.**

No tube was detected at the Wash 2 position on Inc2 when one was expected. This indicates a sensor malfunction. Note that errors 1966-1981 can be turned-off by an .iml file

§Call Technical Service.

1977

**Tube in Place Sensor error. Entering Stop Mode.**

A tube was detected at the Wash 2 position on Inc2 when none was expected. This indicates a sensor malfunction. Note that errors 1966-1981 can be turned-off by an .iml file.

§Call Technical Service.

1978

**Tube in Place Sensor error. Entering Stop Mode.**

No tube was detected at the Wash 2 position on Inc2 when one was expected. This indicates a sensor malfunction. Note that errors 1966-1981 can be turned-off by an .iml file.

§Call Technical Service.

1979

**Tube in Place Sensor error. Entering Stop Mode.**

A tube was detected at the Wash 2 position on Inc2 when none was expected. This indicates a sensor malfunction. Note that errors 1966-1981 can be turned-off by an .iml file.

§Call Technical Service.

1980

**Tube in Place Sensor error. Entering Stop Mode.**

No tube was detected at the Wash 2 position on Inc2 when one was expected. This indicates a sensor malfunction. Note that errors 1966-1981 can be turned-off by an .iml file.

§Call Technical Service.

1981

**Tube in Place Sensor error. Entering Stop Mode.**

A tube was detected at the Wash 2 position on Inc2 when none was expected. This indicates a sensor malfunction. Note that errors 1966-1981 can be turned-off by an .iml file

§Call Technical Service.

1982

**Invalid tube detected in Luminometer at Wash Station 1**

At the end of clearing tubes off of the system, a tube was detected on the Luminometer near wash station 1. This probably indicates that this sensor is stuck high.

§The Instrument will not run until this condition is corrected.
§Call Technical Service.

1983

**Invalid tube detected in Luminometer at Wash Station 2**

At the end of clearing tubes off of the system, a tube was detected on the Luminometer near wash station 2. This probably indicates that this sensor is stuck high.

§Call Technical Service.

1984

**A test assigned to Wash Station 1 was reordered because of the wash station failure.**

Wash Station 1 failed because of a jam. Wash Station 2 is still alive. All tests in the incubator that were to use Wash Station 1 are reordered

§Call Technical Service.

1985

**A test assigned to Wash Station 2 was reordered because of the wash station failure.**

Wash Station 2 failed because of a jam. Wash Station 1 is still alive. All tests in the incubator that were to use Wash Station 2 are reordered

§Call Technical Service.

1986

**Test designated bad - Wash 1 failed - Test Rerun.**

Wash Station 1 had a Bad Spin. The test where the bad spin occurred will be marked bad and reordered.

§Call Technical Service.

10903

**A serious error has occurred with the hepatitis confirmatory test feature. Communications to the LIS**

**has been paused. Please do not reactivate LIS communication and contact Technical Service.**

Database error occurred while sending a report to LIS.

§Call Technical Service.

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**11503**

**8 adjustors are needed. Less than 8 adjustors have been ordered**

One or more of the eight adjustors was deleted or the Instrument was unable to pipette all eight adjustor samples. Adjustment cannot be calculated.

§Check error log for associated errors that need to be resolved.
§If the message persists, call Technical Service.

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**11509**

**Incorrect Kit Parameters**

Scanned kit parameters are incorrect.

§Re-scan the kit.

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**11510**

**Division by zero while transforming dose to golden counts**

Division by zero.

§Call Technical Service.

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**11511**

**CV of Low adjustors not within limit**

Precision of the low adjustor is greater than 10 or 15 %.

§Check associated error messages to determine cause.
§Ensure sufficient volume of adjustor.

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**11512**

**Log(0) or Log(-x) are illegal - Adjustor concentration error**

Adjustment concentration error.

§Call Technical Service.

11513

**CV of High adjustors not within limit**

Precision of the high adjustor is greater than 15%.

§Check associated error messages to determine cause.
§Ensure sufficient volume of adjustor.

11515

**CV of both High and Low adjustors not within limit**

Precision of the low and high adjustors are greater than 10 or 15 %.

§Check associated error messages to determine cause.
§Ensure sufficient volume of adjustor.

11516

**Mean of Low adjustors = 0**

Malfunctioning PMT

§Call Technical Service.

11517

**Mean of High adjustors = 0**

Malfunctioning PMT

§Call Technical Service.

11701

**No Unique Record ID passed to update in worklist object. Contact Technical Service**

While working in the Worklist screen the operator tried to order a test for which a unique record ID was not generated by the system.

§Call Technical Service.

11702

**There is no accession number passed to the worklist object. Contact Technical Service.**

While working in the Worklist screen the operator tried to order a test for which no accession number had been assigned by the system.

§Call Technical Service.

11703

**Attempted to save a record in the worklist but the test is not in the data base**

Attempted to save an imported record from a worklist file or the LIS to the Worklist but the test is not in the data base

§Ensure the kits are in the database.
§If the message persists, call Technical Service.

11704

**This adjustor is already in progress. You need to wait until it is completed to order another one.**

The operator attempted to order a second adjustment for the same kit and lot before one ordered had been completed.

§Wait for initial adjustment to be completed.
§Check the error log for kit errors that need to be resolved.
§If the message persists, call Technical Service.

11705

**This control information does not match what is currently on the system. Record cannot be added at this time. Check your information and try again.**

This control information does not match what is currently on the system. Record cannot be processed.

§Verify that control information, such as lot number and expiration date, is entered correctly.
§If the message persists, call Technical Service.

11800

**Cannot open the DPR path. Startup aborted**

Communication between the User and Control sides cannot be opened.

§Call Technical Service.

11801

**Semaphore failure. Startup Aborted.**

Semaphore failure. Startup Aborted.

§Call Technical Service.

11802

**DPR WRITE failure. Startup Aborted.**

There is a failure of communication between the User and Control side because of a DPR WRITE failure. Startup Aborted.

§Call Technical Service.

11803

**DPR READ failure. Startup Aborted.**

There is a failure of communication between the User and Control side because of a DPR READ failure. Startup Aborted.

§Call Technical Service.

11804

**Communication could not be established with instrument.**

Communication between the User and Control sides cannot be established.

§Call Technical Service.

11805

**The instrument is in Panic Mode. Hit Run to try to run again or log off.**

The instrument is in Stop Mode due to a mechanical jam or similar error.

§Check associated error message to determine cause.
§If the message persists, call Technical Service.

11806

**No Value for Head Pointer**

Problem was encountered when reading the head pointer from a queue.

§Call Technical Service.

11807

**No Value for Tail Pointer**

Problem was encountered when reading the tail pointer from a queue.

§Call Technical Service.

11808

**Problem Incrementing Pointer**

Problem was encountered when a pointer from a queue was incremented.

§Call Technical Service.

| | |
|---|---|
| 11809 | **Error while getting instrument status in initialization**<br>Error while getting instrument status in initialization<br>§Call Technical Service. |
| 12000 | **Control Computer did not shut down properly**<br>MCP was not properly exited when trying to go into Stop or when Logging off. Control side is in host mode.<br>§Call Technical Service. |
| 12001 | **Kit Not Adjusted**<br>For some reason the adjustment was not completed.<br>§Run the kit adjustment.<br>§Check the error log for other issues that need to be addressed.<br>§If the message persists, call Technical Service. |
| 12002 | **Unrecognized Reagent on board for test. Cannot run test.**<br>The kit information has not yet been entered into the database.<br>§Scan and adjust the kit and then attempt to run the test again.<br>§If the message persists, call Technical Service. |
| 12003 | **No reagent on board to run test.**<br>The software does not register the reagent barcode as being present on the reagent carousel.<br>§Verify that sufficient and correct reagents are on board.<br>§Verify kit is scanned into database.<br>§Inspect reagent barcode label for damage.<br>§Ensure Wedge is seated correctly.<br>§If the message persists, call Technical Service. |

12004

**Not enough reagent to run test.**

The indication in the software is that the amount of reagent remaining in Wedge is insufficient to run tests

§Verify that sufficient and correct reagents are on board.
§If the message persists, call Technical Service

12005

**Unrecognized bead on board for test. Cannot run test.**

The kit information has not yet been entered into the database.

§Verify beads are on board.
§Verify kit is scanned into database.
§Ensure Bead Pack is seated correctly.
§If the message persists, call Technical Service.

12006

**No beads on board to run test.**

The software does not register the bead bar code as being present on the bead carousel.

§Verify that sufficient and correct beads are on board.
§Verify kit is scanned into database.
§Inspect bead barcode label for damage.
§Ensure Bead Pack is seated correctly.
§If the message persists, call Technical Service.

12007

**Not enough beads to run test.**

The indication in the software is that the amount of beads remaining in the pack is insufficient to run tests.

§Verify that sufficient and correct beads are on board and add as necessary.
§If the message persists, call Technical Service.

12008

**There is no diluent sample tube on board to run test.**

The software does not register the diluent bar code as being present on the sample carousel.

§Check the barcode is facing out.
§Place sample diluent on board.
§Check for the correct sample diluent.

12009

**Problem Retrieving Tail Pointer from the Loader Q**

Tail pointers are used to determine the number of tests in queue. When calculating time to result and when checking to see if loader or STAT queue is empty, the User side requests the Tail Pointer from the DPR. If the Tail Pointer is not obtained, this error is posted.

§Call Technical Service.

12010

**Problem Retrieving Head Pointer from the Loader Q**

Head pointers are used to determine the number of tests in queue. When calculating time to result and when checking to see if loader or STAT queue is empty, the User side requests the Head Pointer from the DPR. If the Head Pointer is not obtained, this error is posted.

§Call Technical Service.

12100

**Trying to insert unknown result record from result buffer!**

The test record has been deleted before the test resulted.

§Confirm that the record was not deleted from the LIS screen.
§Confirm that a record was not deleted from the Worklist.
§If the message persists, call Technical Service.

12101

**Print Report Function Error**

General error indicating an error occurred when a report was being generated for the printout

§Check for ink in the ink cartridges.
§Check for printer paper.
§Ensure the printer power is on.
§If the message persists, call Technical Service.

12102

**Error occurred inserting 0 into reserved space**

Software communication error.

§Call Technical Service.

12103

**Error occurred inserting record into STAT loader queue**

Software communication error.

§Call Technical Service.

12104

**STAT Loader queue Pointer not updated properly**

An error occurred when attempting to increment the STAT loader queue pointer.

§Call Technical Service.

12105

**Problem Retrieving Head Pointer from the Routine Q**

During the function that checks to see if the Control side has updated the loader queue, a problem occurred in retrieving the Head pointer.

§Call Technical Service.

12106

**Error occurred inserting record into Routine loader queue**

An error occurred while inserting a record into the Routine loader queue.

§Call Technical Service.

12107

**Routine Loader queue Pointer not updated properly**

An error occurred when attempting to increment the Routine loader queue

§Call Technical Service.

12108

**Problem retrieving Result Buffer Head Pointer**

During the function that checks to see if the Control side has updated the Result Buffer, a problem occurred in retrieving the Head pointer.

§Call Technical Service.

12109

**Problem retrieving Result Buffer Tail Pointer**

During the function that checks to see if the Control side has updated the Result Buffer, a problem occurred in retrieving the Tail pointer.

§Call Technical Service.

12110

**Problem Retrieving Head Pointer from the Routine Q**

During the function that checks to see if there is a free space in the routine loading queue to insert another record, an error was detected when retrieving the Head Pointer.

§Call Technical Service.

12111

**Problem Retrieving Tail Pointer from the Routine Q**

During the function that checks to see if there is a free space in the routine loading queue to insert another record, an error was detected when retrieving the Tail Pointer.

§Call Technical Service.

12112

**Problem Retrieving Head Pointer from the STAT Q**

During the function that checks to see if there is a free space in the STAT queue to insert another record, an error was detected when retrieving the Head Pointer.

§Call Technical Service.

12113

**Problem Retrieving Tail Pointer from the STAT Q**

During the function that checks to see if there is a free space in the STAT queue to insert another record, an error was detected when retrieving the Tail Pointer.

§Call Technical Service.

12114

**Test in progress deleted during initialization.**

If the worklist is deleted during initialization, this error indicates that deleted items were still in progress. This occurs only after the user-side computer was previously shut down (e.g., run time error, emergency shut down) while tests were still in progress.

§Call Technical Service.

12115

**Instrument running with Clot Detection Deactivated.**

Upon Initialization, the program has determined that Clot detection is turned off and warns the user that they may not want to operate the instrument in this mode.

§Call Technical Service.

12116

**Unable to determine Clot Detection status.**

Upon Initialization, the program to trying to determine if the clot detection is on or off, if this error occurs it is because of a DPRAM, semaphore issue or an inability of the Control side to read the Board.iml file.

§Call Technical Service.

12300

**LIS- Carriage return or Line Feed missing from message.**

Carriage return and/or Line Feed are required but missing from the message.

§Contact your laboratory LIS provider.
§If the message persists, call Technical Service.

12301

**LIS- Incorrect or Missing Frame Number.**

The frame number for a message is not present or is an incorrect value

§Contact your laboratory LIS provider.
§If the message persists, call Technical Service.

12302

**LIS- Incorrect Checksum.**

The checksum, a scheme to indicate whether a message was received properly, is incorrect.

§Contact your laboratory LIS provider.
§If the message persists, call Technical Service.

12303

**LIS- Message is too short (< 5 characters).**

LIS message received is less than the requisite five characters.

§Contact your laboratory LIS provider.
§If the message persists, call Technical Service.

12304

**LIS- Invalid Password in Header Message.**

The Password received does not match the Password entered in the LIS configuration.

§Contact your laboratory LIS provider.
§If the message persists, call Technical Service.

12305

**LIS- Invalid Sender ID in Header Message.**

The Sender ID received from the LIS does not match the Sender ID entered on the LIS configuration screen.

§Contact your laboratory LIS provider.
§If the message persists, call Technical Service.

12306

**LIS- Invalid Receiver ID in Header Message.**

The Receiver ID received from the LIS does not match the Receiver ID entered on the LIS Configuration screen.

§Contact your laboratory LIS provider.
§If the message persists, call Technical Service.

12307

**LIS- No Header message received.**

Records were received from the LIS without a header message.

§Contact your laboratory LIS provider.
§If the message persists, call Technical Service.

12308

**LIS- Several LIS errors have occurred the past hour. There may be a communication Problem.**

Multiple communication errors occurred between the LIS and the IMMULITE 2000 within an hour.

§Contact your laboratory LIS provider.
§If the message persists, call Technical Service.

12309

**LIS- Null or Missing Patient ID in Patient Record.**

The Patient ID field, a required field in the patient message, is not present.

§Contact your laboratory LIS provider.
§If the message persists, call Technical Service.

12310

**LIS- Invalid Test Code or Format in Order record.**

The test code in an order message from the LIS does not match any of the test codes entered on the IMMULITE 2000.

§Call Technical Service.

12311

**LIS- LIS cannot accept message after sending message 7 times.**

The IMMULITE 2000 unsuccessfully attempted to send a message to the LIS seven times before communication was aborted

§Contact your laboratory LIS provider.
§If the message persists, call Technical Service.

12312

**LIS- Time-out, 30 seconds expired and no data was received from LIS.**

After the initial data was received from the LIS and a response was sent, additional data was not received within 30 seconds and communication was aborted.

§Contact your laboratory LIS provider.
§If the message persists, call Technical Service.

12313

**LIS- EOT received prematurely while receiving data.**

An EOT was sent before the transmission was completed.

§Contact your laboratory LIS provider.
§If the message persists, call Technical Service.

12314

**LIS- An error occurred sending LIS query request. Host query aborted.**

An unrecognized error occurred when sending a query to the LIS.

§Contact your laboratory LIS provider.
§If the message persists, call Technical Service.

12315

**LIS-Time-out, No response from LIS after waiting 15 seconds.**

After data was sent from the IMMULITE 2000 to the LIS, there was no response and communication was aborted.

§Contact your laboratory LIS provider.
§If the message persists, call Technical Service.

12316

**LIS- <ENQ> Contention.**

The LIS was attempting to communicate with the IMMULITE 2000 at the same time that the IMMULITE 2000 was attempting to communicate with the LIS.

§Contact your laboratory LIS provider.
§If the message persists, call Technical Service.

12317

**LIS- No accession number in order record.**

An accession number was missing from an order message received from the LIS.

§Contact your laboratory LIS provider.
§If the message persists, call Technical Service.

12318

**LIS- The LIS encountered an error for a query.**

The LIS informed the IMMULITE that the LIS encountered an error in a request for a patient record from a query message.

§Contact your laboratory LIS provider.
§If the message persists, call Technical Service.

12319

**LIS- The LIS has no information for a record when queried.**

The IMMULITE 2000 requested information from the LIS regarding a particular sample that the LIS did not have

§Contact your laboratory LIS provider.
§If the message persists, call Technical Service.

12320

**LIS- An invalid terminator code was received from the LIS.**

An invalid or unsupported terminator code was received from the LIS.

§Contact your laboratory LIS provider.
§If the message persists, call Technical Service.

12321

**LIS- Unique ID does not match retrieved file. Please call Technical Service.**

All records are stored on the IMMULITE 2000 with a unique number. A retrieved file was expected to have a particular number and was incorrect.

§Call Technical Service.

12322

**LIS- Record could not be marked sent, record not found.**

A sent record could not be found in the database to be sent to the LIS.

§Call Technical Service.

12323

**LIS- Record could not be sent to LIS, record not found.**

A tagged record could not be found in the data base to be sent to the LIS.

§Call Technical Service.

12324

**LIS- There are no "TAGGED" records to sent to the LIS.**

The operator pressed the Send or **Re-Send** buttons on the LIS screen and no records are tagged.

§Call Technical Service.

12325

**LIS- You can only display 10,000 records at one time.**

More than 10,000 records meet the search criteria and the LIS screen cannot display more than 10,000.

§Call Technical Service.

12326

**LIS- Received Order Record before Patient Record.**

The patient message must precede the order message in the LIS message. The LIS has received the order message before receiving the patient message.

§Contact your laboratory LIS provider.
§If the message persists, call Technical Service.

12327

**LIS: Data is being received from the LIS or IMMULITE is already sending data to the LIS.**

The LIS is currently receiving data or the IMMULITE is actively sending data to the LIS.

§Contact your laboratory LIS provider.
§If the message persists, call Technical Service.

12328

**LIS- LIS reports an error in query request.**

There was an error in the query request as it was sent from the IMMULITE to the LIS.

§Contact your laboratory LIS provider.
§If the message persists, call Technical Service.

12329

**LIS- LIS reports no information for Accession Number in query request.**

There was no information for an Accession number in a query.

§Contact your laboratory LIS provider.
§If the message persists, call Technical Service.

12330

**LIS- An error occurred sending LIS query request. Host query aborted.**

An unrecognized error occurred when sending a query to the LIS.

§Contact your laboratory LIS provider.
§If the message persists, call Technical Service.

12331

**LIS- Parse error occurred when downloading in Control format.**

The Control information was sent from the LIS in the wrong format.

§Contact your laboratory LIS provider.
§If the message persists, call Technical Service.

12332

**LIS- Parse error occurred when downloading in Adjustor format.**

The Adjustor information was sent from the LIS in the wrong format.

§Contact your laboratory LIS provider.
§If the message persists, call Technical Service.

12333

**LIS- Control downloaded from LIS is new to the system.**

The control requested in the download from LIS is new to the system.

§Call Technical Service.

12334

**LIS- Parse error occurred when downloading in Verifier format.**

The Calibration verifier information was sent from the LIS in the wrong format.

§Contact your laboratory LIS provider.
§If the message persists, call Technical Service.

12335

**LIS- Sort Error**

An error was exhibited when trying to sort in the LIS.

§Call Technical Service.

12336

**LIS- Mail Error**

An application error generated when the mail procedure was running.

§Call Technical Service.

12337

**LIS- Display Error**

An application error generated when the display procedure was running.

§Call Technical Service.

12338

**LIS- Record Count Error**

An application error generated when the record count procedure was running.

§Call Technical Service.

12339

**LIS- Send LIS Error**

An application error generated when the mail procedure was running.

§Call Technical Service.

12340

**LIS- Sort Error**

An LIS Data Management Screen error – this occurs when sorting by accession number.

§Call Technical Service.

12341

**LIS- Check Message Error**

An error occurred in the Check Sum Message routine when building the message.

§Call Technical Service.

12342

**LIS- Parse Error**

A programmer error was generated during the parsing routine.

§Call Technical Service.

12343

**LIS- Listen Error**

A programmer error occurred when receiving information from the LIS.

§Call Technical Service.

12344

**LIS- Check Error**

A check sum error occurred within the LIS program.

§Call Technical Service.

12400

**Substrate Low.**

The substrate load scale indicates that the volume of fluid remaining in the bottle is lower than the warning level as configured in the database.

§Replenish the Substrate Bottle.
§Check the position of the Substrate Bottle on the load scale.
§If the message persists, call Technical Service.

**Note:** The Instrument continues to process tubes through the Luminometer and flags all bad results. These tests must be repeated.

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12401

**Substrate Empty.**

The substrate load scale indicates that the volume of fluid remaining in the bottle is lower than the low level as configured in the database.

§Replenish the Substrate Bottle.
§Check the position of the Substrate Bottle on the load scale.
§If the message persists, call Technical Service.

**Note:** The Instrument continues to process tubes. These tests must be repeated.

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12402

**Trigger A Low.**

The Trigger A load scale indicates that the volume of fluid remaining in the bottle is lower than the warning level as configured in the database. The Trigger A load cell is not currently active.

§Call Technical Service.

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12403

**Trigger A Empty.**

The Trigger A load scale indicates that the volume of fluid remaining in the bottle is lower than the low level as configured in the database. The Trigger A load cell is not currently active.

§Call Technical Service.

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12404

**Trigger B Low.**

The Trigger B load scale indicates that the volume of fluid remaining in the bottle is lower than the warning level as configured in the database. The Trigger B load cell is not currently active.

§Call Technical Service.

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12405

**Trigger B Empty.**

The Trigger B load scale indicates that the volume of fluid remaining in the bottle is lower than the low level as configured in the data base. The Trigger B load cell is not currently active.

§Call Technical Service.

12406

**Probe Wash Low.**

The Probe Wash load scale indicates that the volume of fluid remaining in the bottle is lower than the warning level as configured in the database.

§Refill the Probe Wash Bottle.
§Ensure Probe Wash bottle is level on the Load Scale.
§Check to see if the tubing is tucked inside the Instrument and does not interfere with the front doors. If the doors are closed on the tubing, it can tip the bottle.
§If the message persists, call Technical Service.

**Note:** The Instrument continues to process tubes. These tests must be reviewed.

12407

**Probe Wash Empty.**

The Probe Wash load scale indicates that the volume of fluid remaining in the bottle is lower than the low level as configured in the database.

§Refill the Probe Wash Bottle.
§Ensure Probe Wash bottle is level on the Load Scale.
§Check to see if the tubing is tucked inside the Instrument and does not interfere with the front doors. If the doors are closed on the tubing, it can tip the bottle.
§If the message persists, call Technical Service.

**Note:** The Instrument continues to process tubes. These tests must be repeated.

12408

**Water Supply Low.**

The Water Supply load scale indicates that the volume of fluid remaining in the bottle is lower than the warning level as configured in the database.

§Refill the Water Supply Bottle.
§Ensure Water Supply bottle is level on the Load Scale.
§Check to see if the tubing is tucked inside the Instrument and does not interfere with the front doors. If the doors are closed on the tubing, it can tip the bottle.
§If the message persists, call Technical Service.

**Note:** The Instrument continues to process tubes. These tests must be reviewed.

12409

**Water Supply Empty.**

The Water Supply load scale indicates that the volume of fluid remaining in the bottle is lower than the low level as configured in the database.

§Refill the Water Supply Bottle.
§Ensure Water Supply bottle is level on the Load Scale.
§Check to see if the tubing is tucked inside the Instrument and does not interfere with the front doors. If the doors are closed on the tubing, it can tip the bottle.
§If the message persists, call Technical Service.

**Note:** The Instrument continues to process tubes These tests must be repeated

12410

**Liquid Waste Almost full.**

The Liquid Waste load scale indicates that the volume of fluid remaining in the bottle exceeds the warning level as configured in the database.

§Empty the Liquid Waste Container.
§Ensure Liquid Waste bottle is level on load Scale.
§If the message persists, call Technical Service.

12411

**Liquid Waste FULL.**

The Liquid Waste load scale indicates that the volume of fluid remaining in the bottle exceeds the full level as configured in the database.

§Empty the Liquid Waste Container.
§Ensure Liquid Waste bottle is level on load scale.
§If the message persists, call Technical Service.

12412

**Solid Waste Almost Full.**

The Solid Waste load scale indicates that the weight of the Solid Waste Container exceeds the warning level as configured in the database.

§Empty the Solid Waste Container.
§Ensure Solid Waste Container is level on Load Scale.
§If the message persists, call Technical Service.

12413

**Solid Waste FULL.**

The Solid Waste load cell indicates that the weight of the Solid Waste Container exceeds the full level as configured in the database.

§Empty the Solid Waste Container.
§Ensure Solid Waste Container is level on Load Scale.
§If the message persists, call Technical Service.

12414

**Tube hopper requires refilling.**

The tube hopper sensor indicates that the level of tubes in the hopper has fallen below the low sensor.

§Check Reaction Tube level and fill as necessary.
§Manually move tubes around to cover the upper sensor.
§If the message persists, call Technical Service.

12415

**Tube Hopper Elevator Error**

Something interfered with the Tube Hopper Elevator's ability to move tubes from the Tube Hopper.

§Open the Tube Hopper and check the elevator path for a jam. Clear any jams.
§If the message persists, call Technical Service.

12500

**Luminometer Temperature Low [Low Severity]**

The temperature in the Luminometer is below the acceptable range.

§Monitor temperature for two hours to determine if temperature is coming into range.
§If the message persists, call Technical Service.

12501

**Luminometer Temperature High [Low Severity]**

The temperature in the Luminometer is above the acceptable range.

§Monitor temperature for two hours to determine if temperature is coming into range.
§If the message persists, call Technical Service.

12502

**Incubator Temperature Low [Low Severity]**

The temperature in the Incubator is below the acceptable range.

§Monitor temperature for two hours to determine if temperature is coming into range.
§If the message persists, call Technical Service.

12503

**Incubator Temperature High [Low Severity]**

The temperature in the Incubator is above the acceptable range.

§Monitor temperature for two hours to determine if temperature is coming into range.
§If the message persists, call Technical Service.

12504

**Reagent Temperature Low**

The temperature in the Reagent Carousel is below the acceptable range.

§Monitor temperature for two hours to determine if temperature is coming into range.
§If the message persists, call Technical Service.

12505

**Reagent Temperature High**

The temperature in the Reagent Carousel is above the acceptable range.

§Monitor temperature for two hours to determine if temperature is coming into range.
§If the message persists, call Technical Service.

12506

**Substrate Temperature Low**

The temperature of the Substrate Probe is below the acceptable range.

§Monitor temperature for two hours to determine if temperature is coming into range.
§If message persists, call Technical Service.

12507

**Substrate Temperature High**

The temperature of the Substrate Probe is above the acceptable range.

§Monitor temperature for two hours to determine if temperature is coming into range.
§If the message persists, call Technical Service.

12508

**Instrument Ambient Temperature Under Cover High**

Indicates that the ambient temperatures under the Instrument cover are above the acceptable range.

§Call Technical Service.

12509

**Bead chamber humidity High for more than 50 cycles**

The humidity reported from the Bead Chamber was above 20% relative humidity for more than 50 cycles.

§Check for high ambient humidity.
§Check to see if the Instrument was left in Diagnostics.
§If the message persists for more than 6 hours, call Technical Service.

12510

**Luminometer Temperature Low**

The temperature of the Luminometer is below the acceptable range.

§Monitor temperature for two hours to determine if temperature is coming into range.
§If the message persists, call Technical Service.

12511

**Luminometer Temperature High**

The temperature of the Luminometer is above the acceptable range.

§Monitor temperature for two hours to determine if temperature is coming into range.
§If the message persists, call Technical Service.

12512

**Incubator Temperature Low**

The temperature of the Luminometer is below the acceptable range.

§Monitor temperature for two hours to determine if temperature is coming into range.
§If the message persists, call Technical Service.

12513

**Incubator Temperature High**

The temperature of the Luminometer is above the acceptable range.

§Monitor temperature for two hours to determine if temperature is coming into range.
§If the message persists, call Technical Service.

12514

**Temperature Mail Event Error**

An error occurred during temperature data collection.

§Call Technical Service.

12600

**Kit found but no matching Volume data. Call Technical Service.**

Information for this kit is missing from the volume table of the main database.

§Call Technical Service.

12601

**Dark count has exceeded the defined limit.**

Dark count has exceeded the defined limit.

§Call Technical Service.

12602

**Dark count is excessively high. Result is invalid. Please notify Technical Service**

Dark count is excessively high.

§Call Technical Service.

12603

**Result cannot be calculated. Kit lot deleted from database.**

Kit lot not in database; deleted during run.

§Rescan kit lot.
§Rerun adjustments, controls, and/or patients.
§If the message persists, call Technical Service.

12604

**The Accession Number has been overwritten.**

Operator overwrote accession number.

§Result may be invalid. Confirm results and/or rerun sample.

12605

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This error will only be seen in conjunction with Event 12604. It allows the software to post the original accession number.

§See Event 12604.

12606

**Multiple racks have been identified with the same rack letter. Please remove all duplicates.**

Multiple racks on board with the same rack letter.

§Remove duplicate racks from sample carousel.

12607

**Error occurred while printing. Verify all results have printed.**

The printer is not installed or the print spooler is disabled.

§Make sure that the printer cartridges are full and installed correctly.
§Check for printer jams.
§If the message persists, call Technical Service.

13000

**Invalid Data was received from the scanner**

Bad scan of the Allergen Wedge barcode. No Allergen Wedge information appears on the reagent screen.

§Call Technical Service.

13001

**Duplicate allergen wedge id.**

There are multiple Allergen Wedges with the same ID.

§Remove duplicate wedges.

13002

**One or more accession numbers on the sample carousel contains an invalid character.**

Invalid character used in the sample barcode

§Enter sample ID manually.
§If the message persists, call Technical Service.

14000

**(Error Number): Unexpected Error. Please Contact Technical Service.**

An unexpected software error has occurred.

§Write down the exact message on the screen for further troubleshooting.
§Call Technical Service.

14001

**Unable to request Dual Port Ram Message Semaphore.**

User software was unable to communicate with the DPR.

§The Instrument will try again. This error will occur periodically during normal operation. Continued instances of this error will lead to other more severe errors.

14011

**Unable to determine current instrument mode.**

The Control computer was unable to determine which mode (Integrated or Non-Integrated) was selected on the analyzer.

§Call Technical Service.

14012

**Unable to set integrated mode on control PC. Please Contact Technical Service**

The Control computer was not set to the Integrated mode that was selected on the analyzer.

§Call Technical Service.

14013

**Unable to set integrated mode on User PC. Please Contact Technical Service.**

The User computer was not set to the Integrated mode that was selected on the analyzer.

§Call Technical Service.

14014

**Unable to set non-integrated mode on Control PC. Please Contact Technical Service.**

The Control computer was not set to the Integrated mode that was selected on the analyzer.

§Call Technical Service.

14015

**Unable to set non-integrated mode on User PC. Please Contact Technical Service.**

The User computer was not set to the Integrated mode that was selected on the analyzer.

§Call Technical Service.

14016

**Database error.**

A problem occurred while querying the worklist for orders.

§Call Technical Service.

14017

**Unable to read the Auto-Rack data.**

An error occurred while trying to get the auto rack data from the DPRam.

§Call Technical Service.

14019

**Unable to update loader queue.**

While using SMS to process orders, an error occurred when trying to load a work order into the Loader queue.

§Processing will continue, but if an error occurs multiple times, call Technical Service.

14020

**Error occurred while sending query to the LIS.**

While the SMS was querying the LIS for a specific accession number, an error occurred.

§Processing will continue, but if an error occurs multiple times, call Technical Service.

14030

**Automation Rack cannot be used to process Control, Adjustor or Verifier.**

A control, adjustor, or verifier was placed on the SMS.

§Rerun the test after placing the control, adjustor, or verifier on the Sample Carousel of the analyzer.
§If the message persists, call Technical Service.

14031

**Please check the LIS screen to verify that all records are untagged. Call Technical Service**

When switching from Integrated to Non-integrated mode, an error occurred while the LIS result records were being untagged.

§Call Technical Service.

14032

**Changed to non-integrated mode. All result records have been untagged.**

When switching between Integrated and Non-integrated modes, all result records are untagged, possibly preventing some records from being sent to the LIS.

§Go to the LIS screen.
§Manually tag results and resend.
§If the message persists, call Technical Service.

14033

**System ordered tests may not have been sent to the worklist. Please Call Technical Services.**

§Call Technical Service.

**14034**

**Error building or sending system ordered test to the Versacell.**

An error occurred when the tests in the SMSHold table in the main data file were being retrieved to sent to the VersaCell, or when the orders are being deleted from the SMSHold table after being retrieved

**14035**

**Error retrieving or deleting records to send to VersaCell.**

An error occurred when test order messages are being created or while they are being transmitted from the IMMULITE 2000/2500 to the VersaCell. (ASTM protocol is used for these messages)

**14036**

**Please select Run VersaCell from the VersaCell start screen.**

VersaCell not running

§If the instrument is in integrated mode, startup the VersaCell program from the Desktop.

**14040**

**Error With Work Order Time Out.**

A sample tube was placed on an Instrument, but an order was not received. This can occur because the order was deleted on the Instrument, but not on the SMS, or because the order was sent to the Instrument, but not saved (e.g., a "~C" control was placed on the SMS).

§If the order was intentionally deleted on the Instrument, delete it on the SMS, re-query as necessary, ensure the query option is active, and run the test manually.
§Do not put "~C" controls on the SMS.
§If the message persists, call Technical Service.

**15000**

**(Acc #): Invalid Online Dilution has been ordered for the sample. Test not run.**

Invalid dilution ordered.

§Reorder the dilution using a valid selection.
§If the message persists, call Technical Service.

15100

**Database Error - Cannot retrieve the dilution factor. Results may not be valid. Call Technical Service.**

While accessing information on the Find/Display screen an error occurred while retrieving a dilution factor from result information.

§Call Technical Service.

15101

**Adjustor CPS Value equal 0. Please notify Technical Service immediately.**

Kit information was correctly scanned into database, or possible database corruption.

§Call Technical Service.

15102

**Error calibrating Substrate Load Scale. Contact Technical Service for assistance.**

While trying to calibrate the Substrate Load scale, an error occurred. The value returned is not acceptable and the default value will be used.

§Call Technical Service.

15103

**Error calibrating ProbeWash Load Scale. Contact Technical Service for assistance.**

While trying to calibrate the Probe Wash Load scale an error occurred. The value returned is not acceptable and the default value will be used.

§Call Technical Service.

15104

**Error calibrating Water Load Scale. Contact Technical Service for assistance.**

While trying to calibrate the Water Load scale an error occurred. The value returned is not acceptable and the default value will be used.

§Call Technical Service.

15105

**Error calibrating Liquid Waste Load Scale. Contact Technical Service for assistance.**

While trying to calibrate the Liquid Waste Load scale an error occurred. The value returned is not acceptable and the default value will be used.

§Call Technical Service.

15106

**Error calibrating Solid Waste Load Scale. Contact Technical Service for assistance.**

While trying to calibrate the Solid Waste Load scale an error occurred. The value returned is not acceptable and the default value will be used.

§Call Technical Service.

15107

**Error in result calculation.**

When calculating the dose, there was a calculation error with a formula.

§Call Technical Service.

15108

**Database Error. Please contact Technical Service.**

Database may be corrupt or there was a problem writing information to the database.

§Call Technical Service.

15114

**Database Error. Qualitative Parameters are not available. Call Technical Service.**

Qualitative parameters are not available, contain incorrect data, or a qualitative test has an invalid result.

§Call Technical Service.

15120

**Failed printing the confirmatory results report.**

An error occurred while printing confirmatory test results.

§Ensure printer is online with adequate paper.

15121

**Failed printing the screen.**

An error occurred while trying to do a screen print confirmatory test option screen.

§Ensure printer is online with adequate paper.

15122

**Failed ordering confirmatory HBS tests.**

When ordering confirmatory tests on the screen, an error occurred when the Save button was selected.

§Check to make sure the required information was entered.
§Contact Technical Service.

15125

**Report cannot be sent to printer**

A report cannot be reprinted for a specific accession number because of a printer issue (printer driver not installed or printer not configured)

15126

**Printer Error**

A Printer error of some type occurred.

§Check that printer is online.
§Check that there is paper and ink.
§Check that cables are secure.

15127

**Report cannot be printed. Patient information is invalid or missing.**

When the program is preparing to print the report either the Patient ID number, the Accession number, or Test type is missing from the record to be printed.

15128

**Error during Report Editing.**

While editing the report format on the screen an error occurs because data or formatting is not correct.

15130

**Error reading Sample carousel Data. Instrument will finish transitioning into Run mode and then enter Sample Pause mode. This could take several minutes…Please wait.**

The User-side software does not know what sample racks were scanned because information was not retrieved from the DPRam.

15132

**Failed printing the reflexive test range report.**

The Reflexive test range report was not able to print because of a printer problem or because the program could not access the data in the database.

17000

**No incubation time data. This is not a valid $IM2K$ Kit Barcode.**

The incubation time in the kit barcode is showing zero for the test kit being scanned in on a 2500, which means this is not a valid 2500 kit.

§Verify that the kit is for the IMMULITE 2000 Instrument.
§If the problem persists, call Technical Service.

17001

**Kit barcode signature incorrect. This is not a valid $IM2K$ Kit Barcode.**

The Kit barcode signature is incorrect for the instrument where the kit is being scanned. Trying to scan a 2500 kit on 2000 instrument or visa versa.

§Verify that the kit is for the IMMULITE 2000 Instrument.
§If the problem persists, call Technical Service.

17008

**Unable to read luminometer belt.**

§Contact Technical Service.

17009

**Error occurred while loading tests onto the STAT loader queue.**

A communications error occurred in the user software.

§The Instrument will re-send the message.

17010

**Error occurred while loading tests onto the routine loader queue.**

A communications error occurred in the user software.

§The Instrument will re-send the message.

17011

**Could not find volume table data for this kit.**

The Test Type and Kit Lot number could not be found in the database where the test volumes are stored.

§Rescan the Kit, and if the problem persists, call Technical Service.

17012

**There is a problem with the registry on this system. Please contact Technical Services.**

The program is trying to determine the Instrument type (2000 or 2500) by reading the registry and cannot find the information.

§The registry information is written during installation of version 4.0 or higher.
§Reinstall program, and if the problem persists, call Technical Service.

17014

**Duplicate accession numbers found on the Sample Carousel.**

2 or more sample tubes with the sample accession number were found during a sample carousel read. Different cases of the same accession number are detected as being duplicates.

17015

**The user side software has shut down due to an unexpected error. Press the RUN IMMULITE button after closing this message to continue the current run. Contact Technical Service to report this error**

Unexpected Error was generated in a procedure during program execution. See Daily Event log file for more information.

17100

**Allergy Rescan configuration has been turned off.**

Allergy Rescan Override configuration setting has been changed from On to Off.

17101

**Allergy Rescan configuration has been turned on.**

Allergy Rescan Override configuration setting has been changed from Off to On.

17102

**User acknowledged that no Allergy wedges were changed while logged off.**

The user acknowledged that no Allergy wedges were changed while logged off by pressing the Yes button of the confirmation (second prompt) message box at initialization.

17103

**User acknowledged that all changed Allergy wedges were rescanned.**

The user acknowledged that all changed Allergy wedges were rescanned by pressing the Yes button on the confirmation (second prompt) message box initiating the transition to Run.

17104

**Deleting Allergy wedge data because of user acknowledgement timeout.**

The IMMULITE is automatically deleting Allergy wedge data because the user failed to respond to the message box initiating the transition to run.

17105

**Deleted Allergy wedge data because of incomplete reagent scans on the previous run.**

The IMMULITE is automatically deleting Allergy wedge data because incomplete reagent scans on the previous run could result in specific allergens to be reported out of place

17111

**No Configured Language! Defaulted to English.**

The program could not find the configuration setting for the Language, the program will log the information in the Event log and continue to run using English as a default.

18000

**PM Appointment**

Message box window title for PM Tracker feature.

18001

**Please call Technical Service to schedule a Preventative Maintenance appointment.**

For Non- RTS customers this message will be displayed when the current test count reached the threshold count set by the FSE indicating a PM is needed.

18002

**PM Schedule notification acknowledged.**

This message goes into the Errorlog database when the User Acknowledges the PM notification message for Non-RTS customers. For RTS customers the message goes in the errorlog automatically when they reach the test count threshold.

18003

**PM Performed--See PM Tracker Log**

This message goes into the Errorlog database when the PM has been performed through the PM Tracker Utility.

§Field Service is only one authorized to do this operation.

18004

**Threshold Test Count Updated--See PM Tracker Log**

This message goes into the Errorlog database when threshold counts are updated through the PM Tracker utility.

§Field Service is only one authorized to do this operation.

19001

**This confirmatory test is not defined. Please Contact Technical Service.**

The confirmatory test is not defined in the confirmatory kit definition table. Either there is an error reading the test name or there is a database problem.

19005

**Kit Error. No valid HBS diluent tube onboard.**

An error occurred while trying to place the HBS Confirmatory test into the queue because there was no diluent available.

19006

**Kit Error. No valid HBS bead pack onboard.**

An error occurred because the program could not find the required beads on board the instrument for the HBS Confirmatory tests being ordered.

19007

**Kit Error. Not enough HBS beads onboard.**

The program has determined that there is not enough beads to run the pair of confirmatory tests that are being ordered and posts the error.

19008

**Kit Error. A valid HBS Negative Control result is not available.**

The program has checked the Control Status of the primary HBS kit that is currently active and the control status is not valid and cannot be used.

19009

**Kit Error. The HBS Negative Control result has expired.**

The program has checked the expiration date of the controls and found that they are expired or have not date.

19010

**Kit Error. No valid HBS reagent wedge onboard.**

There are no matching HBS reagents on board or a reagent that is on board is not available for use.

19011

**Kit Error. Not enough HBS reagent onboard.**

There is not enough tests left in the HBS reagent compartment needed for tests being ordered.

19012

**Kit Error. No valid HBS Confirmatory reagent wedge onboard.**

There are no matching HBS Confirmatory reagents on board or a reagent that is on board is not available for use.

19013

**Kit Error. Not enough HBS Confirmatory reagent onboard.**

There is not enough tests left in the HBS Confirmatory reagent compartment needed for tests being ordered.

19016

**Invalid Confirmatory test ordered from LIS.**

The confirmatory test is sent via the LIS or SMS, does not have the correct format or the test was not found in the Kits table.

19017

**Confirmatory Testing Enabled.**

When confirmatory testing is enabled in the registry, there will be a configuration option to enable/disable Confirmatory, when the box is checked this message will be logged.

19018

**Confirmatory Testing Disabled.**

When confirmatory testing is enabled in the registry, there will be a configuration option to enable/disable Confirmatory, when the box is unchecked this message will be logged.

19021

**Eject rack command failed.**

User Side Failed to write Eject command to DPRam. This may be because the User side thinks it is a invalid rack position, the queue that holds instrument messages is full, or a semaphore cannot be accessed.

19022

**Duplicate rack identified. Rack will be ejected automatically.**

Two or more racks loaded on the system have the same Rack ID.

20000

**Unexpected error while initializing instrument. Contact Technical Service.**

This is the failure message displayed to the operator if the Feature Configuration Component Fails during Start-up. Registry is probably corrupted

§Requires Tech Service intervention to correct registry issue or reinstall software.

20001

**Handheld scanner error. Contact Technical Service.**

This message is displayed to the operator if com port 10 is not detected by the Operating System and an Invalid Port error (8002) is generated.

20100

**AutoStart will not be performed due to insufficient water supply.**

Not enough water to run AutoStart processing.

§Ensure there is sufficient water supply (No RTS)

20101

**Automatic Substrate dispense will not be performed due to insufficient substrate supply.**

Not enough substrate to run substrate dispense processing.

§Ensure there is sufficient substrate (No RTS)

20102

**AutoStart will not be performed due to insufficient probe wash.**

Not enough probe wash to run AutoStart processing.

§Ensure there is sufficient probe wash (No RTS)

20104

**AutoStart will not be performed due to insufficient water and probe wash.**

Not enough water and not enough probe wash for AutoStart processing.

§Ensure there is sufficient probe wash and water (No RTS)

20107

**AutoStart will not be performed due to an error while checking consumables.**

An error was encountered while checking consumables specifically for water, substrate, and probe wash levels.

20108

**Unexpected error during AutoStart processing. Contact Technical Service.**

An unexpected general error in AutoStart processing.

§Retrieve Daily Events log and error log for SW investigation

20109

**AutoStart cancelled by Operator.Unexpected error during AutoStart processing. Contact Technical Service.**

User cancelled AutoStart routine by selecting the cancel button from the interface. This message is logged for informational purposes.
§No action needed (No RTS).

20111

**Unexpected error during AutoStart processing. Contact Technical Service.**

General AutoStart processing error. Unexpected error or Control side may have gone into Stop because of an error.

20120

**Manual AutoStart initiated.**

Manual AutoStart processing has begun.

20121

**Scheduled AutoStart initiated.**

Automatic AutoStart processing has begun.

20122

**Substrate has not been primed. QC Worklist will not run.**

Substrate not in a ready to run state.. It has not been primed in the necessary time frame (2 hours) QC Worklist will not run

20123

**AutoStart processing complete.**

AutoStart processing (daily maintenance tasks) complete.

20124

**AutoStart aborted by Operator.**

Operator selected to abort AutoStart, information will be logged.

20125

**Instrument was in an invalid state to run scheduled AutoStart.**

Instrument not in valid state to launch AutoStart (automatic AutoStart).
§Manual - must be in Stop or splash screen.
§Automatic – must be at desktop, Splash screen, stop mode, or Integrated with no tests running.

20126

**AutoStart was cancelled from the countdown screen.**

Operator selected to cancel AutoStart from the AutoStart countdown screen.
Normal informative message.

20150

**Automatic substrate dispense initiated.**

Normal informative message when automatic substrate dispense is initiated

20151

**Automatic Substrate Dispense complete.**

Normal informative message when automatic substrate dispense is completed.

20152

**Automatic substrate dispense aborted by Operator.**

Operator selected to abort automatic substrate dispense.

20153

**Instrument was in an invalid state to run automatic substrate dispense.**

Instrument not in a defined valid state for Autostart automatic substrate dispense processing.

§Manual: must be in Stop or splash screen.
§Automatic: desktop. Splash screen, stop mode, Integrated with no tests running

20154

**Substrate dispense cancelled from the countdown screen.**

Operator selected to cancel substrate dispense from the countdown screen.

20155

**Substrate dispense processing timed out.**

Can be any of the causes in errors 861-864.

20156

**Failure reported in substrate dispense processing.**

Any error on the control side that causes the instrument to stop substrate dispense processing.

20200

**Unexpected error. AutoStart will not be performed. Contact Technical Service.**

Unexpected error retrieving data in the component that retrieves data from the database.

§Try again.
§If failure still occurs, contact Technical Service. Retrieve daily events log and error log for SW

20201

**Unexpected database error. AutoStart will not be performed. Contact Technical Service.**

More than one record in the AutostartSubstrateDispenseProcessing table. Should only be one record in Table.

20202

**Unexpected error. AutoStart will not be performed. Contact Technical Service.**

Unexpected error in AutostartDailyMaint.DLL component.

§Contact Technical Service. Retrieve daily events log and error log for SW investigation

20203

**Unexpected error. AutoStart will not be performed. Contact Technical Service.**

Error occurred trying to kick off AutoStart processing.

§Retry AutoStart processing may help, otherwise contact Technical Service.

20205

**AutoStart processing timed out waiting for logoff.**

User software took longer than expected to log off the User side software. (Possible hang-up on database backup or RTS transfer).

§Logoff software and try manual AutoStart from splash screen.

20206

**AutoStart failed to launch the IMMULITE 2000 XPi software.**

Failure occurred while trying to launch or re-launch user software from the AutostartDailyMaint.DLL (external component).

§Retry AutoStart processing from splash screen.

20207

**Unexpected error. AutoStart will not be performed. Contact Technical Service.**

Autostart could not read the registry. Registry value missing for AutoStart processing. Possibly corrupted registry keys.

§Retrieve daily events log and error log for SW investigation.

20208

**AutoStart failed to open the daily event log.**

Error occurred while attempting to log an event or an error to the unexpected event log.

§May resolve when AutoStart is run again, otherwise contact Technical Service.
§Retrieve daily events log and error log for SW investigation

20209

**Instrument is not in a valid state for AutoStart processing.**

Instrument is not in one of the defined valid states for AutoStart processing.

§Manual: must be in Stop or splash screen.
§Automatic: desktop. Splash screen, stop mode, Integrated with no tests running

20210

**Unexpected error. AutoStart will not be performed. Contact Technical Service.**

A fatal error occurred while trying to calculate a the memory offset location in the DPRAM.

§Contact technical service Retrieve daily events log and error log for SW investigation

20211

**Unexpected error. AutoStart will not be performed. Contact Technical Service.**

A fatal error occurred while trying to communicate with the DPRAM.

§Retry AutoStart. If that fails, Retrieve daily events log and error log for SW investigation

20212

**Error logging operating system logon time.**

Error occurred when the operating system started that caused the time that the operating system was started to not be logged.

20214

**Error while ordering scheduled QC. One or more QC orders may not run.**

If there is any error in creating the QC worklist orders, then one or more QC may not run.

§No operator action is needed.

20215

**Autostart timed out waiting for substrate dispense to complete.**

The substrate dispense completion message did not get sent/received within the timeout period.
§Get spy file.
§Check that the control side performed the substrate dispense actions.
§Check other error messages that may have occurred around the same time.

20220

**Scheduled QC Worklist has been ordered.**

The QC Worklist was ordered successfully.

20221

**Scheduled QC Worklist has been canceled.**

The QC Worklist was canceled by the operator.

21000

**Instrument lost communication with external systems. Contact Technical Service for assistance.**

Failed to communicate with external subsystem, because we are no longer communicating with the i2i Service.

§Call Tech service to investigate

21001

**Failed to Send Instrument Error to the following subsystem(s): <List of Subsystems> Contact Technical Service if the problem persists.**

Communication send failure. Failed to build Instrument Error message using i2i

§Call Tech service to investigate

21002

**Failed to Send Instrument Status to the following subsystem(s): <List of Subsystems> Contact Technical Service if the problem persists.**

Communication send failure. Failed to build Instrument Status message using i2i.

§Call Tech service to investigate

21003

**Failed to Send Instrument Inventory to the following subsystem(s): <List of Subsystems> Contact Technical Service if the problem persists.**

Communication send failure. Inventory error message. Inventory message was not build based on the requested parameters

§Call Tech service to investigate

21004

**Failed to Send Adjustor Results to the following subsystem(s): <List of Subsystems> Contact Technical Service if the problem persists.**

Communication send failure. Error in building Calibration Test result message

§Call Tech service to investigate

21005

**Failed to Send Control Results to the following subsystem(s): <List of Subsystems> Contact Technical Service if the problem persists.**

Communication send failure. Error in building Control Test Result message

§Call Tech service to investigate

21006

**Failed to Send Patient Results to the following subsystem(s): <List of Subsystems> Contact Technical Service if the problem persists.**

Communication send failure. Error in building Patient Test Result message

§Call Tech service to investigate

21007

**Failed to Send Verifier Results to the following subsystem(s): <List of Subsystems> Contact Technical Service if the problem persists.**

Communication send failure. Error in building Verifier Test Result message

§Call Tech service to investigate

21008

**Failed to Send the QC Comment change to the following subsystem(s): <List of Subsystems> Contact Technical Service if the problem persists.**

Communication send failure. Error in building QC Comments update message

§Call Tech service to investigate

21009

**Failed to Send the Kit Adjustment status to the following subsystem(s): <List of Subsystems> Contact Technical Service if the problem persists.**

Communication send failure. Error in building Kit Adjustment status message

§Call Tech service to investigate

21010

**Configuration file, controlling communications with external subsystems, has changed. Please log off the IMMULITE software for the changes to take effect.**

If the Operator changes the I2I configuration file when the IMMULITE software is running using i2i.

§Operator is not supposed to change the i2i configuration file.

21011

**The channel status for an external subsystem has changed. Cannot communicate with subsystem <name>**

The communication with an external subsystem was paused or deactivated outside of the IMMULITE 2000 software. Channel status can be

- Paused
- Stop
- Not Active
- Error

§Call Tech service to investigate

21012

**Instrument communication feature is currently unavailable, due to start up error(s). Please restart the system to correct this problem. Contact Technical Services if the problem persists.**

Failed to start i2i service because of one of the following issues:

- Invalid i2i Configuration settings provided (such as Profile name)
- Missing or corrupted i2i Configuration file
- i2i Service is not started

§Call Tech service to investigate

21013

**Failed to shutdown the external communications. ??? Contact Technical Services if the problem persists ???**

Failed to shutdown i2i service.

21014

**Unsupported request from external subsystem was received. Instrument will not send a reply to this request. ??? Contact Technical Services if the problem persists ???**

Inventory error message. Inventory message was not built based on the requested parameters

Invalid request for Adjustor result was received for Adjustor< Kit, Lot>

Invalid request for Control (Accession number) result was received

Invalid request for Patient result was received

Invalid request for Kit Adjustment status was received

Invalid request for Verifier result was received

§Call Tech service to investigate

# Appendix I: Hepatitis Confirmatory Test

## Manual Confirmatory Testing

The Hepatitis Confirmatory Testing feature enables the instrument to associate the patient accession number with the Confirmatory Sample ID, perform calculations, and report the percent signal reduction and an interpretation confirmed or unconfirmed.

**NOTE:** Prepare confirmatory samples offline before running manual confirmatory testing.

### HBsAg Positive Control

The HBsAg Positive Control supplied with the IMMULITE 2000 HBsAg (HBS) kit is required and is used as quality control material to monitor assay performance of the HBsAg Confirmatory Kit.

Prepare and run undiluted blocked and unblocked samples of the HBsAg Positive Control once, each time HBsAg Confirmatory tests are performed.

Barcode labels are provided for the Positive Confirmatory Control Blocked (CB) and Control Unblocked (CU) samples.

**NOTE:** A negative HBS control is required for confirmatory calculations and must be run before the HBsAg confirmatory tests. This control is typically run as part of routine HBS testing.

### Order Hepatitis Confirmatory Tests

To order Hepatitis Confirmatory Tests on the Instrument, follow the instructions below.

#### *For the IMMULITE 2000 System and IMMULITE 2500 System*

1. At the instrument window drop-down menu, select **Screens**.
2. Select **Confirm HBS**.
3. Proceed to step 3 in the next section.

#### *For the IMMULITE 2000 XPi instruments*

1. At the instrument window, select **MENU**.
2. At the Menu screen, select **Confirm HBS**.

3. To enter the original sample ID, perform one of these options:
   - Scan the patient sample tube barcode label
   - Manually enter the number into the Original Sample ID field.
4. To enter the confirmatory sample ID, perform one of these options:
   - Scan the confirmatory sample ID barcode label
   - Manually enter the number into the Original Sample ID field.
     Maximum 4 numerical characters.

   All blocked and unblocked fields for undiluted and diluted samples, and positive confirmatory controls will automatically populate.
5. Select the HBS kit lot number from the drop-down list.

   This list displays the number of tests remaining for each kit lot on board the instrument, and is refreshed each time the screen is opened.

   **NOTE:** This is the lot number of the HBS kit used for testing. Do not enter the kit lot of the HBsAg Confirmatory Kit.
6. Select **ORDER** for the appropriate sample type(s) to be run:
   - undiluted
   - diluted
   - both

   The instrument only creates orders for the sample types for which the you selected using the ORDER button.

   **NOTE:** To cancel an order, select **CANCEL** before selecting **ACCEPT**.
7. Select **ACCEPT**.

   The HBS confirmatory test orders are sent to the worklist and the fields are cleared.

## Order Positive Confirmatory Control

Order the positive confirmatory control by performing the steps below.

1. Enter HBS POS in the Original Sample ID field.

   **NOTE:** Do not scan the HBS control barcode label.
2. To enter the positive confirmatory control ID, perform one of these options:
   - Scan the confirmatory control barcode label
   - Manually enter the number into the Confirmatory Sample ID field
3. Select **ORDER** for the Positive Confirmatory Control.
4. Select **ACCEPT**.
5. To print the screen information, select **PRINT SCREEN**.
6. Select **CLOSE** to exit the HBS Confirmatory Test Entry screen.

## Load and Process Manual Confirmatory Samples

After ordering HBsAg confirmatory tests, follow the instructions below to load the samples on the Instrument for processing.

1. Lift the sample access door to enter SAMPLE PAUSE mode.

   **NOTE:** The instrument does not query the LIS for the HBsAg confirmatory test samples.

2. Place the prepared and labeled Hepatitis confirmatory samples in the rack(s) and select **RUN**.

   The instrument processes the tests:

   - The confirmatory test samples print automatically, qualitative or qualitative and ratio results and results are not automatically sent to the LIS.
   - Reflexive testing is not performed on HBS confirmatory samples.

## Reviewing Results of Manual Confirmatory Testing

Detailed confirmatory results are available on the HBS Confirmatory Report. Follow the instructions below to print the HBS Confirmatory Report.

### *For the IMMULITE 2000 System and IMMULITE 2500 System*

1. At the instrument window drop-down menu, select **Screens**.
2. Select **Confirm HBS**.
3. Proceed to step 3 in the next section.

### *For the IMMULITE 2000 XPi instruments*

1. At the instrument window, select **MENU**.
2. At the Menu screen, select **Confirm HBS**.
3. Select **DATE TIME RANGE**.

   The Select Time Method screen displays.

4. Select dates and times from the FROM and TO fields.
5. Select **OK**.
6. Select **PRINT RESULTS**.

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