theranos	Quality Operating Procedure	Document Number: CL QOP-00003 Revision: C
	CLIA Laboratory	Effective Date: 01/28/2015
Document Control		

Author(s):

Signature: Langly Gee	Date: 1/28/15
Name: Langly Gee	Title: QA/QC Manager

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Reviewer(s):

Signature: Langly Gee	Date: 1/28/15
Name: Langly Gee	Title: QA/QC Manager

Signature:	Date:
Name:	Title:

Approver(s):

Signature: DocuSigned by: Lynette Sawyer 5B8A611AFE8D481...	Date: 5/5/2015
Name: Lynette Sawyer	Title: Laboratory Director

Signature:	Date:
Name:	Title:

Signature:	Date:
Name:	Title:

1. PURPOSE

1.1. The purpose of this procedure is to provide for a system and instructions, and to assign responsibilities for establishment, review, authorization, issue, distribution, and revision of controlled documents.

2. SCOPE

2.1. This procedure applies to the following categories of documents:

- 2.1.1. Quality Manual
- 2.1.2. Policies, Program documents and Plans
- 2.1.3. Standard Operating Procedures
- 2.1.4. Forms
- 2.1.5. Reports

3. DEFINITIONS AND ABBREVIATIONS

Controlled Document	Any document that defines methods employed to control the operation of all areas of the laboratory, has an effect on the quality of assays or Quality System and is revision controlled through the DCO process.
Document Change Order (DCO)	The process by which a document is created or revised.

4. RESPONSIBILITIES

4.1. It is the responsibility of the Quality Assurance / Quality Control Manger (QA/QC) or designee to establish and maintain the document control system. This entails authorizing the assignment of and issuing new and revised controlled document numbers, and maintaining either a manual file of original copies of controlled documents or computerized document control system. Reference copies will be issued and distributed to authorized personnel in the CLIA Laboratory.

5. PROCEDURE

5.1. Documents categorized into one of the types mentioned in section 2.1 are established and controlled following the rules that apply to controlled documents, as defined in this procedure.

5.2. Identification

5.2.1. Controlled documents are identified by:

5.2.1.1. Unique title and controlled document number,

5.2.1.2. Effective date and revision level, and

5.2.1.3. Identification of the approving/issuing authority.

5.2.2. All controlled documents are identified with respect to their revision level by a consecutive letter and the effective date.

5.3. Initiation of new documents and revisions

5.3.1. Laboratory personnel on all levels are encouraged to critically evaluate the documents they use and request revisions to correct errors and inconsistencies.

5.3.2. Anyone in the CLIA Laboratory may request the issue of a new document, or a revision of an existing document. The person wishing to initiate a document or a revision submits a draft of the proposed document to his or her manager or supervisor. The manager responsible for approving and issuing the document may revise or reject the draft.

5.4. Initial issue

5.4.1. Prior to issue and release by the Laboratory Director, documents are also reviewed for adequacy, correctness, and conformity to quality policies by the QA/QC Manager or designee.

5.4.2. Approved and released documents are identified with Document Change Order (DCO) number and the effective date. DCO numbers are tracked in a log and kept by the QA/QC Manager. Hand-written approval signatures or electronic signatures on documents are acceptable. Reference CL QOP-00004.

5.5. Revisions

5.5.1. Changes to documents are reviewed and approved by the Laboratory Director. The issuing of revisions follows the same procedure that applies to the issuing of initial documents.

5.5.2. Revised documents are formally released through the DCO process. (Reference CL QOP-00004)

5.5.3. When documents are changed without the document being re-issued on a higher revision level, approved deviation is issued. Printouts of documents may not be changed by handwritten corrections.

5.6. Placement of initial issues and revisions

5.6.1. Original documents are stored in a secured central location by the QA/QC Manger or designee.

5.6.2. Documents are placed with authorized laboratory personnel in the CLIA Laboratory (see section 5.7).

5.6.3. When revised documents are placed, previous revisions are removed and store electronically in an obsolete folder.

5.7. Uncontrolled copies

5.7.1. Documents issued to personnel for informational purposes are stamped REFERENCE USE across the title page or alternatively it may be handwritten clearly across the title page.

5.8. Retention of obsolete documents

5.8.1. At least one copy of obsolete controlled documents is retained.

5.8.2. Obsolete documents are retained as specified in CL QOP-00010.

5.8.3. Retained copies of obsolete documents are stamped OBSOLETE.

6. RECORDS

6.1. Documents will be stored per CL QOP-00010 Record and Specimen Retention.

7. ATTACHMENTS

7.1. Not applicable

8. REFERENCES

8.1. CL QOP-00004 Document Initiation, Revision, Approval And Distribution

8.2. CL QOP-00010 Record and Specimen Retention.

9. REVISION HISTORY

REVISION HISTORY			
Revision Level	**Effective Date**	**Initiator**	**ECO Number**
A	06/09/2011	A. Gelb	CL ECO-00001
B	02/19/2014	L. Gee	CL ECO-00150
C	01/28/2015	L. Gee	CL DCO-00073
Section Number	**Description and Justification of Changes**		
ALL	Initial Release		
All	Annual Review, change header logo		
All	Annual Review, Change Document Control Analyst to QA/QC Manger		

Document Initiation, Revision, Approval And Distribution

Author(s):

Signature: Langly Gee	Date: 1/28/15
Name: Langly Gee	Title: QA/QC Manager

Reviewer(s):

Signature: Langly Gee	Date: 1/28/15
Name: Langly Gee	Title: QA/QC Manager

Signature:	Date:
Name:	Title:

Approver(s):

Signature: DocuSigned by: Lynette Sawyer 966A61145EBD481...	Date: 5/5/2015
Name: Lynette Sawyer	Title: Laboratory Director

Document Initiation, Revision, Approval And Distribution

1. PURPOSE

1.1 To describe the procedure for: submission, review, approval, and distribution of new or revised documents or processes.

2. SCOPE

2.1 THIS PROCEDURE APPLIES TO:

2.1.1 Controlled documents include but are not limited to the Quality Systems Manual (QSM), Quality Management Plan (QMP), Policies (POL), other Plan (PLN), Quality Standard Operating Procedure (QOP), all other Standard Operating Procedures (SOP), Form (FRM-#####-F#), other attachments (ATT-#####-A#), Report (RPT), Template (TMP), Job Description (JOB) and Delegation (DEL).

3. DEFINITIONS AND ABBREVIATIONS

Term	Definition
Approval	Approval of a DCO signifies agreement with all information contained on the form.
Controlled Document	Any document that defines methods employed to control the operation of all areas of the laboratory, has an effect on the quality of assays or Quality System and is revision controlled through the DCO process.
Effective Date	The date on which a document takes effect.
Document Change Order (DCO)	The process by which a document is created or revised.
Originator	The person initiating the DCO.
Product/Process Documents	The Procedures, Quality Control Specification, and Test Methods that describe the testing process.
Supporting Documentation / Technical Data	Any documentation/data supporting the justification for a DCO. Example: Instrument, test method and/or process validations, highlights of quantitative, qualitative, and/or statistically significant results; reference to supporting technical data.
Change Impact	That Section of the DCO that requires the Initiator to determine the effect of the Changes on the Processes, Regulatory Impact and whether Verification/Validation and Risk Management is required.

4. RESPONSIBILITY

4.1 AUTHOR

4.1.1 The author writes a new document or modifies an existing document.

4.1.1.1 Ensures that new documents or revisions are in line with current Theranos policy and procedures.

4.1.1.2 Ensures that correct formatting is in place.

4.1.1.3 Proof reads document for errors, omissions and clarity.

4.1.1.4 In the case of a document revision, provides an accepted change version of the document complete with an incremented revision number.

4.2 ORIGINATOR

4.2.1 The originator submits a new document or the revision to an existing document or deletes an existing document by filing a DCO. (The originator may or may not be the author)

4.2.1.1 Ensures that new documents or revisions are in line with current Theranos policy.

4.2.1.2 Ensures that correct formatting is in place.

4.2.1.3 Proof reads document for errors, omissions and clarity.

4.2.1.4 Obtains a DCO number from the Quality Assurance / Quality Control Manager.

4.2.1.5 In the case of a revision, a mark-up / redlined document, tracking all of the changes and an accepted change version of the document with an incremented revision number are submitted.

4.2.1.6 Attaches any supporting documentation as applicable.

4.3 REVIEWER / APPROVER

4.3.1 The reviewer / approver is the designated individual responsible for reviewing the document and determining the impact and validity of the document relative to their area of responsibility and expertise. Most often this includes the Laboratory Director who reviews new documents as well as existing SOPs annually.

4.3.1.1 Ensures that new documents or revisions are in line with current company policy.

4.3.1.2 Considers the impact of the new or revised document relative to your area of responsibility and expertise. Include any supporting documentation as applicable.

4.3.1.3 If the new or revised document is acceptable then approves the document through Document Control.

4.3.1.4 If the new or revised document is not acceptable then fails the document through Document Control.

4.3.1.5 The **effective date** of a document for the CLIA Laboratory is by default the date it is signed by the Approver (Laboratory Director or designee) unless otherwise specified.

4.4 QUALITY ASSURANCE / QUALITY CONTROL MANAGER

4.4.1 The Quality Assurance / Quality Control Manger or designee is the person responsible for processing the DCO.

4.4.1.1 Ensures document is complete and correct. In the case of a revised document ensure that the mark-ups / redlines of the current revision and an accepted change version of the document with an incremented revision number.

4.4.1.2 Upon approved, reviews, verifies and records new document, or in the case of a revision, the accepted change version of the document.

4.4.1.3 Responsible for making a hard copy of new/revised documents and filing in Document Control. Obsolete copies are stamped OBSOLETE and filed in document control files.

5. PROCEDURE

Not applicable

6. RECORDS

Records will be maintained for the minimum period specified in CL QOP-00010 Record and Specimen Retention.

7. ATTACHMENTS

7.1 APPENDIX I Signature Matrix

8. REFERENCES

CL QOP-00010 Record and Specimen Retention

9. REVISION HISTORY

REVISION HISTORY			
Revision Level	**Effective Date**	**Initiator**	**DCO Number**
A	06/09/2011	A. Gelb	CL ECO-00001
B	01/03/2012	A. Gelb	CL ECO-00038
C	05/23/2012	A. Gelb	CL ECO-00054
D	02/19/2014	L. Gee	CL ECO-00150
E	01/28/2015	L. Gee	CL DCO-00073
Section Number	**Description and Justification of Changes**		
All	Initial Release		
2.1, APPENDIX I	Document identifiers and Approval Matrix updated		
2.1.1	Added document types Report and Template		
4.3 and 4.4	Order reversed, effective date clarified, analyst responsibilities updated		
All	Annual Review, change header logo		
All	Annual Review, Update to current practice		

10. APPENDIX I

ORIGINATOR / REVIEWER APPROVAL MATRIX

ONLY IF SIGNIFICANT CHANGES OCCUR

Significant changes would include, for example:

Any major modification to the process or test method. Minor changes, such as those made for typographical errors or clarification purposes, will not typically require approval

Signature Matrix

DOCUMENT TYPE	CEO	LABORAOTRY DIRECTOR	QUALITY ASSURANCE	HR
Quality Systems Manual and related documents	X*	X	X	
Standard Operating Procedure (SOP)		X	X	X*
Validations		X	X	
Test Methods and Reports (TM)		X	X	
Clinical Documents		X	X	
Job Descriptions		X	X	X*
Personnel records				X

X* As Required

X Required

Record and Specimen Retention

Author(s):

Signature: Langley Gee	Date: 1/28/15
Name:Langly Gee	Title:QA/QC Manager

Signature:	Date:
Name:	Title:

Signature:	Date:
Name:	Title:

Reviewer(s):

Signature: Langley Gee	Date: 1/28/15
Name: Langly Gee	Title: QA/QC Manager

Signature:	Date:
Name:	Title:

Approver(s):

Signature: DocuSigned by: Lynette Sawyer 566A614FEBD481...	Date: 5/5/2015
Name: Lynette Sawyer	Title: Laboratory Director

Signature:	Date:
Name:	Title:

Signature:	Date:
Name:	Title:

Record and Specimen Retention

Record and Specimen Retention

1 PURPOSE

1.1 This Standard Operating Procedure (SOP) defines the minimum required retention times for various records, reports and specimens.

2 SCOPE

2.1 This document advises the Client Solutions Department at Theranos on the protocol for specimen and records retention.

3 RESPONSIBILITIES

3.1 It is the responsibility of the authorized personnel in CLIA Laboratory at Theranos to follow the procedure outlined in this SOP.

4 DEFINITIONS AND ABBREVIATIONS

4.1 Not applicable

5 PROCEDURE

5.1 The laboratory will retain the original report or an exact duplicate of each test report, including preliminary and final reports, of all reports of anatomical and clinical laboratory tests and examinations, which are readily retrievable, for the following periods:

5.1.1 All reports-no less than 3 years.

5.2 Although record retention requirements are determined by applicable state and federal law and regulation, as well as by local needs, all records are retained for at least three (3) years.

5.3 An "exact duplicate" is an exact copy of the information reported. It includes the name and address of the laboratory performing the test. The exact copy need not be paper, but may be retrieved from the computer system as long as it contains the exact information sent to the individual ordering the test. A manual log containing duplicate information is also acceptable. For tests requiring an authorized signature or containing identifiers, the exact duplicate must include the signature or identifiers.

5.4 RETENTION TIMES: Following are the minimum required retention times for various records, validation documents, reports and specimens.

Item	Retention Times
Equipment records	3 years-daily, weekly, monthly performance testing and function checks. Life of the equipment-major repairs, parts replacement and annual maintenance.
Validation documents	For the life of the test plus 3 years
Test requisitions (originals)	7 years as required in the event of a CMS audit of patient medical records (3 years required by State law)
Personnel records	Duration of employment plus 2 years
Records of Testing	2 years

Test Report	3 years- as required by law. Name of person contacted if the laboratory test or examination result was a critical or panic value-3 years as required by state law.
Proficiency Testing	3 years-records of test handling, preparation, processing, examination, results of reporting, the signed attestation statement and feedback reports.
Quality Control	3 years-all others as required by state law.
Instrument Printouts	3 years-required by CLIA unless the record data are retrievable in an alternate manner.
Discontinued Procedures	2 years-all others.
Outpatient records	A minimum of 7 years or until patient age 18-whichever is longer.
Clinical Laboratory Specimens	Suggested retention times: Serum/CSF/Body fluids (except urines)-48 hrs Urines-24 hours Peripheral blood smears/body fluid smears-7 days Microbiology permanently stained slides-7 days

6 RECORDS

6.1 See section 5.

7 ATTACHMENTS

7.1 Not applicable

8 REFERENCES

8.1 CLIA (42CFR Part 493)

8.2 California Business and Professions Code, Sec 1271, 1265.

8.3 Code of Federal Regulations, Title 42, Sec. 493.1109.

9 REVISION HISTORY

REVISION HISTORY			
Revision Level	**Effective Date**	**Initiator**	**ECO Number**
B	06/24/11	A. Gelb	CL EC0-00018
C	02/19/2014	L. Gee	CL ECO-00150
D	01/28/2015	L. Gee	CL DCO-00073
Section Number	**Description and Justification of Changes**		
Title and Header	Change document number from 00011 to 00010 due to clerical error		
All	Annual Review, change header logo		
All	Annual Review, no changes		

theranos	Standard Operating Procedure	Document Number: **CL SOP-02010** Revision: D
	CLIA Laboratory	Effective Date: 09/30/2014

Cleaning Spills of Biohazardous Materials including Bloodborne Pathogens

Author(s):

Signature:	Date: 9/25/14
Name: Godfred Masinde, PhD	Title: Technical Supervisor

Reviewer(s):

Signature:	Date: 9/25/14
Name: Lina Castro	Title: CLS, Safety Officer

Signature:	Date: 9/25/2014
Name: Steve Morin	Title: Technical Supervisor

Approver(s):

Signature: DocuSigned by: Lynette Sawyer 566A8114FEBD481...	Date: 5/5/2015
Name: Adam Rosendorff, MD Lynette Sawyer	Title: Laboratory Director

The Laboratory Director or designee will review this procedure at least annually including revisions.

Reviewed By:	Date:	Comments:

Cleaning Spills of Biohazardous Materials including Bloodborne Pathogens

Cleaning Spills of Biohazardous Materials including Bloodborne Pathogens

1 PURPOSE

The purpose of this procedure is to minimize the possibility of disease transmission by establishing procedures for the safe handling of spills of human blood, blood products or other potentially infectious materials.

2 SCOPE

This procedure covers the employees and clients at Theranos, Inc. who may have the potential to be exposed to human blood or other potentially infectious human blood materials in the performance of their job duties. Only Class 1 and Class 2 agents are relevant to CLIA laboratory operations.

3 DEFINITIONS AND ABBREVIATIONS

3.1 A **biohazard** can be defined as any organism, or material produced by such an organism, that is known or suspected to cause human or animal disease. Biohazardous/infectious material falls under Class D, Division 3 of the Workplace Hazardous Materials Information System (WHMIS), and includes:

3.1.1 microorganisms such as viruses, fungi, parasites, and bacteria and their toxic metabolites

3.1.2 human or other mammalian blood and body fluids

3.1.3 unfixed and fixed tissues and specimens from humans and non-human primates

3.1.4 cell lines and other tissue cultures

3.1.5 certain types of nucleic acids, such as DNA derived from pathogenic organisms, human oncogenes or transformed cell lines

3.1.6 genetically altered organisms, including plants

3.1.7 zoonotic agents (diseases that normally exist in animals but that can infect humans)

3.2 A **Class 1 Agent** (Biosafety Level 1) is a microorganism that is unlikely to cause human disease or animal disease

3.3 A **Class 2 Agent** (Biosafety Level 2) is a pathogen that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment. Laboratory exposures may cause serious infection, but effective treatment and preventative measures are available and the risk of spread of infection is limited.

3.4 A **Class 3 Agent** (Biosafety Level 3) is a pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another. Effective treatment and preventive measures are available in most instances. Prion diseases such as Creutzfeldt-Jakob disease are a special case due to their resistance to decontamination. BSL-3 is not relevant to CLIA Laboratory operations.

3.5 **Exposure to biohazardous agents** may occur via puncture wounds or as a result of absorption through the respiratory tract, digestive system, skin and mucous membranes: such exposures may result while handling

microorganisms, animals, cell cultures and tissues or diagnostic specimens. Investigators who are uncertain as to whether a material is biohazardous or not should consult the safety manager.

3.6 **Sharps** are any item capable of causing puncture wounds or cuts. This includes discarded hypodermic syringes, cannulas, needles, scalpel blades, cover slips, microscope slides, all glass or plastic pipettes (including Pasteur pipettes), broken glass, and metal shards. All sharps must be handled and disposed properly to prevent injuries to anyone who may come in contact with them from the original user, to other lab members, to the custodian, to the refuse truck driver, and to the landfill operator. Sharps that may be contaminated with potentially infectious materials are subject to additional requirements.

4 RESPONSIBILITIES

4.1 Safety Manager

4.1.1 Provide employee and client training in these procedures as necessary.

4.1.2 Maintain copies of any "Incident Investigation Report" (Attachment 8.1)

4.1.3 Provide consultation to employees who may be exposed to Human Bloodborne Pathogens or other potentially infectious materials. Theranos, Inc. will inform client managers and supervisors of company procedures for client rights and the organization's procedures.

4.2 Managers & Supervisors

4.2.1 Provide the resources necessary to ensure that Personal Protective Equipment (PPE) is available for Theranos employees.

4.2.2 Ensure that all employees exposed to human bloodborne pathogens or other potentially infectious materials are offered Hepatitis B vaccinations.

4.2.3 Ensure that all injured or contaminated employees are documented on the Incident Investigation Report Form (Attachment 8.1) and reported to the Safety Manager.

4.2.4 Following an incident, ensure that the "Incident Investigation Report" provisions are completed and documented. (Attachment 8.1)

4.3 Employees and Client Employees

4.3.1 Understand the applicable components of this procedure.

4.3.2 Adhere to the practices and procedures of Universal/Standard Precautions.

4.3.3 Report any exposure, accident, injury, or illness to managers or supervisors and to the Safety Manager.

5 MATERIALS AND REAGENTS

5.1 Class 1 (Biosafety Level 1) Equipment

5.1.1 Disposable gloves

5.1.2 Lab coat

5.2 Class 2 (Biosafety Level 2) Equipment

5.2.1 Impervious coveralls, such as Tyvek or lab coats depending on volume

5.2.2 Impervious boot covers, preferably disposable

5.2.3 Full face shield or goggles and mask

5.2.4 Disposable gloves

5.2.5 Disposable absorbent towels

5.2.6 Freshly-prepared 10% household chlorine bleach solution (Clorox® or equivalent) (1 part bleach and 9 parts water; or add a scant ½ cup bleach to 1 quart of water)

5.3 Dustpan

5.4 Tongs

5.5 Sign to prevent entry to the area being cleaned.

6 PROCEDURE

6.1 Biological spills outside biological safety cabinets will generate aerosols that can be dispersed in the air throughout the laboratory. Appropriate protective equipment is particularly important in decontaminating spills involving microorganisms that require either Biosafety Level 2 or Biosafety Level 3 containment. The following procedures are described in terms of the risk posed by the organism(s) involved. The term Class refers to risk

group, as defined by the World Health Organization. You should know the assigned risk group of the organisms with which you are working. If not, contact your supervisor or EHS.

6.2 Spills Involving Class 1 Organisms

6.2.1 Soak up gross spill with paper towels

6.2.2 Place paper towels in heavy plastic bag

6.2.3 Soak more paper towels in disinfectant and place over the spill area, or create a berm with paper towels and pour disinfectant over the spill area.

6.2.4 Allow disinfectant to remain in contact with spill area for 20 minutes.

6.2.5 Soak up disinfectant with clean paper towels and place in heavy plastic bag.

6.2.6 Notify lab supervisor

6.3 Spills Involving Class 2 Organisms

6.3.1 The appropriate personal protective equipment for cleaning up a spill of a Class 2 organism depends on the severity of the spill. The appropriate outer garment depends on the severity of the spill. If the spill is small something like a lab coat is sufficient so long as it is unlikely that your outer garment can become saturated with the spilled material. Impervious coveralls, such as Tyvek, are necessary if the spill is large and it is likely that your outer garment can become significantly saturated. Likewise, the appropriate eye protection depends on the severity of the spill. If splashing is likely, as with a large spill, goggles and a face shield are necessary to protect mucous membranes (e.g., eyes, nose and mouth). If the spill is small and splashes are unlikely, safety glasses with side shields will do. Also, don't forget about other exposed portions of the body or

garments that could come into contact with the spilled body fluid. It may be necessary to wear rubber boots if you must step into or traverse areas where the spill occurred.

6.3.2 Alert others to the spill. If someone is available to provide assistance, have them provide surveillance so that people don't wander into the spill area.

6.3.3 If you feel that you are unable to respond to the spill, notify your supervisor or the safety manager, or call 911 after hours.

6.3.4 Gather necessary supplies and put on appropriate PPE.

6.3.5 Remove contaminated sharps (e.g., broken glass) from the spilled material and place in a rigid, water-tight container. Don't use your hands to pick up the sharps rather use a mechanical device such as tongs.

6.3.6 Spread an absorbent material over the area of the spill, working from the outside edges toward the middle. This keeps the spilled material from spreading.

6.3.7 Allow the absorbent to soak up the liquid and carefully place it into a biohazardous waste receptacle.

6.3.8 Create a small berm with paper towels around the outer edges of the spill. Treat all surfaces of the spill area with a freshly-prepared 10% solution of household bleach or other suitable disinfectant. It is best to gently pour the bleach solution on the spill area, as opposed to spraying, since spraying could create aerosols.

6.3.9 Allow the bleach to stay in contact with the surface for 15-30 minutes. Afterwards, absorb any remaining bleach solution on paper towels and place into a biohazardous waste container.

6.3.10 If you haven't already done so, notify your supervisor of the spill.

6.4 Cleaning Blood Spills on Non-Carpeted Floors

6.4.1 A hard, non-carpeted surface is the most common setting for blood spills. These surfaces include tile, ceramic, vinyl, linoleum, metal, wood, cement, and any other non-absorbent flooring such as a pool deck.

6.4.2 Cleaning up blood and other bodily fluids off these surface types is easier than absorbent surfaces, but there are still important steps for you to consider.

6.4.3 Spills on hard surfaces often spread over larger areas so it will be necessary to contain the spill quickly. The procedures for cleaning up spills on these surfaces are:

6.4.3.1 Block off the area until cleanup and disinfection is complete. No visitors or unprotected staff members should be able to access the area.

6.4.3.2 Put on disposable gloves, mask, goggles, shoe covers.

6.4.3.3 Cover the spill (including sharps) with paper towels or other absorbent material.

6.4.3.4 Gently pour bleach solution – 1 part bleach to 9 parts water – onto all contaminated areas.

6.4.3.5 Let bleach solution remain on contaminated area for 20 minutes and then wipe up remaining bleach solution. Disinfect the area until is completely clean.

6.4.3.6 All non-disposable cleaning materials such as mops, brushes and rags need to be disinfected by saturating with bleach solution and allowed to air dry.

6.4.3.7 Remove gloves and other PPE and place in a biohazard bag with all other soiled cleaning materials.

6.4.3.8 Put on new gloves and double bag and securely tie up garbage bags and discard.

6.4.3.9 Discard your gloves in biohazard bin.

6.4.3.10 Thoroughly wash hands with soap and water.

6.5 Blood Spills on Carpeted Floors

6.5.1 Blood spills on carpeted floors are some of the most difficult to clean up due its absorbent nature. The majority of buildings contain at least some amount of carpeting, which is why it is important to know how to respond to spills in these areas. Many of the procedures for cleaning up blood on carpet will be the same as any other area, but there are a few additional concerns. In addition, there is no way to disinfect carpet completely so the best option is to sanitize as thoroughly as possible.

6.5.2 Work Quickly: Blood or other bodily fluids can harden or set up quickly on carpeting making it much more difficult to clean. Respond quickly, but make sure to follow all safety precautions like wearing appropriate PPE, securing the area, and ensuring the injured individual is safe.

6.5.3 Use Appropriate Products: Bleach and other decontamination products can damage or destroy carpet. The best way to clean these areas is to use manufacturer approved carpet shampoos and cleaners. Make sure you select a product with some anti-microbial properties to help sanitize the area as thoroughly as possible.

Another recommendation is that after the area is cleaned and dried repeat the process once or twice more since the absorbent nature of carpet can still conceal some pathogens.

6.5.4 Steam Clean: Depending on the nature and size of the spill, it is advisable to perform a steam clean of the carpet. Steam cleaners will clean, remove debris, and sanitize carpeting more completely than conventional washing. Although there is some additional cost to steam cleaning, it is the best way to protect against bloodborne pathogens.

6.5.5 Change Carpet Tiles: Removable carpet tiles are a great way to protect against exposure to bloodborne pathogens. Carpet tiles are often less expensive than traditional carpet, and if a certain area becomes heavily soiled with blood they can easily be removed and replaced. If your organization is equipped with carpet tiles be sure to dispose of them properly after being saturated with blood or any other potentially infectious bodily fluid.

6.5.6 The basic protocol for cleaning carpets and removing the threat of bloodborne pathogens is listed below. Please note that even when these steps are followed there is no guarantee that the threat of bloodborne pathogen exposure is 100% eliminated.

6.5.7 Put on Disposable Gloves: No matter what type of surface you're cleaning, always put gloves on first.

6.5.8 Contain the Spill: After a spill, it is important to keep it as contained as possible to avoid allowing the affected area to spread. Create a barrier around the spill with an absorbent material.

6.5.9 Initial Disinfect: Once the area is contained, spray the affected area with an appropriate carpet detergent to help kill some of the surviving pathogens. After spraying the area, allow it to sit for 10 minutes so the disinfectant has time to work.

6.5.10 Blot up Excess Fluids: Use disposable towels or rags to blot as much excess fluid as you can and then carefully dispose of the soiled rags in a sealable bag.

6.5.11 Extract Absorbed Fluids: The carpet will absorb some of the fluid so removing them will be the next step. Use a wet-vacuum to thoroughly wet and remove any fluids. Repeat the process of wetting and suctioning several

times. While wetting the affected area be sure to prevent any water from spreading beyond the initial boundary.

6.5.12 Re-disinfect: After vacuuming, thoroughly re-saturate the area with an appropriate disinfectant. Follow your carpet manufacturer's recommendations since certain products can damage carpet fibers and dyes.

6.5.13 Let Sit: After completely disinfecting the area, allow the disinfectant to set and work for up to 20 minutes to make sure it has the full effect.

6.5.14 Third Disinfect: Repeat the previous two steps of disinfecting and then allowing to sit for 10-20 minutes.

6.5.15 Rinse: Once the final round of disinfecting is complete, rinse the area one last time to remove any remaining detergent or disinfecting solution. After rinsing, wet-vacuum the area.

6.5.16 Dry: Next, dry the area thoroughly with rags to draw out any remaining moisture and then place fans near the area to completely dry it,

6.5.17 Wrap up: After the area is clean, properly dispose of all rags and PPE contaminated by the spill. In addition, thoroughly clean all other equipment used during the spill cleanup.

6.6 Blood Spills on Furniture

6.6.1 Like bodily fluid spills on carpet, spills on furniture are difficult to clean as well. There are, however, certain steps you can take to make sure it is as clean and safe as possible. As is the case with blood spills on carpet, it is important to contain the spill as quickly as possible.

6.6.2 Cleaning blood off of furniture then depends on what type of furniture is contaminated. Cloth furniture needs more treatment than wood or metal furniture. Depending on the type of cloth furniture and the degree of the spill, the best cleaning method is to remove the cloth covering, if possible, and launder it by itself on a warm wash cycle. If the cloth furniture does not have a removable cover, then it is best to treat the spot as you would a blood spill on carpet and disinfect, let sit, and repeat several times.

6.6.3 There are also professional services that can clean furniture much more effectively and thoroughly if the spill is severe enough. Blood spills on metal and wood furniture are not as laborious as those on cloth furniture, but it is important to point out that bloodborne pathogens are still a threat. Metal, wood and any other non-porous furniture should be cleaned just like a blood spill on a non-carpeted surface.

6.7 Contaminated clothing

6.7.1 Notify your supervisor immediately.

6.7.2 If blood or other potentially infectious materials penetrate a garment, the garment will be removed immediately or as soon as feasible.

6.7.3 Contaminated laundry will be handled as little as possible with a minimum of agitation. Handle clothing with gloves.

6.7.4 Contaminated laundry will be placed and transported in bags or containers labeled or color-coded. When a facility utilizes Universal Precautions in the handling of all soiled laundry, alternative labeling or color-coding is

sufficient if it permits all employees to recognize the containers as requiring compliance with Universal Precautions.

6.7.5 If blood or other potentially infectious materials had soaked through so that there is skin contact, the clothes must be removed. Following removal, wash those areas where exposure is evident, even to the point of taking a shower.

6.8 Exposure to mucus membranes

6.8.1 Notify your supervisor immediately

6.8.2 If blood or PIM has come into contact with any of the mucous membranes (eyes, nose, lips) they need to be thoroughly washed with soap and water and flush the area with water for 15 minutes.

6.8.3 If there is contact with open wounds or cracks in the skin, there is a risk of exposure.

6.8.4 Immediately and thoroughly wash your hands with water and an antiseptic cleaner if contaminated with a body fluid. These occurrences are considered to be an Exposure Incident and it is important to follow the procedures outlined in the Theranos Bloodborne Pathogen Safety Plan.

6.8.5 Allow minor wounds or punctures to bleed freely. Application of antiseptics when caring for the wound is appropriate. However, the application of caustic agents such as bleach or chemical disinfectants into the wound is not recommended.

6.8.6 Exposure to the eye(s) or mucous membranes are treated by flushing with clean water (eye wash) or saline for up to 15 minutes.

7 RECORDS

Records of spills and investigations thereof will be maintained for 3 years.

8 ATTACHMENTS

8.1 CL FRM-02006-F2_Incident Investigation Report.

9 REFERENCES

9.1 California Code of Regulations Title 8 Section 5193.

9.2 WHO. 2000. WHO infection control guidelines for transmissible spongiform encephalopathies. Report of a WHO consultation, Geneva, Switzerland, 23-26 March1999, http://www.who.int/csr/resources/publications/bse/whocdscsraph2003.pdf.

10 REVISION HISTORY.

REVISION HISTORY			
Revision Level	**Effective Date**	**Initiator**	**ECO Number**
A	06/09/2011	A. Gelb	CL ECO-00003
B	06/13/2011	A. Gelb	CL ECO-00016
C	8/5/2014	G. Masinde	CL DCO-00040
D	9/23/2014	L. Castro	CL DCO-00055
Section Number	**Description and Justification of Changes**		
6.3.9	Revised decontamination time		
ALL	Annual Review		
6.4, 6.5, 6.6, 6.7,6.8	Blood spill Cleanup		

theranos	PLAN	Document Number: CL PLN-02043 Revision: B
	CLIA Laboratory	Effective Date: 09/22/2014
CLIA DISASTER PREPAREDNESS PLAN		

Author(s):

Signature:	Date: 9/17/14
Name: Godfred Masinde, PhD (Reviewing Author)	Title: Technical Supervisor

Reviewer(s):

Signature:	Date: 9/16/2014
Name: Langly Gee	Title: QA/QC Manager

Approver(s):

Signature: DocuSigned by: Lynette Sawyer	Date: 5/5/2015
Name: Adam Rosendorff, MD Lynette Sawyer	Title: Laboratory Director

The Laboratory Director or designee will review this procedure at least annually including revisions.

Reviewed By:	Date:	Comments:

Contents

CLIA DISASTER PREPAREDNESS PLAN

1. Purpose

1.1. To provide a plan of action in the event of a natural disaster or emergency that interrupts normal business. Disaster preparedness is the process of planning for an adverse event that could impact the company. This Disaster Preparedness Plan defines how risks associated with the CLIA Laboratory will respond to an emergency. It outlines the necessary contact information and back up methods that will be implemented to protect personnel, equipment, and laboratory facilities whenever an emergency event threatens laboratory operations, or when directed by the Federal or Local Emergency Management.

2. Scope

2.1 This plan applies to the CLIA Laboratory at Theranos, Inc.

3. Definitions and Abbreviations

3.1. Disaster or emergency: An event that causes serious loss or destruction of property or life that impacts the delivery of services to clients. Potential disaster/emergency events include but are not limited to: electrical/heating/AC failures, natural disasters (e.g. fire, earthquake, flood, or tsunami), terrorist event, or pandemic.

3.2. Hazardous Materials (HAZMAT): Dangerous solids, liquids, or gases that can harm people, other living organisms, property, or the environment.

4. Duties and Responsibilities

4.1. Security Officers: Duties and Responsibilities

4.1.1. Determine initial condition and extent of emergency situation, response criteria and potential for escalation.

4.1.2. Authorize evacuation of facility.

4.1.3. Collect and disseminate intelligence information.

4.1.4. Control affected areas until relieved by proper authority.

4.1.5. Provide radio and telephone communications to command staff.

4.1.6. Conduct any necessary searches of area.

4.1.7. Secure and maintain continuous security of buildings.

4.1.8. Preservation of emergency scene and evidentiary materials.

4.1.9. Maintain up-to-date lists of emergency response agencies and personnel.

4.1.10. Provide initial first aid to injury victims.

4.1.11. Provide or assist with rescue efforts.

4.2. Laboratory Technical Supervisor and/or Laboratory Director

4.2.1. Suspend, resume and continue laboratory operational activities.

4.2.2. Authorize evacuation of laboratory.

4.2.3. Select and/or approve appropriate strategies to meet the emergency as it relates to the laboratory.

5. Contact information

5.1. Emergency Contact information

Contact	Phone	Twitter
Emergency	911	
Fire Department	650-329-2184 (non-emergency)	Twitter: @PaloAltoFire
Police Department	650-329-2413 (non-emergency)	
Utilities-Electric	650-496-6914 (to report an outage)	
Utilities-Natural Gas	650- 329-2579 (to report a leak or an outage)	
Utilities-Water	650- 329-2579 (to report a leak or an outage)	

5.2. Company contact information

Contact	Title	Work Phone number	Additional number
Theranos	Front office	650-838-9393	
David Do	Security	650-856-7306	
Edgar Paz	Security	650-470-0328	Mobile 650-644-8398
Tim Kemp	Facilities	650-470-6121	Mobile 650-862-4556

5.3. CLIA Lab contact information

Employee	Work Cell Phone	Personal Phone
Hoda Alamdar	650-492-9409	408-821-2762

5.4. Referral Laboratory contact information

Referral Lab	Address	Phone number
ARUP Laboratories	500 Chipeta Way Salt Lake City, Utah, 84108	800-583-2787
UCSF at Mount Zion	2330 Post St., First Floor San Francisco, CA 94115	415-885-7531

6. Hazard Information

6.1. Reagents
6.1.1. Refer to the MSDS.

6.2. Equipment
6.2.1. Large equipment is bolted down for earthquake protection.

6.3. Environmental
6.3.1. Obey the following:
6.3.1.1. Fire Safety and Evacuation Plan (CL PLN-02020)
6.3.1.2. Earthquake Safety Plan (CL PLN-02040)
6.3.1.3. Disaster Recovery Plan (CL PLN 02041)
6.3.1.4. Housekeeping and Material Safety Storage Plan (CL PLN-02031)
6.3.1.5. Employee Safety and Health (CL PLN-02007)
6.3.1.6. Injury and Illness Prevention Program (CL PLN-02024)

7. Safety Equipment

7.1. Fire Extinguishers
7.2. Eye wash station
7.3. Safety Shower
7.4. Chemical Spill Kit
7.5. Fire Safety Cabinet

8. Emergency Notification

8.1. In case of an emergency, information will be communicated to the company by way of:
8.1.1. the building fire alarm system
8.1.2. an Emergency E-Mail Notification
8.1.3. Palo Alto voice-recorded emergency hotline 650-329-2420.

8.2. To report an Emergency
8.2.1. Contact the Police, Fire, or Emergency Medical Response by dialing 911.
8.2.2. Contact the Security office at extension x290 or the operator by dialing 0.
8.2.3. Contact the CLIA Lab employees by emailing the 'CLIA Lab' routing to communication instructions that can be obtained through mobile devices.

8.3. In the event that the laboratory is unable to perform patient testing samples will be sent to our reference laboratory until patient testing can resume.
8.3.1. Contact the respective reference laboratory to inform them of the increase in sample volume from our facility due to the emergency event.

9. Laboratory Shutdown

9.1. Shut down operations that could be affected by the loss of electricity, water, gas or other services.
9.2. Close the sash on all chemical fume hoods in the event that ventilation is lost.
9.3. Remove all infectious materials from biosafety cabinets, and autoclave, disinfect, or safely store them as appropriate.
9.4. Ensure that all chemical, biological, radioactive materials and hazardous waste containers are properly covered, sealed, and stored properly.
9.5. Ensure that all gas valves are closed.
9.6. Power off all electronics equipment (e.g. analyzers, computers, incubators, hoods).
9.7. Review storage of perishable items. Consolidate valuable items within storage units that have backup systems or store items in duplicate locations as appropriate. Review safety precautions for the use of alternate cooling methods (e.g. liquid nitrogen, dry ice, etc.), if used.
9.8. Ensure that water reactive chemicals are in sealed containers and stored in areas that are unlikely to become wet.
9.9. Check that all gas cylinders are secured. Remove regulators and install transport caps where possible.
9.10. Elevate equipment, materials and supplies, including electrical wires and chemicals, off of the floor, particularly in lower elevations that are prone to flooding.
9.11. Close all doors, including cabinets, storage areas, offices and utility chase-ways. Lock all exterior lab doors before leaving.
9.12. Secure lab notebooks and backup critical data on computers.

10. Revision History

REVISION HISTORY			
Revision Level	**Effective Date**	**Initiator**	**ECO Number**
A	04/01/2013	K. Elenitoba-Johnson	CL ECO-00111
B	09/22/2014	Godfred Masinde	CL DCO-00053
Section Number	**Description and Justification of Changes**		
All	Initial Release		
All	Annual Review		

Cleaning Spills of Biohazardous Materials including Bloodborne Pathogens

Author(s):

Signature:	Date: 9/25/14
Name: Godfred Masinde, PhD	Title: Technical Supervisor

Reviewer(s):

Signature:	Date: 9/25/14
Name: Lina Castro	Title: CLS, Safety Officer

Signature:	Date: 9/25/2014
Name: Steve Morin	Title: Technical Supervisor

Approver(s):

Signature: DocuSigned by: Lynette Sawyer 586A81F4EEBD48...	Date: 5/5/2015
Name: Adam Rosendorff, MD	Title: Laboratory Director

Lynette Sawyer

The Laboratory Director or designee will review this procedure at least annually including revisions.

Reviewed By:	Date:	Comments:

Cleaning Spills of Biohazardous Materials including Bloodborne Pathogens

1 PURPOSE

The purpose of this procedure is to minimize the possibility of disease transmission by establishing procedures for the safe handling of spills of human blood, blood products or other potentially infectious materials.

2 SCOPE

This procedure covers the employees and clients at Theranos, Inc. who may have the potential to be exposed to human blood or other potentially infectious human blood materials in the performance of their job duties. Only Class 1 and Class 2 agents are relevant to CLIA laboratory operations.

3 DEFINITIONS AND ABBREVIATIONS

3.1 A **biohazard** can be defined as any organism, or material produced by such an organism, that is known or suspected to cause human or animal disease. Biohazardous/infectious material falls under Class D, Division 3 of the Workplace Hazardous Materials Information System (WHMIS), and includes:

3.1.1 microorganisms such as viruses, fungi, parasites, and bacteria and their toxic metabolites

3.1.2 human or other mammalian blood and body fluids

3.1.3 unfixed and fixed tissues and specimens from humans and non-human primates

3.1.4 cell lines and other tissue cultures

3.1.5 certain types of nucleic acids, such as DNA derived from pathogenic organisms, human oncogenes or transformed cell lines

3.1.6 genetically altered organisms, including plants

3.1.7 zoonotic agents (diseases that normally exist in animals but that can infect humans)

3.2 A **Class 1 Agent** (Biosafety Level 1) is a microorganism that is unlikely to cause human disease or animal disease

3.3 A **Class 2 Agent** (Biosafety Level 2) is a pathogen that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment. Laboratory exposures may cause serious infection, but effective treatment and preventative measures are available and the risk of spread of infection is limited.

3.4 A **Class 3 Agent** (Biosafety Level 3) is a pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another. Effective treatment and preventive measures are available in most instances. Prion diseases such as Creutzfeldt-Jakob disease are a special case due to their resistance to decontamination. BSL-3 is not relevant to CLIA Laboratory operations.

3.5 **Exposure to biohazardous agents** may occur via puncture wounds or as a result of absorption through the respiratory tract, digestive system, skin and mucous membranes: such exposures may result while handling

microorganisms, animals, cell cultures and tissues or diagnostic specimens. Investigators who are uncertain as to whether a material is biohazardous or not should consult the safety manager.

3.6 **Sharps** are any item capable of causing puncture wounds or cuts. This includes discarded hypodermic syringes, cannulas, needles, scalpel blades, cover slips, microscope slides, all glass or plastic pipettes (including Pasteur pipettes), broken glass, and metal shards. All sharps must be handled and disposed properly to prevent injuries to anyone who may come in contact with them from the original user, to other lab members, to the custodian, to the refuse truck driver, and to the landfill operator. Sharps that may be contaminated with potentially infectious materials are subject to additional requirements.

4 RESPONSIBILITIES

4.1 Safety Manager

4.1.1 Provide employee and client training in these procedures as necessary.

4.1.2 Maintain copies of any "Incident Investigation Report" (Attachment 8.1)

4.1.3 Provide consultation to employees who may be exposed to Human Bloodborne Pathogens or other potentially infectious materials. Theranos, Inc. will inform client managers and supervisors of company procedures for client rights and the organization's procedures.

4.2 Managers & Supervisors

4.2.1 Provide the resources necessary to ensure that Personal Protective Equipment (PPE) is available for Theranos employees.

4.2.2 Ensure that all employees exposed to human bloodborne pathogens or other potentially infectious materials are offered Hepatitis B vaccinations.

4.2.3 Ensure that all injured or contaminated employees are documented on the Incident Investigation Report Form (Attachment 8.1) and reported to the Safety Manager.

4.2.4 Following an incident, ensure that the "Incident Investigation Report" provisions are completed and documented. (Attachment 8.1)

4.3 Employees and Client Employees

4.3.1 Understand the applicable components of this procedure.

4.3.2 Adhere to the practices and procedures of Universal/Standard Precautions.

4.3.3 Report any exposure, accident, injury, or illness to managers or supervisors and to the Safety Manager.

5 MATERIALS AND REAGENTS

5.1 Class 1 (Biosafety Level 1) Equipment

5.1.1 Disposable gloves

5.1.2 Lab coat

5.2 Class 2 (Biosafety Level 2) Equipment

5.2.1 Impervious coveralls, such as Tyvek or lab coats depending on volume

5.2.2 Impervious boot covers, preferably disposable

5.2.3 Full face shield or goggles and mask

5.2.4 Disposable gloves

5.2.5 Disposable absorbent towels

5.2.6 Freshly-prepared 10% household chlorine bleach solution (Clorox® or equivalent) (1 part bleach and 9 parts water; or add a scant ½ cup bleach to 1 quart of water)

5.3 Dustpan

5.4 Tongs

5.5 Sign to prevent entry to the area being cleaned.

6 PROCEDURE

6.1 Biological spills outside biological safety cabinets will generate aerosols that can be dispersed in the air throughout the laboratory. Appropriate protective equipment is particularly important in decontaminating spills involving microorganisms that require either Biosafety Level 2 or Biosafety Level 3 containment. The following procedures are described in terms of the risk posed by the organism(s) involved. The term Class refers to risk

group, as defined by the World Health Organization. You should know the assigned risk group of the organisms with which you are working. If not, contact your supervisor or EHS.

6.2 Spills Involving Class 1 Organisms

6.2.1 Soak up gross spill with paper towels

6.2.2 Place paper towels in heavy plastic bag

6.2.3 Soak more paper towels in disinfectant and place over the spill area, or create a berm with paper towels and pour disinfectant over the spill area.

6.2.4 Allow disinfectant to remain in contact with spill area for 20 minutes.

6.2.5 Soak up disinfectant with clean paper towels and place in heavy plastic bag.

6.2.6 Notify lab supervisor

6.3 Spills Involving Class 2 Organisms

6.3.1 The appropriate personal protective equipment for cleaning up a spill of a Class 2 organism depends on the severity of the spill. The appropriate outer garment depends on the severity of the spill. If the spill is small something like a lab coat is sufficient so long as it is unlikely that your outer garment can become saturated with the spilled material. Impervious coveralls, such as Tyvek, are necessary if the spill is large and it is likely that your outer garment can become significantly saturated. Likewise, the appropriate eye protection depends on the severity of the spill. If splashing is likely, as with a large spill, goggles and a face shield are necessary to protect mucous membranes (e.g., eyes, nose and mouth). If the spill is small and splashes are unlikely, safety glasses with side shields will do. Also, don't forget about other exposed portions of the body or

garments that could come into contact with the spilled body fluid. It may be necessary to wear rubber boots if you must step into or traverse areas where the spill occurred.

6.3.2 Alert others to the spill. If someone is available to provide assistance, have them provide surveillance so that people don't wander into the spill area.

6.3.3 If you feel that you are unable to respond to the spill, notify your supervisor or the safety manager, or call 911 after hours.

6.3.4 Gather necessary supplies and put on appropriate PPE.

6.3.5 Remove contaminated sharps (e.g., broken glass) from the spilled material and place in a rigid, water-tight container. Don't use your hands to pick up the sharps rather use a mechanical device such as tongs.

6.3.6 Spread an absorbent material over the area of the spill, working from the outside edges toward the middle. This keeps the spilled material from spreading.

6.3.7 Allow the absorbent to soak up the liquid and carefully place it into a biohazardous waste receptacle.

6.3.8 Create a small berm with paper towels around the outer edges of the spill. Treat all surfaces of the spill area with a freshly-prepared 10% solution of household bleach or other suitable disinfectant. It is best to gently pour the bleach solution on the spill area, as opposed to spraying, since spraying could create aerosols.

6.3.9 Allow the bleach to stay in contact with the surface for 15-30 minutes. Afterwards, absorb any remaining bleach solution on paper towels and place into a biohazardous waste container.

6.3.10 If you haven't already done so, notify your supervisor of the spill.

6.4 Cleaning Blood Spills on Non-Carpeted Floors

6.4.1 A hard, non-carpeted surface is the most common setting for blood spills. These surfaces include tile, ceramic, vinyl, linoleum, metal, wood, cement, and any other non-absorbent flooring such as a pool deck.

6.4.2 Cleaning up blood and other bodily fluids off these surface types is easier than absorbent surfaces, but there are still important steps for you to consider.

6.4.3 Spills on hard surfaces often spread over larger areas so it will be necessary to contain the spill quickly. The procedures for cleaning up spills on these surfaces are:

6.4.3.1 Block off the area until cleanup and disinfection is complete. No visitors or unprotected staff members should be able to access the area.

6.4.3.2 Put on disposable gloves, mask, goggles, shoe covers.

6.4.3.3 Cover the spill (including sharps) with paper towels or other absorbent material.

6.4.3.4 Gently pour bleach solution – 1 part bleach to 9 parts water – onto all contaminated areas.

6.4.3.5 Let bleach solution remain on contaminated area for 20 minutes and then wipe up remaining bleach solution. Disinfect the area until is completely clean.

6.4.3.6 All non-disposable cleaning materials such as mops, brushes and rags need to be disinfected by saturating with bleach solution and allowed to air dry.

6.4.3.7 Remove gloves and other PPE and place in a biohazard bag with all other soiled cleaning materials.

6.4.3.8 Put on new gloves and double bag and securely tie up garbage bags and discard.

6.4.3.9 Discard your gloves in biohazard bin.

6.4.3.10 Thoroughly wash hands with soap and water.

6.5 Blood Spills on Carpeted Floors

6.5.1 Blood spills on carpeted floors are some of the most difficult to clean up due its absorbent nature. The majority of buildings contain at least some amount of carpeting, which is why it is important to know how to respond to spills in these areas. Many of the procedures for cleaning up blood on carpet will be the same as any other area, but there are a few additional concerns. In addition, there is no way to disinfect carpet completely so the best option is to sanitize as thoroughly as possible.

6.5.2 Work Quickly: Blood or other bodily fluids can harden or set up quickly on carpeting making it much more difficult to clean. Respond quickly, but make sure to follow all safety precautions like wearing appropriate PPE, securing the area, and ensuring the injured individual is safe.

6.5.3 Use Appropriate Products: Bleach and other decontamination products can damage or destroy carpet. The best way to clean these areas is to use manufacturer approved carpet shampoos and cleaners. Make sure you select a product with some anti-microbial properties to help sanitize the area as thoroughly as possible.

Another recommendation is that after the area is cleaned and dried repeat the process once or twice more since the absorbent nature of carpet can still conceal some pathogens.

6.5.4 Steam Clean: Depending on the nature and size of the spill, it is advisable to perform a steam clean of the carpet. Steam cleaners will clean, remove debris, and sanitize carpeting more completely than conventional washing. Although there is some additional cost to steam cleaning, it is the best way to protect against bloodborne pathogens.

6.5.5 Change Carpet Tiles: Removable carpet tiles are a great way to protect against exposure to bloodborne pathogens. Carpet tiles are often less expensive than traditional carpet, and if a certain area becomes heavily soiled with blood they can easily be removed and replaced. If your organization is equipped with carpet tiles be sure to dispose of them properly after being saturated with blood or any other potentially infectious bodily fluid.

6.5.6 The basic protocol for cleaning carpets and removing the threat of bloodborne pathogens is listed below. Please note that even when these steps are followed there is no guarantee that the threat of bloodborne pathogen exposure is 100% eliminated.

6.5.7 Put on Disposable Gloves: No matter what type of surface you're cleaning, always put gloves on first.

6.5.8 Contain the Spill: After a spill, it is important to keep it as contained as possible to avoid allowing the affected area to spread. Create a barrier around the spill with an absorbent material.

6.5.9 Initial Disinfect: Once the area is contained, spray the affected area with an appropriate carpet detergent to help kill some of the surviving pathogens. After spraying the area, allow it to sit for 10 minutes so the disinfectant has time to work.

6.5.10 Blot up Excess Fluids: Use disposable towels or rags to blot as much excess fluid as you can and then carefully dispose of the soiled rags in a sealable bag.

6.5.11 Extract Absorbed Fluids: The carpet will absorb some of the fluid so removing them will be the next step. Use a wet-vacuum to thoroughly wet and remove any fluids. Repeat the process of wetting and suctioning several

times. While wetting the affected area be sure to prevent any water from spreading beyond the initial boundary.

6.5.12 Re-disinfect: After vacuuming, thoroughly re-saturate the area with an appropriate disinfectant. Follow your carpet manufacturer's recommendations since certain products can damage carpet fibers and dyes.

6.5.13 Let Sit: After completely disinfecting the area, allow the disinfectant to set and work for up to 20 minutes to make sure it has the full effect.

6.5.14 Third Disinfect: Repeat the previous two steps of disinfecting and then allowing to sit for 10-20 minutes.

6.5.15 Rinse: Once the final round of disinfecting is complete, rinse the area one last time to remove any remaining detergent or disinfecting solution. After rinsing, wet-vacuum the area.

6.5.16 Dry: Next, dry the area thoroughly with rags to draw out any remaining moisture and then place fans near the area to completely dry it,

6.5.17 Wrap up: After the area is clean, properly dispose of all rags and PPE contaminated by the spill. In addition, thoroughly clean all other equipment used during the spill cleanup.

6.6 Blood Spills on Furniture

6.6.1 Like bodily fluid spills on carpet, spills on furniture are difficult to clean as well. There are, however, certain steps you can take to make sure it is as clean and safe as possible. As is the case with blood spills on carpet, it is important to contain the spill as quickly as possible.

6.6.2 Cleaning blood off of furniture then depends on what type of furniture is contaminated. Cloth furniture needs more treatment than wood or metal furniture. Depending on the type of cloth furniture and the degree of the spill, the best cleaning method is to remove the cloth covering, if possible, and launder it by itself on a warm wash cycle. If the cloth furniture does not have a removable cover, then it is best to treat the spot as you would a blood spill on carpet and disinfect, let sit, and repeat several times.

6.6.3 There are also professional services that can clean furniture much more effectively and thoroughly if the spill is severe enough. Blood spills on metal and wood furniture are not as laborious as those on cloth furniture, but it is important to point out that bloodborne pathogens are still a threat. Metal, wood and any other non-porous furniture should be cleaned just like a blood spill on a non-carpeted surface.

6.7 Contaminated clothing

6.7.1 Notify your supervisor immediately.

6.7.2 If blood or other potentially infectious materials penetrate a garment, the garment will be removed immediately or as soon as feasible.

6.7.3 Contaminated laundry will be handled as little as possible with a minimum of agitation. Handle clothing with gloves.

6.7.4 Contaminated laundry will be placed and transported in bags or containers labeled or color-coded. When a facility utilizes Universal Precautions in the handling of all soiled laundry, alternative labeling or color-coding is

sufficient if it permits all employees to recognize the containers as requiring compliance with Universal Precautions.

6.7.5 If blood or other potentially infectious materials had soaked through so that there is skin contact, the clothes must be removed. Following removal, wash those areas where exposure is evident, even to the point of taking a shower.

6.8 Exposure to mucus membranes

6.8.1 Notify your supervisor immediately

6.8.2 If blood or PIM has come into contact with any of the mucous membranes (eyes, nose, lips) they need to be thoroughly washed with soap and water and flush the area with water for 15 minutes.

6.8.3 If there is contact with open wounds or cracks in the skin, there is a risk of exposure.

6.8.4 Immediately and thoroughly wash your hands with water and an antiseptic cleaner if contaminated with a body fluid. These occurrences are considered to be an Exposure Incident and it is important to follow the procedures outlined in the Theranos Bloodborne Pathogen Safety Plan.

6.8.5 Allow minor wounds or punctures to bleed freely. Application of antiseptics when caring for the wound is appropriate. However, the application of caustic agents such as bleach or chemical disinfectants into the wound is not recommended.

6.8.6 Exposure to the eye(s) or mucous membranes are treated by flushing with clean water (eye wash) or saline for up to 15 minutes.

7 RECORDS

Records of spills and investigations thereof will be maintained for 3 years.

8 ATTACHMENTS

8.1 CL FRM-02006-F2_Incident Investigation Report.

9 REFERENCES

9.1 California Code of Regulations Title 8 Section 5193.

9.2 WHO. 2000. WHO infection control guidelines for transmissible spongiform encephalopathies. Report of a WHO consultation, Geneva, Switzerland, 23-26 March1999, http://www.who.int/csr/resources/publications/bse/whocdscsraph2003.pdf.

10 REVISION HISTORY.

REVISION HISTORY

Revision Level	Effective Date	Initiator	ECO Number
A	06/09/2011	A. Gelb	CL ECO-00003
B	06/13/2011	A. Gelb	CL ECO-00016
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Section Number	Description and Justification of Changes
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Theranos LIS Application User Guide

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	CLIA Laboratory	Effective Date: 01/27/2015
Theranos LIS Application User Guide		

1 PURPOSE

1.1 The purpose of this document is to serve as an instruction manual for users of the Theranos LIS software application.

2 SCOPE

2.1 This document details the numerous features offered by the Theranos LIS software application and the steps users take to utilize each of these features.

3 DEFINITIONS AND ABBREVIATIONS

3.1 Theranos LIS (TLIS): The software application used by laboratory personnel to view, edit and send test and result information, create and modify provider, physician and patient records, and edit and store clinical and processing information for assays run by Theranos.

3.2 Requisition: An electronic request created from a lab order, that includes all the necessary information to process the test, report the results, and bill for services.

3.3 Provider Record: A record for a provider of physician services, laboratory services, or PSC services. Most provider records stored in TLIS will be individual physician offices, physician groups, or hospitals.

3.4 Physician Record: A record for an individual physician that contains demographic, contact, and licensure information. There may be more than 1 physician record for a unique physician, as a physician record can only be connected to 1 provider record.

3.5 Patient Record: A record for an individual patient for whom a lab order has been received by Theranos. There will only be 1 patient record for each unique patient.

3.6 User Record: A record for each LIS System User. Laboratory Admin users are able to access this screen to create new users and change user roles.

3.7 Review List: A List of requisitions for which some result values have been entered but not yet reviewed by qualified personnel. A requisition is added to the Review List when at least one of the result status' for a given test is set to "Under Lab Review."

3.8 Pending List: A Lists of assays for which results have not yet been added or uploaded. This List can be sorted or filtered by a number of different variables, including test name, machine, PSC location, region, and date of sample collection.

3.9 Visit Status Dashboard: A dashboard that allows users to sort visits by visit status.

3.10 Critical Review List: A list that displays all critical values with status Under Lab Review across a defined period of time.

3.11 Redraw Request Review List: A list that displays all redraws that have been requested and approved over a given period of time. Users may approve and cancel redraws in this list.

3.12 Rerun List: A list that display all reruns that have been requested and approved over a given time period. Users may approve and cancel reruns in this list.

3.13 Import from Device: A feature that allows users to review results that have been uploaded to LIS from the device, prior to those results appearing in the patient visit record. This results have a status of "Ready for Import." Users are able to Import, Re-Run, and Void results from this screen.

3.14 Requisition List: A List of all requisitions created in TLIS, including those for which the patient has not yet arrived at the PSC and those for which results have been reported. This List can also be sorted or filtered by a number of different variables, including patient name, doctor name, PSC location, and visit date.

3.15 Test Status: The status of a test on an order, the first being "Ordered" and the last being "Results Reported." Other statuses include "Specimen at PSC," "Test in Process," and "Results Under Review."

3.16 Result Status: The status of a result, as defined in the requisition detail screen. Only result values with statuses marked as "Available" will be shown on the result report sent to physicians and patients.

3.17 Quantitative Reference Range: A range that defines what the Normal, High, Low and potentially Critical High and Critical Low values are for a given Assay. These ranges may only be uploaded by the Lab Director and should not be modified by other TLIS users.

3.18 Enumerative Reference Range: A range that defines a result as being either one value or the other, such as "Negative" or "Positive." These ranges may only be uploaded by the Lab Director and should not be modified by other TLIS users.

3.19 Critical Value: A value that falls within the "Critical Low" or "Critical High" range as defined by the reference range entered into TLIS. These values may indicate an immediate clinical concern and will trigger the CLIA Laboratory's critical value reporting process.

3.20 CPT Codes: A set of codes used for billing purposes that are specific to a laboratory test or set of similar laboratory tests. CPT codes are used in TLIS to identify specific tests.

3.21 LOINC Codes: A set of codes used to uniquely identify clinical outcomes. In laboratory services, these codes and associated common names serve as the description of a result for a given test.

3.22 ICD-9 Codes: A set of codes used to uniquely identify diagnostic reasoning for a medical procedure. These codes are both used to signal to the service provider reasoning as to why a certain set of tests have been ordered, as well as for billing purposes in order to justify medical necessity for a procedure.

3.23 Theranos Test List Directory: A glossary of all tests and panels offered by Theranos, including variations on each test name.

4 RESPONSIBILITY

4.1 Theranos Laboratory Personnel

4.1.1 Theranos Lab Personnel are responsible for utilizing TLIS in day-to-day lab operations and for maintaining data integrity in the system.

4.2 Theranos Laboratory Director

4.2.1 The Theranos Lab Director is responsible for maintaining data that can only be accessed by lab admin users such as reference ranges, CPT to LOINC code mapping, and user accounts.

4.3 Theranos IT Support

4.3.1 The Theranos IT Support team is responsible for maintaining system infrastructure and ensuring the TLIS application is secure and accessible at all times.

5 MATERIALS AND EQUIPMENT

5.1 Theranos Computer

5.2 Access to Theranos Network

6 TIMING

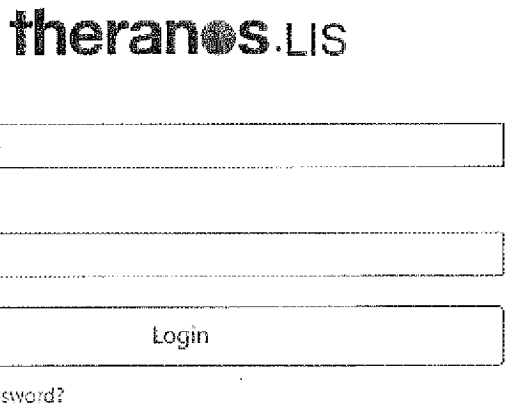
6.1 Use of the TLIS application will occur frequently throughout the course of normal business operation.

7 PROCEDURE

Part I: Login and System Settings

Logging into TLIS

1. Download the TLIS application by accessing the following URL < https://labcheckin.theranos.com/LIS2.0.App/publish.htm> and selecting "Launch."
2. After the download completes, search for TLIS in the Windows start menu.
3. Start the application
4. Enter the Username and Password provided by the system administrator



Login Screen

Contingencies:

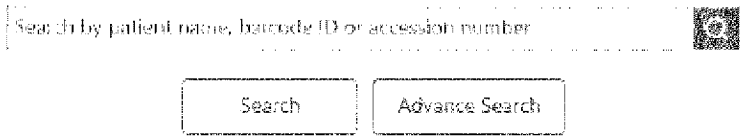
1. User is not able to download the application
   a. Contact the corporate Helpdesk for assistance in downloading internal applications
2. User is not able to log into the application
   a. Contact the System Administrator in order to reset your username and password

Part II: Visits

Visit Search

By clicking on the "Visits" tab on the top menu bar, the user will be directed to the Visit Search screen.

Users may enter a patient name, barcode ID or accession number in the visit search bar to search for a visit. Any ID associated with any container on a visit may be entered – including both collection containers and aliquot containers.

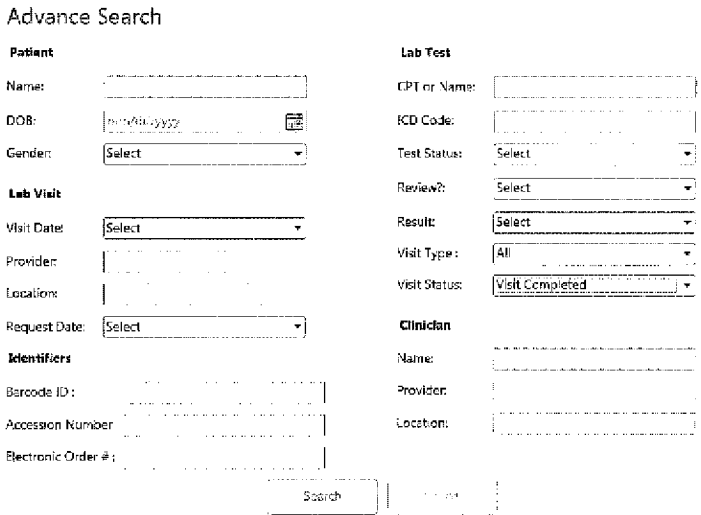


Visit Search

Users may also utilize the Advanced Search feature to narrow the search for visits using a number of different variables, as seen in Figure H below.

For example, setting the Lab Visit Provider to "Walgreens", the Location to "WAG13596" and the Date to Yesterday will display all visits completed yesterday at Walgreens Store 13596.

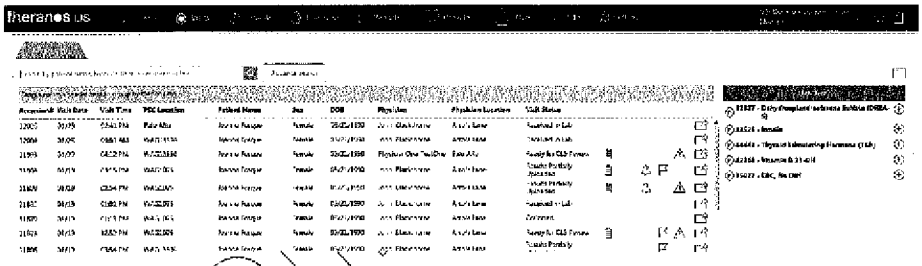
Note: Setting visit status to "Visit not Started" will display outstanding electronic lab orders for which the patient has not yet arrived at the PSC.



Advanced Visit Search

Once a patient has visited a patient service center, a specimen has been collected and the visit has been completed in the PSC application, TLIS users will be able to access the Visit Details screen in order to view, edit, release and send results to physicians and patients.

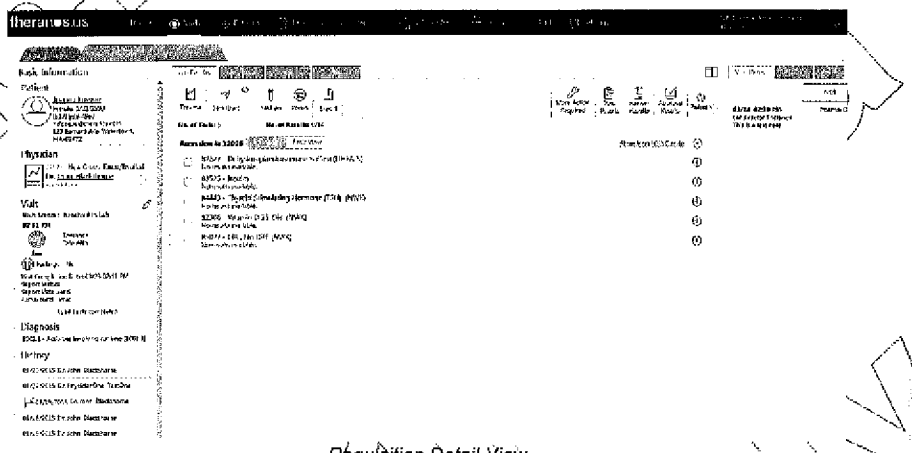
As discussed in section IA above, users may search for a visit quickly in Visit Search screen. This brings users to the Requisition List View screen.



Requisition List View

Users may also access visits via the Pending List, Visit Status Dashboard, Critical Review List, Redraw Request List, Rerun Review List and Import from Device list – simply by clicking on the record.

The Visit Details Screen contains all information related to that specific visit, and is split up into 3 major sections – Basic Information, Core Information, and the Notes & Audit Trail sidebar.



Requisition Detail View

Visit Details

Basic Information

The Basic Information section includes patient demographic information, physician demographic information, visit information and visit status, diagnosis codes, and past visit history. Users are not able to edit this information. This section also includes hyperlinks to the Patient record and Physician record, accessed by clicking on the patient name or physician name.

Key details in the Basic Information section include:

Order: Describes the order type. Order types include:

- Paper: scanned into the PSC app and transcribed into the Super Mario App
- Electronic: sent directly from an Electronic Medical Record application
- Faxed/Emailed: Created directly in LIS
- Standing Order: Order is a standing order
- Redraw: Order is a redraw order

Visit Status: Describes the current status of the visit. Visit Status designations include:

Collected
- >=1 container status = Received
- 0 result values exist on visit

Received in Lab
- >=1 container status = Received
- 0 result values exist on visit

Results Partially Uploaded
- >=1 container status = Received in Lab and All result values = Null OR
- >=1 result value <> null

All Results Ready for CLS Review
- All result values = Available, Under Lab Review or Void by Lab
- >=1 result value = Under Lab Review

Sent to Doctor
- Visit status = Open
- Notification sent to doctor

Closed
- Visit = Closed

Fasting: Describes the fasting status of the patient during the visit.

- Yes: Physician requested patient to be fasting and patient indicated during visit that they were in fact fasting.
- No: Either physician did not request patient to be fasting, or patient indicated during visit that they were not fasting.
- Unknown: Physician requested patient to be fasting and patient indicated during visit that they were not sure if they had fasted for the appropriate time.

Report Status: Indicates whether a preliminary or final report has been sent.

Turnaround Time: Indicates the TAT for the visit.

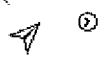
Diagnosis: Lists all ICD-9 diagnosis codes as specified on the lab order.

Lab Results Tab

The Lab Results section shows all of the tests and associated results and result values for the patient visit.

Action Buttons

Preview Click this button to view result report as it would be seen by the Lab, Doctor and Patient. Users may also preview partial reports by indicating the Test Codes they wish to see displayed.



Send(Fax) Click this button to send results via Fax, Email or Electronically (if available). The default method will be circled in Green. If results are sent outside of the system, users will click "Sent Manually" in order to log that the report has been sent.

Redraw Click this button to request a redraw, view existing redraw details, or directly approve a redraw request. Users must first select a Test Code prior to clicking Redraw.

Rerun Click this button to request a rerun, view existing rerun details, or directly approve a rerun. Useres must first select a Result Code prior to clicking Rerun.

Click this button to void all results or checked results.

Click this button to set all results or checked results to status Under Lab Review.

Click this button to set all results or checked results to status Doctor Only.

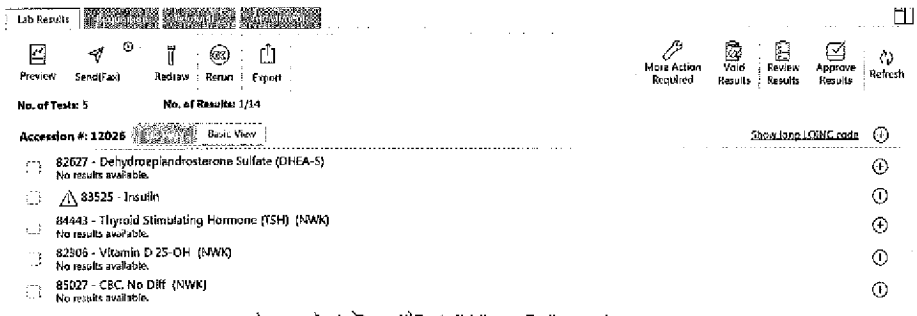
Click this button to refresh the visit. This will update the visit status and audit trail after changes have been made to the visit.

Click this button to add an action to a visit. This will indicate to other LIS users that a pending task must be completed prior to results being sent and the visit being closed. Some actions include:

- Slide Review: Indicates a slide review must be completed
- Review Image: Indicates that the Nanotainer image must be reviewed
- Verify Results: Indicates that a result must be examined and verified, beyond the normal review process
- Critical Review: Indicates that a critical result must be reviewed and the doctor called

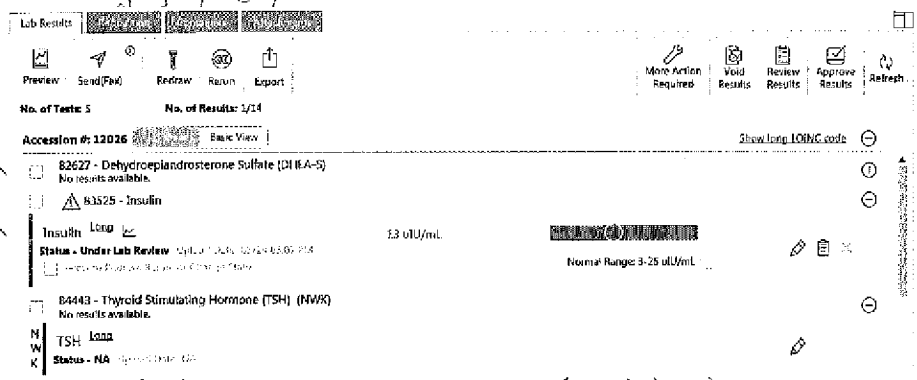
Viewing Results

By default, each row under this section shows the Test Code and Test Name for all tests included during that visit, with results collapsed underneath the Test row.



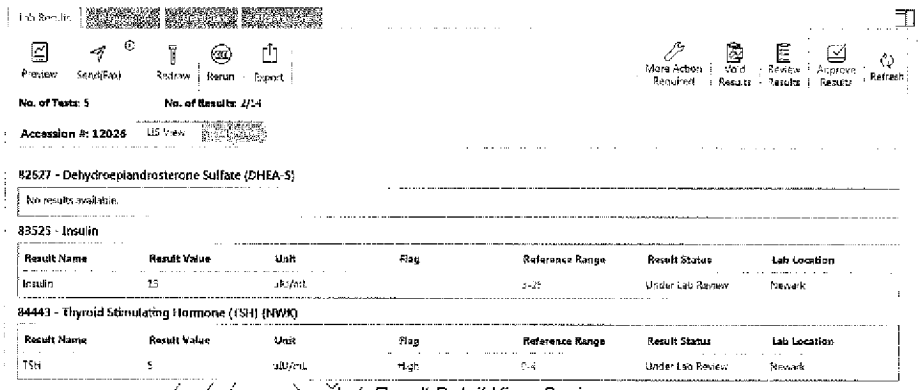
Lab Result Detail View, Collapsed

By clicking on the "+" icon at the far right side of each test row, an accordian List appears that shows the result name for a given test, as well as the current value, previous value, flag, result status, and reference range. Prior to any results being entered, the status is set to "NA," and no other information appears.



Lab Result Detail View, Expanded

Clicking on "Basic View" will change to a simple, tabular result view.



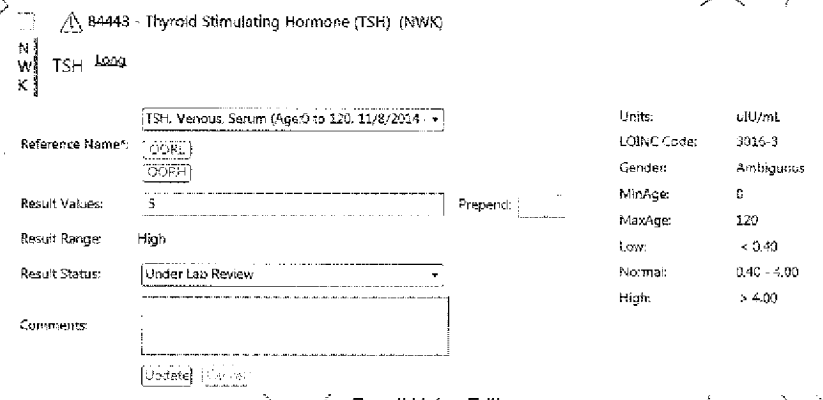
Lab Result Detail View, Basic

Adding & Editing Results

Result values are generally added programatically to LIS after a user of a Bridge Application has sent the results from the analyzer to LIS, and an LIS user has Imported the result successfully.

After this process is complete, the result status will be set to "Under Lab Review." This signifies that the result must be reviewed by a CLS prior to being confirmed and released.

To edit or add results, click on the blue "Edit" button on the right hand side of the result row.



Result Value Edit

Reference Ranges: Users must first select a reference range prior to entering a result value. **Careful!** Reference ranges may vary for patients of different age or gender – double check to confirm that the

range selected matches the demographic background of the patient. Age and Gender information for the reference range is shown on the right side of the edit result screen.

Result Status: Once a reference range is selected, users may enter a result value, and select a result status.

- Under Lab Review: Indicates a result must be reviewed by licensed laboratory personnel prior to being released to the physician and patient.
- Doctor Only: Indicates that a result has been reviewed and released by licensed laboratory personnel, but only to the Doctor.
- Available: Indicates that a result has been reviewed and released by licensed laboratory personnel, and is available to both the Doctor and Patient.
- Void by Lab: Indicates that result has been voided by laboratory personnel.
- On Hold: Indicates that a result is on hold. Such results will have a pending Action found by clicking on the More Action button.

OORL/OORH: Clicking on the OORL or OORH button will automatically set the result value to the upper or lower limit of quantification, and add a "<" or ">" symbol in front of the result.

Users may also manually enter "<" or ">" in the Prepend field to indicate that the result is above or below the quantification limit of the assay. This symbol will appear in front of the entered result value on the result report.

Careful! Deleting a result will remove the result value completely from the LIS user interface. If there is only 1 result row, the user will not be able to add a new result after deletion.

Requisition Tab

The requisition section displays each lab order associated with the patient visit. If the patient utilized multiple lab orders during the visit, the details of each specific order will be separated and displayed in this section.

Users can also find copies of any scanned paper orders in this section, as well as the Super Mario technician that transcribed the order.

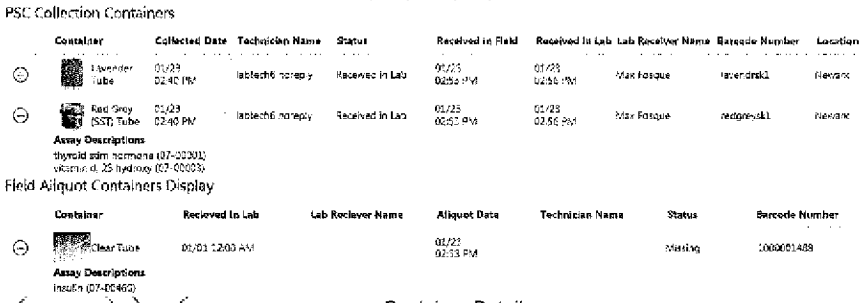
Containers

The containers section displays information related to each container associated with the visit, as well as the current location. Expanding a container row displays all assays that will be run from that container.

- PSC Collection Containers: Containers collected during the patient visit
- Field Aliquot Containers: Containers used to transfer part of a sample from the local laboratory to a reference laboratory.
- Lab Aliquot Containers: Containers used to transfer part of a sample to a different container to run a certain subset of assays in the local laboratory.

Container Status

- None: Container has been collected in the PSC
- Received in Field: Container has been received at the local laboratory and is being sent to a reference laboratory
- In Transit: Container is in transit from the local laboratory to the reference laboratory
- Received in Lab: Container has been received in the laboratory at which it will be processed



Container Details

Attachments

This section includes any attachments which have been uploaded by TLIS users. Such attachments may include faxed lab orders, copies of documentation sent to state health authorities, or any other information relative to the visit that the lab wishes to save electronically.

Part III: Left Menu Screens

The Pending List is used to view assays that have not yet been run in the laboratory. Users may filter the pending list by Date Range, Lab Type, Assay Type and Sample Location.

Each record ("row") on the Pending List is an Assay. An Assay is the chemistry run to fulfill one or more reportable results. I.e., one assay is run to fulfill 3024-7 Thyroxine.Free, and one assay is run to fulfill 34714-6 Prothrombin Time, 5902-2 INR No Therapy and 6301-6 INR Warfarin Therapy.

There may be multiple assays active in the system for a given test. For example, Free T4 has two active Assays – one run in Normandy and one run in Jurassic Park. Both of these assays fulfill the same reportable (3024-7 Thyroxine.Free).

Logic

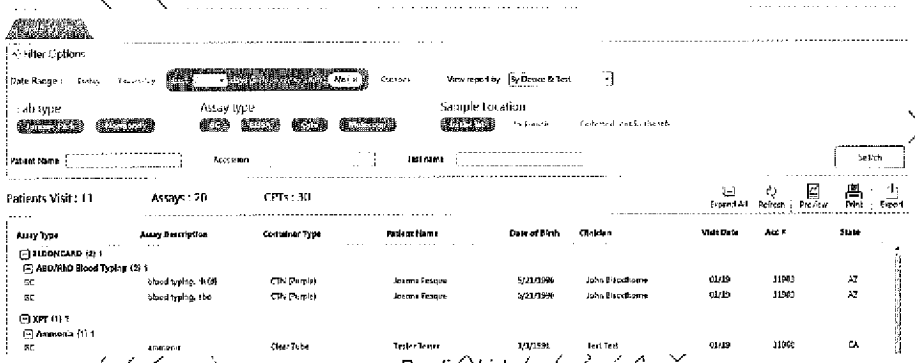
- >=1 LOINC associated with the Assay does not have an existing result value
- Visits Status <> Closed

Effect of Reruns

- After a rerun has been requested, a result is considered pending. Until the rerun is approved and the rerun result is uploaded, any assays to which that result is mapped will appear on the Pending List.
- Users may override this by cancelling the rerun or closing the visit.

Effect of Redraws

- Once a redraw has been approved, all assays on the visit mapped to the Redraw CPT are removed from the Pending List.



Pending List

The Visit Status Dashboard is a dashboard that groups visits by their status. This allows users to focus on visits in different states of completion.

For example, users concentrating on reviewing and releasing results will navigate to the "Ready for CLS Review" section to see all visits that are ready to be reviewed and sent.

Visits in the Ready for CLS Review, More Action Required, Ready to Send and Missing sections need to be monitored frequently in order to clear out records and get results reported to doctors and patients.

Visits in Collected, In-Transit, Results Partially Uploaded, and Prelim Sent to Doctor are pending further action elsewhere in the system. These lists are more for informational purposes, or to search for specific visits.

Logic

Note: The patient visit must be completed in the PSC Application for the visit record to be displayed in the Visit Status Dashboard.

Collected

- >=1 container status = Collected
- 0 result values exist on visit

In-Transit

- >=1 container status = In Transit
- 0 result values exist on visit

Results Partially Uploaded

- >=1 container status = Received in Lab and All result values = Null OR
- >=1 result value <> null

All Results Ready for CLS Review

- All result values = Available, Under Lab Review or Void by Lab
- >=1 result value = Under Lab Review

More Action Needed

- There is a pending Action associated with the visit

Prelim Sent to Doctor

- Notification sent to doctor
- Visit Status <> Closed

Sent to Doctor and Closed

- Visit status = Closed
- Notification sent to doctor

Missing

- >=1 container status = Missing

Effect of Reruns

- After a rerun has been requested, a result is considered pending. Until the rerun is approved and the rerun result is uploaded, the visit will remain in Results Partially Uploaded.
- Users may override this by cancelling the rerun or closing the visit

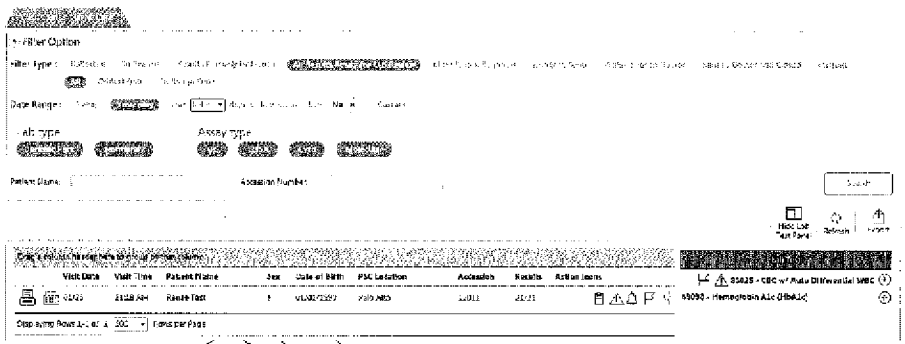
Effect of Redraws

- Once a redraw has been approved, all LOINC codes on the visit associated with the redraw CPT are ignored by the logic.

Icons

In the Lab Test column, certain icons will be displayed that indicate the status of results for any given test:

- Result Pending
- Result Under Review
- Result on Hold
- Result Available
- Critical Result



Visit Status Dashboard

The Critical Review List contains a list of all visits for which a critical value has been uploaded to the system.

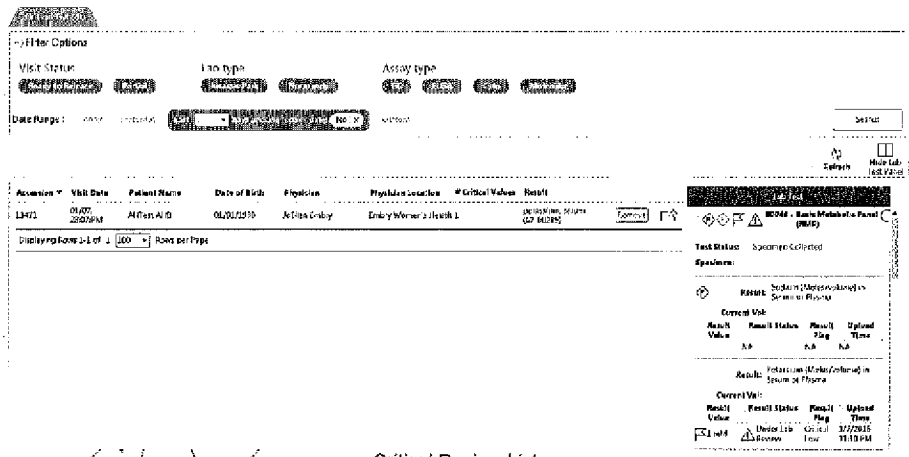
Records will only appear in the Critical Review list if the result status is set to "Under Lab Review." If the result is voided, or released (set to "Doctor Only" or "Available"), the record clears from the Critical Review List.

Users may also remove records from the Critical Review list by clicking the "Remove" button. However, users must enter a reason, as well as entering their username and password, prior to removing such a record.

The Critical Flag appears on a result row when the result is considered Out of Range – Critical. This could be Critical High, Critical Low, or another designation – i.e. "Positive" or "Toxic."

Laboratory personnel may utilize the Critical Review list to get a snapshot of all Critical values for which action has not yet been taken. Those monitoring the list may use it as a tool to assist in calling critical values to the ordering clinician, a process documented in the Critical Value Call SOP.

Commented [MF1]: Reference the Critical Value SOP



Critical Review List

The Redraw Request Review screen allows users to view all redraw requests and either approve or cancel the request.

Redraw requests are initiated by licensed laboratory personnel when it is determined that a valid result cannot be obtained for a test included in the patient visit. This may be due to a number of factors, from preanalytic human errors to post-analytic process errors. Upon creatin of a redraw request, users are required to document the reason for making that request, in order to help track the trends of requests over time.

Once a redraw has been requested, it must be approved by licensed personnel prior to the patient's redraw visit.

Users may also cancel redraw requests if they determine that it in fact will be possible to run the test and produce an accurate result.

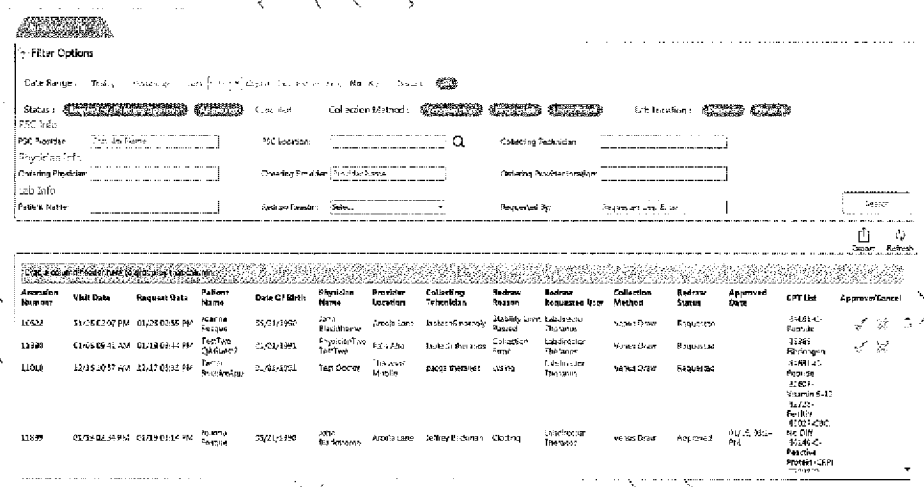
The list may be filtered by Request Date, Redraw Status, Collection Method and Lab Location. Users can also use the various Info filters to search for specific groups of redraw requests.

Users wishing to view and approve redraw requests will filter the list by Status, "Requested and Pending Approval." This allows those with permission to approve redraw requests the ability to search for all outstading requests, investigate any potential discrepancies, and approve the request if there are no other available options to run the sample.

On each row, users can see the Requester, the Reason why the redraw was requested, the Redraw Status, as well as the Collection Method of the original visit – among other details.

Upon approval, a new electronic lab order is created that will allow the patient to proceed through the PSC visit much faster than normal – skipping check-in and payment.

PLEASE NOTE! Approved redraw requests cannot be cancelled.



Redraw Request Review

The Rerun Review screen allows users to view existing rerun requests and either approve or cancel such requests.

Rerun requests can be initiated either in the Import from Device screen, or the Visit Details screen. The Rerun screen is only used for approving and cancelling reruns.

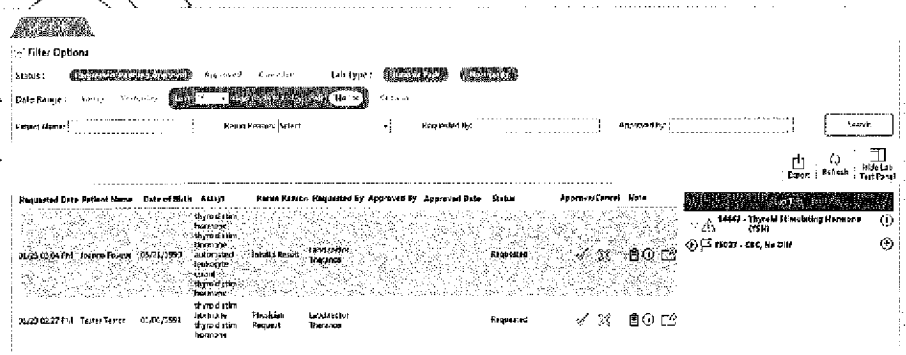
Rerun requests are initiated by licensed laboratory personnel for a number of different reasons. Reruns may be requested when it is determined that a second result is desired to confirm validity of the first result, Reruns may also be requested if the first run fails to produce a result at all.

Once a rerun has been requested, it must be approved by licensed personnel. Upon approval, a new record is added to the LIS and Device Pending Lists, as well as the Rerun App. Additionally, an empty result row is added to the associated result(s) in the visit details, awaiting the rerun result value to be uploaded or entered.

Users may cancel rerun requests if they determine that the first result is valid and can be released to the patient and doctor.

Dilution factors can also be applied to rerun requests. Applying a dilution factor will cause the result(s) to be multipled by that factor when sent from the device to LIS. For example, entering a dilution factor of "0.1" for the Testosterone assay would allow laboratory personnel to perform a 10x dilution on that sample and run the sample without making any device-level modifications. The result would then be multipled by 10 upon being sent to LIS.

PLEASE NOTE! Users should NOT enter a dilution factor in LIS if the dilution and associated calculation is performed by the analyzer. Dilution factors will also not be calculated if a result is added manually to LIS.



Rerun Screen

The Import from Device function allows users to review results immediately after they are sent from the analyzer, and import those results into LIS for final review.

The Import from Device dashboard, the first screen displayed upon navigating to this feature, shows all results ready for import for each device type. Clicking on the Device Name grouping will further segment the results by those ready for import from each individual device in the laboratory.

Result records in the Import from Device list have a status of "Ready for Import," and will ONLY appear in this screen. Results will not be displayed in any other screen in LIS (Visit Details, Critical Review, etc.) until a user selects and imports the result.

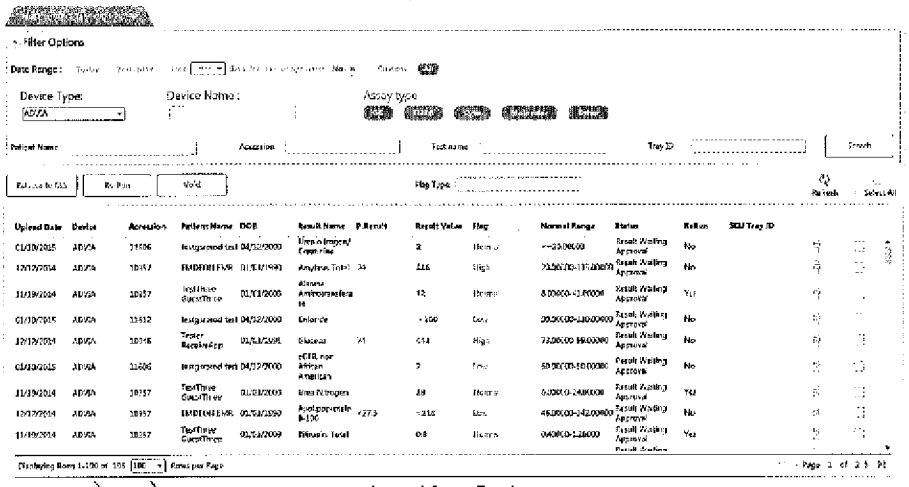
Users may also request or directly approve reruns, void results, or place a further action needed flag on results from the Import from Device screen. Voiding a result will cause it to appear in the visit details, with a status of Void by Lab. Placing a further action on a result will cause it to appear in the visit details, with a status of On Hold. The visit will then appear in the More Action Needed section of the Visit Status Dashboard.

Users may filter results by Date Uploaded, Assay Type, Device Type, Unique Device and Test. Users may also search for specific patient visits.

Users may also wish to display only normal or abnormal results. Filtering by Flag Type allows users to search for results with specific flags.

As in the Visit Details, green results are Normal, Orange are Abnormal, Grey are Indeterminate and Red are Critical.

Upon selecting a result or batch of results for import and confirming the import, the result status is changed to Under Lab Review and the results will appear in the Visit Details section.

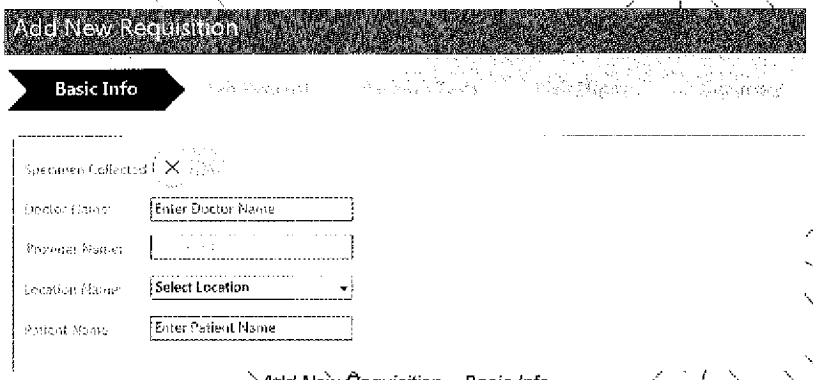


Import from Device

Part III: Adding a Lab Order

Users may wish to add a lab order to the system when an order has been faxed or emailed to Theranos from a physician's office or patient.

To do so, users will naviate to Add → Add Requistion found at the top of the screen. Users will then be prompted to enter a Provider Name, Location Name, Doctor Name, and Patient Name.

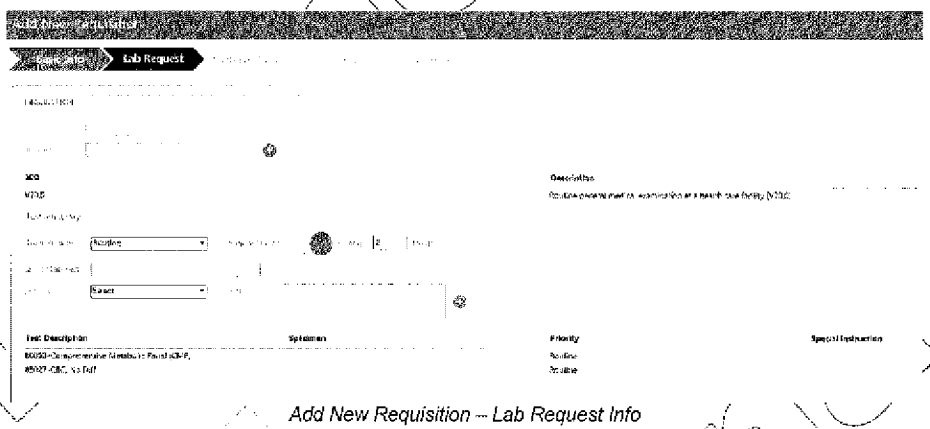


Add New Requisition – Basic Info

Please Note! The information entered in each of the fields must already exist in the system. Prior to creating a requisition, users must ensure that a valid lab order has been received and all necessary information is available. Required information includes:

1. Provider: Provider name, address, location and fax number
2. Physician: Physician name, NPI number, provider, location, phone number, specialty
3. Patient: Name, date of birth, gender

Once the existing Provider, Provider Location, Doctor Name and Patient Name have been entered, the user advances to the "Lab Request" screen.



Add New Requisition – Lab Request Info

On this screen, the user will specify all Tests and ICD-9 codes indicated on the patient lab order, as well as any notes or special instructions provided by the ordering clinician. The user will also specify the order priority, fasting status, and fasting hours, if noted on the patient lab order. Finally, users will select the Tests to add to the order. Active tests are listed in black, Inactive tests in red. Users are not able to add Inactive tests to a visit.

Once all the necessary information has been entered, users will click the "Next" button, which will direct users to the Summary Screen. Users will review and confirm all information is correct, and save the requisition. The order will now appear as an electronic order in the patient profile when the patient checks in at the PSC.

Note: To create a standing order, select the Standing Order box on the Summary Screen and specify the frequency and length of time as directed by the ordering physician.

Contingencies:

- If there are no ICD-9 codes indicated on the patient lab order, users mustcontact the ordering clinician to determine the correct ICD-9 codes.
- If there are tests on the patient lab order that are not offered by Theranos, users will contact the ordering clincian and inform them of the tests that are not offered. Users will notify the clinician that Theranos will be happy to process all other tests on the order, and will proceed per the instruction of the ordering clinician.
- If there are tests on the patient lab order that are not offered by Theranos, and the lab order was submitted to Theranos by the patient, users will contact the patient and communicate the same message as stated above.

Part IV: Physician and Patient Records

Physician Records

Physician records will exist for each individual clinician who refers patients to Theranos – this includes Nurse Practitioners as well as the various different types of Physicians who are legally allowed to order laboratory tests. Physician records may also be created in advance so as to save time when an order comes in from a new physician.

Important! Because a physician can only be linked to a single Provider, an individual physician may have two or more separate physician records in TLIS. For example, if Dr. Jane works at Palo Alto Medical Foundation on Monday, Wednesday and Friday, and she works at Stanford on Tuesday and Thursday, there will be two separate physician records for Dr. Jane.

To access the List of physician records in TLIS, user will click on the "Physicians" tab in the top bar of the application. Then, users may either seach for a specific physician by name, or run a wide-open search that will display all physician records in TLIS. Users may then sort this List by NPI number, Name, and Phone Number.

Physician Detail View

By clicking on a physician record from the physician List, the user will navigate to the physicina detail view screen. The physician detail view screen allows users to view basic information for the physician, past and pending requisitions that the physician has submitted to Theranos, as well as notifications related to the physician – including when results for past requisitions have been communicated to the physician by email or fax.

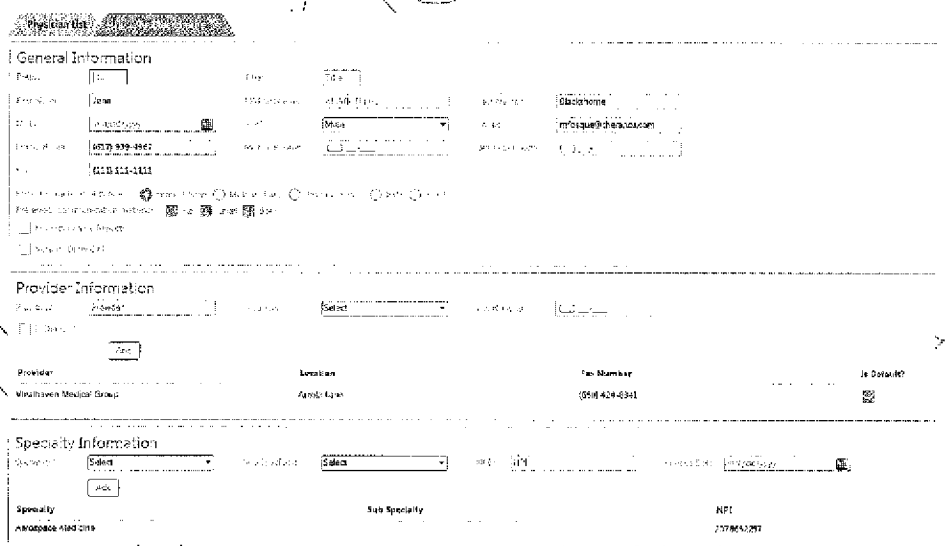
Users may edit the physician record by clicking on the blue "Edit" button in the top right hand corner of the application. This allows users to update demographic informaiton, contact information, as well as the Provider and Provider locations(s) to which that physician record is connected.

Key Items

- Preferred Communication Method: Indicates how the physician prefers to receive results. If the physician's office has an electronic connection to the Theranos LIS, this will always be the

preferred method. On each Visit associated with that physician, the preferred method will be circled in green.

- No Preliminary Reports: Indicates that the physician does not wish to receive preliminary reports. If the user attempts to send a preliminary report for a visit associated with that physician, an alert message will appear.
- Venous Draw Only: Indicates that all visits for which that physician is the ordering physician will default to a venous draw for the collection method. This is done automatically through the PSC Application.



Edit Physician Details Screen

Note: If a user changes the Provider that a physician record is connected to, all existing or past requisitions that the physician has submitted from the previous Provider will remain unchanged (i.e., the requisitions will reference the previous Provider, not the new Provider).

Creating a Physician Record

Physician records, like Provider records, may either be created in advance or created when a lab order is received by email or fax from a physician for which a physician record does not currently exist in the system. Physician records will also be created in Super Mario when scanned lab orders are received from the PSC from physicians for which a physician record does not currently exist (not currently in Production – Physician records will currently be created in TLIS when such an order is received in Super Mario).

The following fields are required in order to create a new Physician record:

1. First Name
2. Last Name
3. Provider: The individual physician office, physician group or hospital where that physician works.. Remember! There may be another physician record for the same individual, if that individual treats patients at more than one Provider.
4. Location: The provider location where the physician treats patients. Many physicians treat patients at various locations in a physician group or hospital network – in this case, users are able to select multiple different locations, and mark one as the default location.
5. Gender
6. Preferred Method of Contact: Users must enter either a home, mobile or business phone number for the physician. Users may also enter an email address, though it is not required.
7. Specialty
8. NPI Number: If the user does not know the physician's NPI number, it can be found by searching the Federal NPI database at the following address: https://npiregistry.cms.hhs.gov/NPPESRegistry/NPIRegistrySearch.do?subAction=reset&searchType=ind. If the user is unable to find the NPI number, a dummy number can be entered. However, the user should document the record and ensure the correct information is obtained in a timely manner.

Patient Records

Patient records will exist for each individual patient for whom a lab order is submitted to Theranos. Unlike physician records, there will only be 1 patient record per unique individual. Patient records are only connected to physician records through a requisition (or multiple requisitions). In other words, there is no option to choose a Physician in the patient record – patient records can be linked to multiple physician records, depending on which physician submitted the requisition!

To search for a patient record, the user will navigate to the patient search screen by clicking on the "Patients" button in the top menu bar.

Patient Detail View

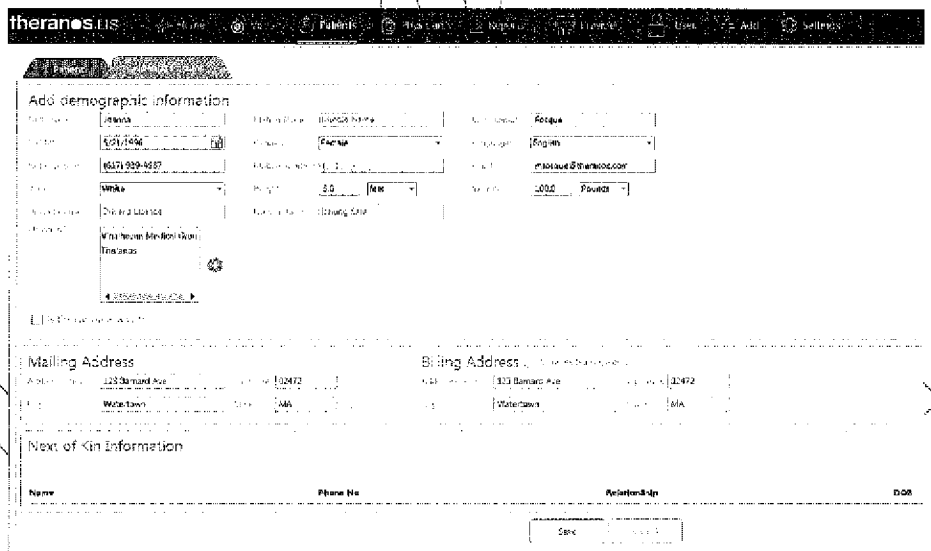
Once a user has searched for and selected a patient record from the patient List, the user will navigate to the patient detail view screen. This screen allows users to basic information for the patient, and results from past visits.

Note: Users may not enter or edit result values in the patient detail view screen – this must be done only in the requisition view screen, discussed above. Only users with access to result information will be able to view results in the patient detail view screen.

Edit Patient Details

Users may modify demographic and address information, as well as adding next of kin information, on the edit patient details screen. Note that editing patient information will update all historical visits for that patient.

Note: Patient records may be created by a check-in technician in the PSC application during the patient's visit to the PSC. Users should double-check patient records in TLIS to ensure all information entered by the check-in technician is accurate and up to date.



Edit Patient Detail

Creating a Patient Record

There are two ways in which a patient record is created in TLIS. For new patients arriving at the PSC with a paper copy of their lab order, who have had no prior interaction with Theranos, patient records are created in the PSC application at the point of care. Technicians will collect demographic information, insurance information, as well as next of kin information (if necessary). Upon completion of the patient visit, this information will be saved and a new record created in TLIS.

Users may also create a patient record directly in TLIS. This will occur when lab orders are faxed or emailed to Theranos for patients that have had no previous interaction with the company. To do so, from the patient search screen, users will click on "New Patient."

The following information is required in order to create a new patient record:

- First and Last Name
- Gender
- Language
- Date of Birth
- Preferred Method of Contact (either home phone or mobile phone)
- Next of Kin Information: Required for patients under the age of 18; if entering information for a minor, users must first create a profile for the parent or guardian

8 RECORDS

8.1 N/A

9 ATTACHMENTS

9.1 N/A

10 REFERENCES

10.1 Theranos Critical Value Reporting Process

10.2 Theranos Patient Service Center Application User Guide

10.3 Theranos Super Mario Application User Guide

11 REVISION HISTORY

REVISION HISTORY			
Revision Level	**Effective Date**	**Initiator**	**DCO Number**
A	1/27/2015	M. Fosque	CL DCO-00071
Section Number	**Description and Justification of Changes**		
All	Initial Release		

Maintenance of the iRICELL® 3000 WorkCell for Urinalysis

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Approver(s):

Signature: DocuSigned by: Lynette Sawyer	Date: 5/5/2015
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Lynette Sawyer

1 PURPOSE/ PRINCIPLE

The purpose of this procedure is to provide a guide for daily, weekly, monthly, and quarterly maintenance of the iRICELL® 3000 WorkCell for urinalysis.

2 SCOPE

This procedure applies to all CLIA Laboratory personnel using the iRICELL® 3000 WorkCell.

3 DEFINITIONS AND ABBREVIATIONS

Not applicable.

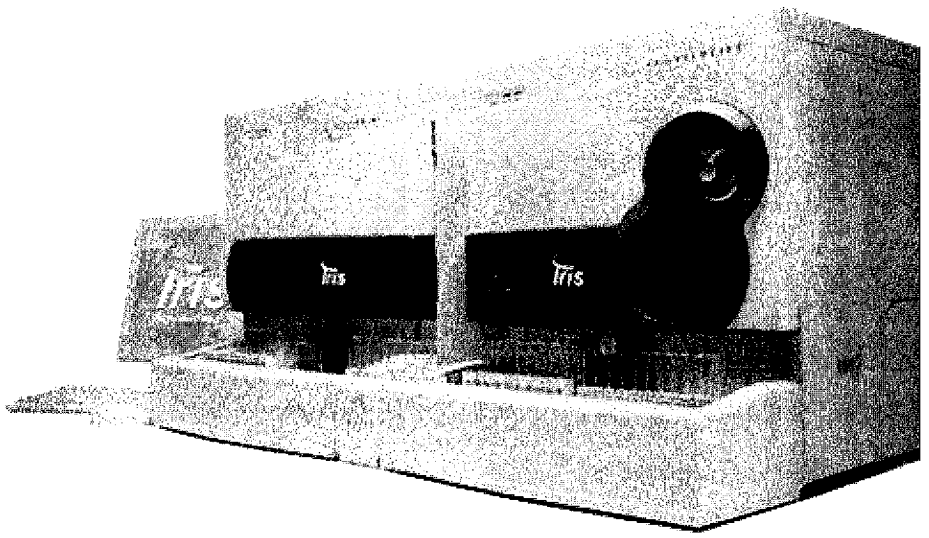
4 RESPONSIBILITIES

4.1 It is the responsibility of supervisors to ensure that the personnel using the instrument are aware of all safety precautions.

4.2 It is the responsibility of all testing personnel to follow Universal/ Standard Precautions, this SOP and any related SOPs referenced below.

5 MATERIALS AND EQUIPMENT

5.1 iRICELL® 3000 WorkCell: A complete automated urinalysis system consisting of the iChem® VELOCITY™ urine chemistry and iQ® 200 Elite urine microscopy systems.



REF	iChem® VELOCITY™ Materials	Storage	Opened Stability
800-7212	iChem® VELOCITY™ Urine Chemistry Strips	2 to 30 °C	5 days on Module
475-7022	iChem Wash	20 to 28 °C	3 months
800-7211	iRISpec CA/CB/CC Controls	2 to 8 °C	15 days
800-7703	iChem CalChek Kit	2 to 8 °C	90 days
	iQ® 200 Materials		
800-3103	iQ Calibrator	2 to 8 °C	24 hours
800-3104	iQ Focus/Positive/Negative Control Kit	2 to 8 °C	30 days
475-0021	Iris Diluent	20 to 28 °C	date on bottle
475-0003	Iris System Cleanser	20 to 28 °C	date on bottle
475-0047	iQ Lamina	20 to 28 °C	date on bottle

6 LABORATORY PRECONDITIONS

The system has few special environmental requirements. It uses alternating current at 100V to 240V and 50 Hz to 60 Hz. (Input voltage and frequency selection does not require customer intervention.) Uninterruptible power supplies are recommended for the iRICELL® to maintain system operation during short power outages and brownouts. This allows for an orderly shutdown of instruments without the loss of data.

Select a room to set up the unit where the temperature can be controlled between 68 °F (18 °C) and 8 °F (28 °C), and relative humidity noncondensing in a range of 20% - 80%.

7 CALIBRATION

7.1 Calibration Materials

7.1.1 Five (5) Reflectance CalChek with fixed calibration values.

7.1.2 Three (3) Specific Gravity CalChek: 1.002, 1.030, and 1.060.

7.1.3 Four (4) Color CalChek: colorless, straw, normal yellow and amber.

7.1.4 Three (3) Clarity CalChek: in straw color with slightly cloudy, cloudy, and turbid clarities.

Note: CalChek strips are SINGLE USE ONLY. Reuse will cause calibration failure.
Storage and Use: Refer to package insert for more information concerning the storage and use of the products.

7.2 Frequency

CalCheks should be performed quarterly on the iChem® VELOCITY™ system. If the instrument was moved, a CalCheks should be performed to make sure that the instrument is properly calibrated.

8 CALIBRATION PROCEDURE AND VERIFICATION

8.1 iChem Reflection CalChek

8.1.1 Remove all chemistry test strips from the Strip Provider Chamber and place all five CalChek into the Strip Provider chamber.

Note: After loading the CalChek, rotate the Strip Loader 180 degrees to transfer the strips onto the Strip Provider Module.

8.1.2 Click the **Instrument** button on the top right side of the main screen.

8.1.3 Click on the **Maintenance** button located at the bottom of the Instrument screen.

8.1.4 Click on the **Reflectance Check** button. Then follow the instructions on the screens.

Note: After entering CalChek strip information, verify that the Lot ID number and expiration date from the CalChek strip container matches the data from the screen and modify if necessary.

8.1.5 After completion of Reflection Calibration, verify calibration results have **PASS** and click on **Finish** to complete Reflectance CalChek.

Note: Reflectance CalChek results can be reviewed in the **Quality Review** screen.

8.1.5.1 Repeat the run using the same lot number.

8.1.5.2 Repeat the run u sing new lot number.

8.1.5.3 If the CalChek failed again, contact Technical Services or distributor.

8.2 iChem Specific Gravity, Color, and Clarity CalChek

8.2.1 Obtain iChem CalChek solution tubes as needed according to the table below:

Pos #	Contents	Value	Barcode
1	Specific Gravity CalChek solution	1.002 +/- 0.003	Y
2	Specific Gravity CalChek solution	1.030 +/- 0.005	N
3	Specific Gravity CalChek solution	1.060 +/- 0.005	N
4	Color CalChek solution	Colorless	Y
5	Color CalChek solution	Straw	N
6	Color CalChek solution	Normal yellow	N
7	Color CalChek solution	Normal amber	N
8	Clarity CalChek solution	Slightly cloudy	Y
9	Clarity CalChek solution	Cloudy	N
10	Clarity CalChek solution	Turbid	N

8.2.2 Gently invert the tubes one or two times for proper mixing.

8.2.3 Remove caps from tubes on the rack according to the table above.

8.2.4 Load the Calibration rack onto the ride side of the iChemVELOCITY sampler.

8.2.5 The rack will be processed and all calculations performed automatically. The CalCheck liquid reagents can be re-used within eight (8) hours.

8.2.6 When CalChek is successful, the date/time of the new SG/CC CalChek will be displayed on the shift summary screen.

8.2.7 The SG/CC Calcheck status (Pass/Fail) can be reviewed in the QC Review screen.

8.2.8 SG/Color/Clarity CalChek Failure

8.2.8.1 Repeat the CalChek run using the same tube solutions.

8.2.8.2 Repeat the run using new lot number.

8.2.8.3 If the CalChek failed again, contact Technical Services or distributor.

9 MAINTENANCE

9.1 Daily

9.1.1 Emptying and cleaning the Waste Container daily or every 300 strips.

9.1.1.1 Open the waste container door.

9.1.1.2 Remove the waste container and discard used test strips according to local regulations.

9.1.1.3 Clean the waste container with Iris System Cleanser diluted 1:10 and rinse with tap water.

9.1.1.4 Thoroughly dry the waste container.

9.1.1.5 Reinstall the waste container and close container door.

9.1.2 Discard Liquid Waste

9.1.2.1 Remove the drain bottle cap and tubing from the drain bottle.

9.1.2.2 Discard the liquid waste.

9.1.2.3 Clean the drain bottle with a mild detergent and water, and then rinse with tap water.

9.1.2.4 Insert drain tube into the drain bottle and tighten the cap.

9.1.3 Clean the Sample Transport Module

9.1.3.1 Moisten a tissue with Iris System Cleanser diluted 1:10 and wipe the Sample Transport Module to remove any deposits.

9.1.3.2 Wipe again using distilled water.

9.1.3.3 Wipe dry.

9.1.4 Clean the Load/Unload Trays

9.1.4.1 Moisten a tissue with Iris System Cleanser diluted 1:10 and wipe the Sample Transport Module to remove any deposits.

9.1.4.2 Wipe again using distilled water.

9.1.4.3 Wipe Dry.

9.1.5 Clean the Instrument Surfaces

9.1.5.1 Moisten a tissue with Iris System Cleanser diluted 1:10 and wipe the Sample Transport Module to remove any deposits. Check under the belts and pulleys.

9.1.5.2 Wipe again using distilled water.

9.1.5.3 Wipe Dry.

9.1.6 Check Wash supply and iQ Lamina supply.

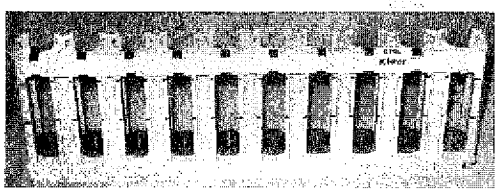
9.1.6.1 If needed, replace Wash and/or iQ Lamina.

Note: Replace wash filter each time the Wash is replaced and replace iQ Lamina filter every four (4) bottles.

9.1.7 Run Daily QCs for the iChemVelocity.

Note: Do not shake IRISpec CA, CB, or CC.

9.1.7.1 Aliquot 3mL of the IRISpec CA, CB, and CC on position 8, 9, and 10 on the iChem QC rack as indicated below:



Position	Insert Color	Volume	Contents	Function	Barcode
8		3 mL	CA Control	Primary control	No
9		3 mL	CB Control	Primary control	No
10		3 mL	CC Control	Primary control	No

9.1.7.2 Load iChem® VELOCITY™ Urine Chemistry Strips in the Chemistry Strip Loader.

9.1.7.3 Place rack on the iChem® VELOCITY™ Sample Loader. Sample should start running automatically.

9.1.8 Run Daily QCs for the iQ® 200

Note: Shake iQ Focus and Positive well. Allow Controls to reach room temperature before running on instrument.

9.1.8.1 Aliquot 3 mL of Cleanser, Diluent, Diluent, iQ Positive Control, iQ Negative Control, and 6 mL of iQ Focus and place them on the iQ QC rack as indicated below:

Position	Insert Color	Vol	Contents	Function	Barcode
1	None	3 mL	Iris System Cleanser	Cleans lines	No
2	Gray	3 mL	Iris Diluent	Rinses Cleanser from lines	No
3	Gray	3 mL	Iris Diluent	Rinses Cleanser from lines	No
4	None		**Empty**		
5	Dark Blue	6 mL	iQ Focus	Focuses camera	Yes
6	Orange	3 mL	iQ Positive Control	Primary lot positive control	Yes
7	Light Blue	3 mL	iQ Negative Control	Primary lot negative control	Yes

9.1.8.2 Place the iQ QC rack on the iQ Sample Loader and press **Start**.

9.2 Weekly

9.2.1 Clean the Strip Provider Module

9.2.1.1 Make sure the System is in **Standby** mode.

9.2.1.2 Click on the **Instrument** button on the top right side of the main screen.

9.2.1.3 Click on the **Go Off Line** button. The system status will change to Off Line.

9.2.1.4 Turn the power off by pressing the  green power button located on the left side of the chemistry system.

9.2.1.5 Access the Strip Provider Module

A. Open the front door, the right side door and the waste container door.

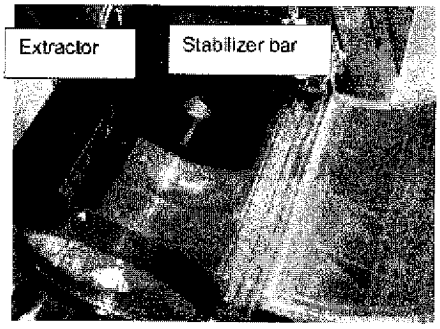
B. Loosen the thumbscrew holding the barcode reader shield and then tilt the shield to the horizontal position to the right.

C. Pull the blue knob to release the strip provider module and then tilt the strip provider module to the right.

D. Loosen the two screws holding the strip provider module top cover to access the inside of the strip provider module.

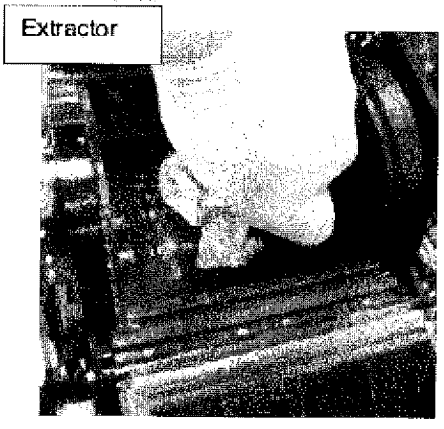
9.2.1.6 Remove and discard all chemistry test strips present inside the Strip Provider Module.

9.2.1.7 Manually, rotate the black stabilizer bar to the left toward the extractor as indicated below:



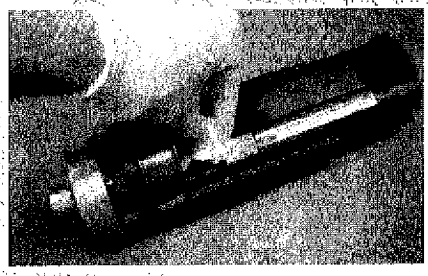
9.2.1.8 Using a dry, lint-free tissue, collect and remove all dust from the front and rear disks using downward motion. Replace the wipe every time dust is collected.

9.2.1.9 Using a dry, lint-free tissue, wipe and collect to remove all dust from the lower body in the direction away from the extractor. Do not push any dust inside the extractor. Replace the dry lint-free wipe every time dust is collected.



9.2.1.10 Using a dry, clean brush, collect and remove the dust in the grooves between the front and the rear disks and the lower body. Collect and remove the dust where the wiper

9.2.1.11 Remove and extend the strip loader. Using dry-lint free tissue, collect and remove all dusk present inside and outside the strip loader. Replace the dry-lint free wipe every time dust is collected.



9.2.1.12 Re-install the strip loader in the instrument and turn it to the lock position.

9.2.1.13 Close and replace the Strip Provider Module.

9.2.1.14 Close the front and left side doors.

9.2.1.15 Turn on the power and click on the **Go on line** button. The system status will change to On Line.

9.2.1.16 Let the system warm up for 10 minutes before resuming operation.

9.3 Monthly

9.3.1 Clean the iChem® and iQ® Wash Station Bath

9.3.1.1 Make sure the System is in **Standby** mode, as indicated on the top left of the instrument screen.

9.3.1.2 Click on the **Instrument** button on the top right side of the main screen.

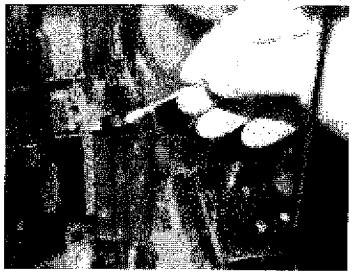
9.3.1.3 Click on the **Go off line** button. The system status will change to **Off Line**.

9.3.1.4 Turn the power off by pressing the green button located on left side of the chemistry system.

9.3.1.5 Open the front door to access the wash station bath.

9.3.1.6 Using a cotton sway moistened with DI water, remove salt deposits present on the wash bath as indicated below.

Note: Do not insert the cotton swab inside the wash tube, cotton particles may clog the tubing connectors.



9.3.1.7 Clean the inside of the Rinse/Bath on the iQ system using a moisten cotton swab with DI water.

9.3.1.8 Close the front door.

9.3.1.9 Turn the power on by pressing the green button on the left side of the chemistry system.

9.3.1.10 Click on the **Go On Line** button. The system status will change to On Line.

9.3.2 Clean the Strip Conveyor System

9.3.2.1 Make sure the system is in **Standby** mode. 

9.3.2.2 Click on the **Instrument** button on the top right side of the main screen.

9.3.2.3 Click on the **Go off line** button. The system status will change to **Off Line**.

9.3.2.4 Turn off the power by pressing the green button located on the left side of the chemistry system.

9.3.2.5 Access the Strip Conveyor.

9.3.2.6 Pull out and then push down the blue latch securing the Strip Conveyor.

9.3.2.7 Pull the handle to remove the Strip Conveyor System from its location.

9.3.2.8 Dip the Strip Conveyor System into warm soapy water.

9.3.2.9 Rinse under tap running warm water while turning the knob to rotate the links.

9.3.2.10 Shake off any excess water and wipe using lint-free tissue. Allow 50 min to dry.

9.3.2.11 After the Strip Conveyor System is completely dry, re-install it inside the analyzer.

9.3.2.12 Close the front and side door.

9.3.2.13 Turn the power on by pressing the green button located on the left side of the chemistry system.

9.3.2.14 Click on the **Go on line** button. The system status will change to **On Line**.

9.3.2.15 Let the system warm up for 50 minutes before use.

9.3.3 Perform iQ Calibration

9.3.3.1 Run Cleanser, Diluent, Diluent, and Focus on the iQ Control Rack according to table below:

Position	Insert Color	Volume	Contents	Barcode
1	None	3 mL	Iris System Cleanser	No
2	Gray	3 mL	Iris Diluent	No
3	Gray	3 mL	Iris Diluent	No
4	None		Empty	
5		6 mL	iQ Focus	Yes

9.3.3.2 Allow iQ instrument to go into **Standby** mode.

9.3.3.3 Run iQ Calibration.

A. Match Labeled Calibration tubes (1-10) with iQ Calibration rack location.

9.3.3.4 Allow iQ instrument to go into **Standby** mode.

9.3.3.5 Run Daily Controls to verify successful calibration.

9.3.4 Quarterly Maintenance

9.3.4.1 Perform Reflectance/SG/CC CalChek. Refer to 8.1 iChem Reflectance CalChek for procedure.

9.3.4.2 Replace Wash Solution Container and Wash Solution Filter.

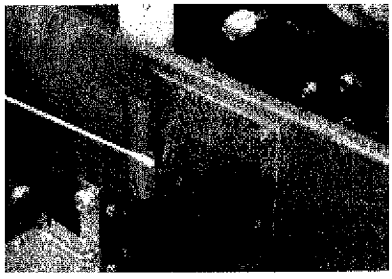
9.3.5 As Needed Maintenance

9.3.5.1 Cleaning the Sample Tube Detector

Note: This should be performed only if the detector is missing tubes. Contact Technical Services or an authorized distributor before cleaning the window.

A. Make sure the instrument is in **Standby** mode.

B. Using a cotton swab moistened with DI water, wipe the sample tube detector. Dry using a clean cotton swab.



9.3.5.2 Cleaning the Barcode Reader Window

Note: Contact Technical Services before cleaning the window.

A. Make sure the System is on **Standby** mode.

B. Click on the **Instrument** button on the top right side of the main screen.

C. Click on the **Go off line** button. The system status will change to **Off Line**.

D. Turn the power off by pressing the green button located on the left side of the chemistry system.

E. Open the front door to access the barcode reader.

F. Using a tissue moistened with DI Water, wipe the barcode reader window. Dry using a clean tissue.

G. Close the front door.

H. Turn on the power by pressing the green button located on the left side of the chemistry system.

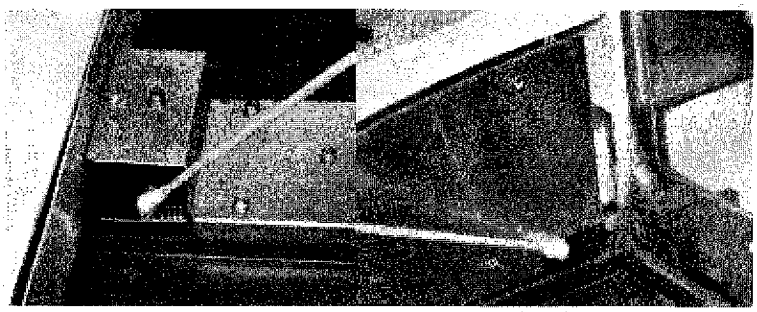
I. Click on the **Go on line** button. The system status will change to **On Line**.

9.3.5.3 Cleaning the Optical Sensors on the Sample Transport Module

A. Make sure the System is on **Standby** mode.

B. Using a cotton swab moistened with DI water, wipe the optical sensors located on the front right and back left corners of the sampler.

C. Dry using a clean swab.



9.3.5.4 Clean the iQ Sample Filter

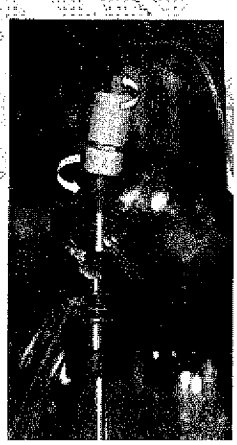
Note: Cleaning the sample filter is recommended when a carryover is suspected. When the Negative control count is 10 or greater or when the Negative control count is greater than 5 from the previous Negative control.

A. Put system to Standby by clicking on the Instrument button then Go off line.

B. Turn the power off by pressing the green button located on the right side of the iQ system.

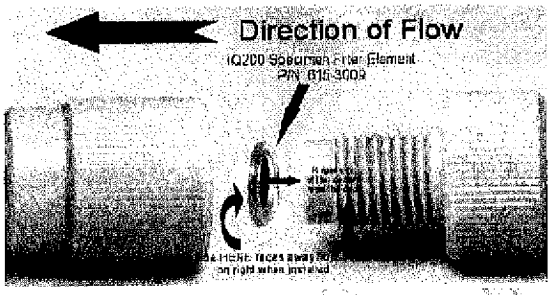
C. Open the front door and locate the sample filter: it is a light brown cylinder located above the sample probe.

D. Remove the sample filter by unscrewing the green tubing counter clockwise and then rotating the bottom fitting clockwise.



E. When the sample filter housing has been removed, place it over a clean horizontal surface.

F. Unscrew the filter housing. The filter is located inside between the top and the bottom housing. See picture below.



G. Soak the filter in cleanser and then rinse with DI water.

H. Re-insert the filter housing making sure that concave side of the element is facing the bottom portion of the filter housing as seen in the picture above.

I. Reconnect the green fittings by turning the sample filter only. Rotate the top fitting clockwise; rotate the bottom fitting counter clockwise.

J. Close the front door and turn on the power by pressing the green button located at the bottom right of the iQ system.

K. Click on the Go On line button and perform Flowcell Cleaning.

9.3.5.5 Cleaning the iQ Flowcell

A. Make sure system is in Standby.

B. Load three (3) test tubes onto positions 1, 2, and 3 of the control rack. These positions are normally used for Cleanser, Diluent, Diluent (no labels needed). Fill each tube with 10 mL.

C. Load the control rack on the sampler and press the Start button.

D. Repeat 3 to 5 times.

E. Run normal control rack to verify Flowcell has been cleaned.

9.3.6 Backing up the System

9.3.6.1 The system must be offline to perform a backup. If the system is online, click the Go off line button.

9.3.6.2 Click the Backup button.

9.3.6.3 System will direct you to insert a storage device. Insert the backup storage device.

Note: If a blank CD-R disc is used, the system pop open the Easy CD Creator. The select a project window will appear. Select **Data CD**, then **Direct CD**. Choose Format and **Start Format**.

9.3.6.4 Click OK to start the backup.

9.3.7 Long-term Shutdown

Note: If the system is not used for more than a week, crystal formation may occur that can cause damage. This can be avoided using the long-term shutdown procedure.

9.3.7.1 Clean the Wash Station Bath

9.3.7.2 Perform Daily Maintenance

9.3.7.3 Turn the power off by pressing the green button located on the left side of the chemistry system.

9.3.7.4 Turn the main power off by switching the Main power switch located on the back of the chemistry system.

9.3.8 Startup after Long-term Shutdown

9.3.8.1 Turn on power using **Main** power switch on the back of the system.

9.3.8.2 Wait until the Instrument screen is displayed. Make sure the status on the top left corner of the screen is "**OFF**".

9.3.8.3 Press the green **ON/OFF** button on the front of the system. The status should change to **Standby**.

9.3.8.4 Logon to the system. After startup, the wash solution bottle located inside the system will refill automatically.

9.3.8.5 Prime the System Lines.

A. Place three (3) tubes in the first three positions of the Control rack. Fill each tube with Iris Diluent.

B. Run the Control rack twice (2) to prime the internal lines.

9.3.8.6 Run CalChek.

9.3.8.7 Run Control Rack.

10 TROUBLESHOOTING

10.1 If an error occurs, the alarm will be displayed on the right side of the Instrument screen. Yellow alarms are warning alarms while red alarms will halt the system from running samples.

10.2 Alarms will display the warning/failure along with the time that the warning/failure occurred.

10.3 Alarm flags are only removed when the problem is remedied.

10.3.1 Double-click on the alarm and follow the instructions on troubleshooting, referring to the Operator's Manual as needed.

10.3.2 If the problem persists, contact the Field Service Engineer.

11 PROCEDURAL NOTES

Not applicable

12 LIMITATIONS

Not applicable

13 SAFETY

13.1 Make sure that the instrument working area is clean and kept clear.

13.2 Promptly clean any fluid spills.

13.3 Decontaminate with 5% sodium hypochlorite (1 part bleach and 19 parts water) solution, if needed.

13.4 Follow local guidelines for disposal of waste material according to federal, state and local laws.

13.5 If any part of the system breaks down, contact Iris Diagnostics Technical Support

14 RECORDS

14.1 Maintenance, Calibration and QC records will be kept electronically on board the instrument or archived on external storage for a minimum period of three years.

15 ATTACHMENTS

15.1 CL FRM-0621-F1 iQ® Series Maintenance Log.

15.2 CL FRM-0621-F2 iChem® VELOCITY™ Maintenance Log.

16 REFERENCES

16.1 iRICELL iChem® VELOCITY™ Operator's Manual

16.2 iQ® 200 Series Operator's Manual

16.3 iChem® VELOCITY™ Maintenance Quick Reference Guide

16.4 iQ® Maintenance Quick Reference Guide

17 REVISION HISTORY

REVISION HISTORY

Revision Level	Effective Date	Initiator	ECO Number
A	10/11/2011	A. Gelb	ECO-00021
B	12/5/2014	M. Rockymore	CL DCO-00067

Section Number	Description and Justification of Changes
All	Initial release
All	Annual Review

theranos	Standard Operating Procedure	Document Number: CL SOP-06022 Revision: B
	CLIA Laboratory	Effective Date: 12/5/2014

Operation of the iRICELL® 3000 WorkCell for Urinalysis

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1. PRINCIPLE

The iRICELL® 3000 WorkCell is an automated urine chemistry system performing measurements of urine physical and chemical constituents consists of two modules: the iChem® VELOCITY™ and the iQ® 200 Elite.

The iChem® VELOCITY™ utilizes test strips read by Wavelength Reflectance, and specific gravity using the Refractive Index. It produces quantitative results for specific gravity, semi-quantitative results for glucose, blood, leukocyte esterase, bilirubin, urobilinogen, pH, protein, ketones and ascorbic acid; and qualitative results for nitrites, color and clarity.

The iQ® 200 Series system auto-identifies and processes specimens in 10-position racks by mixing, sampling, and analyzing automatically. The iQ® 200 Series Automated Urine Microscopy System presents a specimen sandwiched between enveloping layers of lamina to a microscope coupled to a CCD (charge coupling device) video camera. Individual particle images are isolated within each frame. It has the Auto-Particle Recognition (APR™) software, a highly trained neural network, which uses size, shape, contrast and texture features to classify each image into one of 12 categories: RBCs, WBCs, WBC Clumps, Hyaline Casts, Unclassified Casts, Squamous Epithelial Cells, Non-squamous Epithelial Cells, Bacteria, Yeast, Crystals, Mucus and Sperm. Additionally, 27 predefined sub-classifications are available for identifying specific types of casts, crystals, non-squamous epithelial, dysmorphic and others. Particle concentration is then calculated using the number of particles images and the volume analyzed.

2. SCOPE

This procedure applies to all authorized CLIA Laboratory personnel using the iRICELL® 3000 WorkCell. It is the responsibility of supervisors to ensure that all the personnel using the iRICELL® system are aware of all safety precautions. It is the responsibility of all personnel to follow Universal/ Standard Precautions, this SOP and any related SOPs referenced below.

3. DEFINITIONS AND ABBREVIATIONS

iChem® VELOCITY™ Abbreviations:

BIL-Bilirubin	NIT-Nitrite
URO-Urobilinogen	LEU-Leukocytes
KET-Ketones	SG-Specific Gravity
ASC-Ascorbic Acid	CLA-Clarity
GLU-Glucose	PRO-Protien

iQ® Abbreviations:

RBC-Reb Blood Cells	NSE-Non-squamous Epithelial Cells
WBC-White Blood Cells	BACT-Bacteria
WBCC-White Blood Cell Clumps	UNCX-Unclassified Crystals
SQEP-Squamous Epithelial Cells	HYAL-Hyaline Casts
UNCC-Unclassified Casts	BYST-Yeast

SPRM-Sperm MUCS-Mucous

4. MATERIALS AND EQUIPMENT

5.1 iRICELL® 3000 WorkCell: iChem® VELOCITY™ and iQ® 200 Elite systems

5.2 Computer with monitor, keyboard, and mouse

5. REAGENTS

REF	iChem® VELOCITY™ Materials	Storage	Opened Stability
800-7212	iChem® VELOCITY™ Urine Chemistry Strips	2 to 30 °C	5 days on Module
475-7022	iChem® Wash	20 to 28 °C	3 months
800-7211	iRISpec CA/CB/CC Controls	2 to 8 °C	15 days
800-7703	iChem CalChek Kit	2 to 8 °C	90 days
	iQ® 200 Materials		
800-3103	iQ Calibrator	2 to 8 °C	24 hours
800-3104	iQ Focus/Positive/Negative Control Kit	2 to 8 °C	30 days
475-0021	Iris Diluent	20 to 28 °C	date on bottle
475-0003	Iris System Cleanser	20 to 28 °C	date on bottle
475-0047	iQ Lamina	20 to 28 °C	date on bottle

6. LABORATORY PRECONDITIONS

The system has few special environmental requirements. It uses alternating current at 100V to 240V and 50 Hz to 60 Hz. (Input voltage and frequency selection does not require customer intervention.) Uninterruptible power supplies are recommended for the iRICELL® to maintain system operation during short power outages and brownouts. This allows for an orderly shutdown of instruments without the loss of data.

Select a room to set up the unit where the temperature can be controlled between 68 °F (18 °C) and 8 ° F (28 °C), and relative humidity noncondensing in a range of 20% - 80%.

7. QUALITY CONTROLS AND QUALITY ASSURANCE

8.1 The system stores patient results and control records for 10,000 results or up to 18 months (whichever is greater), after which the system will overwrite the oldest results.

8.1.1 Control data can be either automatically entered into the system (i.e.,. iQ® controls) using barcode labels or manually entered (ie. iChem® VELOCITY™ controls).

8.1.1.1 To manually enter a new lot of controls, click on the **Instrument** button.

8.1.1.2 Click on the **Go off line** button.
8.1.1.3 Click on **Consumables** button located at the bottom of the Instrument screen.
8.1.1.4 Click on the **Chemistry QC** button.
8.1.1.5 Enter the new control lot in the Lot ID field.
8.1.1.6 Enter the new control expiration date in the Expiration field then click **Next**.
8.1.1.7 Select the lower and upper limits for CA listed then click **Next**.
Note: Color, Clarity, and Ascorbic Acid are not applicable for CA and CB. Ascorbic Acid is applicable for CC.
8.1.1.8 Repeat for the above step for CB and CC.
8.1.1.9 After completion, click OK.

8.2 Detailed control records can be traced/search under **Consumables - Traceability**.
8.3 For running daily controls, refer to CL SOP-0621 Maintenance of the iRICELL® WorkCell.
8.4 QC review
8.4.1 Click **Instrument**.
8.4.2 Click **Quality Review**.
Note: Data can be sorted by clicking on the column header. A repeated click will toggle between ascending and descending order. The default is Date/Time – ascending order.
8.4.3 Alternatively, **QC Statistics** provides a Levey-Jennings Chart to aid users to track QC trends and shifts.

8. PROCEDURE

8.1 Logon with correct Identifier and Password.
8.2 Perform Daily Maintenance per CL SOP-0612 Maintenance of the iRICELL® WorkCell.
8.3 Verify successful Calibrations/QCs/Focus/Reflectance/SG. Color. Clarity on the Instrument Screen.
8.3 Specimen Preparation

Note: Use only fresh urine specimens as defined in the protocol GP16-A3, Urinalysis; Approved Guideline - Third Edition, Clinical and Laboratory Standards Institute (CLSI), Wayne, PA, 2009.
Collect urine in a **sterile** container using Clean Catch specimen technique (CLSI protocol, section 5.4.6). If a specimen cannot be processed within an hour after collection, cap the container tightly, store at 2-8 °C and also transport refrigerated and/or on cold packs. Store at 2-8 °C upon receipt. Bring the specimen to room temperature before testing.

Note: Do not add disinfectants or detergent to specimen. Do not centrifuge urine specimens and keep specimens out of direct sunlight.

Note: Dilute samples if grossly bloody, very dense, contains heavy mucous/amorphous and/or short sample.

8.3.1 The iRICELL® requires at least 4mL of sample to run on the iChem® VELOCITY™ and iQ® systems. If only running on either the iChem® VELOCITY™ or the iQ®, 3 mL is sufficient.

8.3.2 Apply barcode labels to sample tubes, placing the start of the barcode (not the barcode label) approximately ½ inch below the top of the 16x100mm tube. Make sure barcode labels are properly oriented in the rack.

Note: Barcodes accepted are Code 128, Code 39, Codabar and Interleave 2 of 5 (I 2 of 5).

8.3.3 Alternatively, Manual Orders can also be performed if barcodes are not available or if the sample requires dilutions.

Note: Chemistries only run on straight undiluted samples. After sample dilution, place rack only on the iQ systems.

A. Click on Instrument on the top right side of the main screen.
B. Click on the Manual Orders button located on the lower left side of the Instrument screen.
C. Select the rack number to be used (1-23).
D. Enter Specimen information
   - Specimen Identifier
   - Fluid Type-select URN.
   - Dilution-select appropriate dilution for the sample.
   - Work Order-Select Run.
E. Place the sample tube into the corresponding position of the selected sample rack.
F. Repeat steps D for all unbarcoded samples or diluted samples.
G. For unbarcoded samples, place rack on the iChemVelocity® Loading Sampler and samples will be processed automatically. For diluted samples, place rack on the iQ® 200 Loading Sampler and hit the **Start** button.

8.4 Load rack onto the iChem® VELOCITY™ Sample Loader and samples will automatically be processed.

Note: After running the chemistries, the system will transfer the rack to the iQ® system to perform the microscopy.

8.4.1 The iChem® VELOCITY™ will automatically run SG, Color, CLA, BIL, URO, KET, ASC, GLU, PRO, Blood, pH, NIT, and LEU for each sample.

8.4.2 The iQ® will mix the ~2uL of sample with Lamina and run the sample through a flow cell. The camera will capture and classify urine particles by size, contrast, shape, and texture through the Auto-Particle Recognition Program. Particles are separated into the following category:

Category	Abbreviation	Picture (example only)
Red blood cells	RBC	
White blood cells	WBC	
White blood cell clumps	WBCC	
Squamous epithelial cells	SQEP	

Non-squamous epithelial cells	NSE	
Bacteria	BACT	
Crystals	UNCX	
Hyaline Casts	HYAL	
Unclassified Casts	UNCC	
Yeast	BYST HYST	
Sperm	SPRM	
Mucous	MUCS	

9. REPORTING OF RESULTS

After completion of both the chemistry and the microscopy, results will appear in the Worklist screen.
Review specimen results

9.1 To view specimen results, double-clicking on the specimen ID.

9.2 If any of the classification results are flagged as yellow, review the results.

Note: Green flag means results are below minimum verification value, and are accepted as normals. Flagged yellow results are are within the particle verification range, and need to be reviewed by the CLS. Flagged red results are results that are above the maximum verification value, and are accepted as abnormals.

- Select **Edit**.
- Review each of the categories. For every category except for UNCC and UNCX, if 50% of the images are correct, it is not necessary to re-classify.
  Note: Scan the background of each classification for bacteria.
- To classify, select the appropriate general category on the right side of the Specimen screen, then if available, the sub-category choices will be available below the general categories. Click on the appropriate image to re-classify. When finished, unselect to default category by clicking on the original category located on the top left and select the **Next** button. Repeat for all category except for NSE, UNCC and UNCX.
  Note: Once an image has been re-classified, the image will be invisible.
- For NSE, classify only renal and transitional cells.
- For UNCX, only re-classify crystals, cast, renal and transitional cells.
- For UNCC, only re-classify casts, renal and transitional cells.

Note: If a single mistake occurs, simply click on the invisible image. The image will appear again returning that image to the original classification.
Note: If multiple mistakes occurred, select the **Redo** button to reset and start over.

- After completion of re-classifying, if bacteria was present in the background, increase the level of bacteria concentration according to the amount of bacteria perceived in the background. To adjust bacteria concentration, click on the **Bacteria Concentration** button.
- After completion of review, select **Accept** to finalize results.
- Patient results will automatically be printed out and/or transferred to LIS if instituted.
- Calculations are automatically done by this machine.

10. MAINTENANCE

See procedure on CL SOP-06021 Maintenance of the iRICELL® 3000 WorkCell for Urinalysis.

11. TROUBLESHOOTING

If an error occurs, the alarm will be displayed on the right side of the Instrument screen. Yellow alarms are warning alarms while red alarms will halt the system from running samples. Alarms will display the warning/failure along with the time that the warning/failure occurred. Alarm flags are only removed when the problem is remedied.

Double-click on the alarm and follow instructions on troubleshooting, referring to the Operator's Manual as needed. If problem persist, contact the Field Service Engineer.

12. LIMITATIONS

The iRICELL® 3000 cannot classify particles less than 3 microns (i.e.bacteria) and it requires a CLS to manually adjust detection levels.

Manual microscopy is required to confirm the following results:

12.1 Oval Fat Bodies-Confirm using a polarized light microscopy.
12.2 Fat-Confirm using a polarized light microscopy.
12.3 Trichomonas-Confirm the presence of the flagella by motility.
12.4 Any Cellular Cast- to ID the cell type if unable to determine from images.

13. SAFETY

13.1 Make sure that the instrument working area is clean and kept clear.
13.2 Wear PPE. Do not pipette by mouth.
13.3 Do not eat, drink, smoke, apply cosmetics, or handle contact lenses.
13.4 Promptly clean any fluid spills.
13.5 Decontaminate with 5% sodium hypochlorite (1 part bleach to 19 parts water) solution, if needed.

13.6 Consult MSDS in case of chemical spill.
13.7 Follow local guidelines for disposal of waste material according to federal, state and local laws.
13.8 If any part of the system breaks down, contact Iris Technical Support.
13.9 Refer to user's manual for additional safety information.

14. RECORDS

Maintenance and QC records will be kept electronically for a minimum period of three years.

15. ATTACHMENTS

18.1 CL FRM-06022-F1 Iris Diagnostics iChem® VELOCITY™ Training/Competency Checklist.
18.2 CL FRM-06022-F2 Iris Diagnostics iQ® Series Training/Competency Checklist.

16. REFERENCES

19.1 iRICELL® iChem® VELOCITY™ Operator's Manual
19.2 iQ® 200 Series Operators Manual
19.3 iChem® VELOCITY™ Maintenance Quick Reference Guide
19.4 iQ® Maintenance Quick Reference Guide
19.5 IRIS Train-the-Trainer Program

17. REVISTION HISTORY

REVISION HISTORY			
Revision Level	**Effective Date**	**Initiator**	**ECO Number**
A	10/24/2011	A. Gelb	ECO-00022
B	12/5/2014	M. Rockymore	CL DCO-00067
Section Number	**Description and Justification of Changes**		
All	Initial release		
All	Annual Review		

Operation and Maintenance of the Siemens BCS® XP Coagulation System

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1 PURPOSE/ PRINCIPLE

1.1 The BCS® XP System with optional bi-directional interface provides automated coagulation testing on demand for a variety of coagulation tests including clotting, chromogenic, immunochemical and agglutination methodologies. Multiple assays can be simultaneously performed with a large on-board reagent capability.

2 SCOPE

2.1 This procedure applies to all authorized CLIA Laboratory personnel using the Siemens BCS® XP System.

3 DEFINITIONS AND ABBREVIATIONS

3.1 CLRW: Clinical Laboratory Reagent Water

4 RESPONSIBILITIES

4.1 It is the responsibility of the supervisors to ensure that all the personnel using the analyzer are aware of all safety precautions.

4.2 It is the responsibility of all personnel to follow Universal/ Standard Precautions, this SOP and any other SOPs reference below.

5 MATERIALS AND EQUIPMENT

5.1 Instrument components:

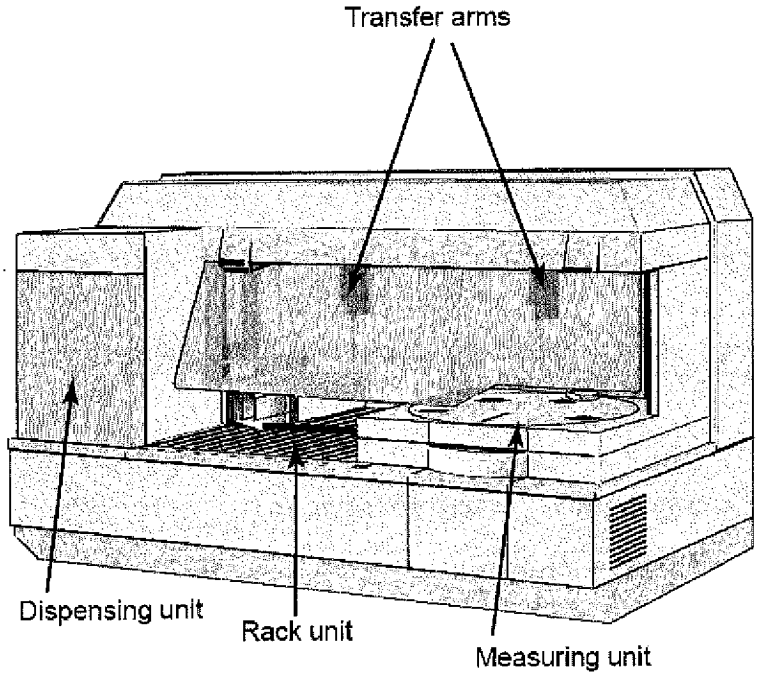

Figure 5.1. Instrument components (Figure 6-1 from the BCS® XP System Manual)

5.1.1 Rack Lanes (1-14)

5.1.1.1 Rack Lanes 1-4 are only for the Reagent Cooler racks (cooled to 13-15°C). Reagent cooler racks can hold 20 ml bottles and 5 ml bottles using the 5ml adapters.

5.1.1.2 White racks are used for non-refrigerated reagents, calibrators, controls, and deficient plasmas. Uses Rack Lanes 5-14.

5.1.1.3 Specimen racks with teal trim can hold 5cc Vacutainer®s, 1.8cc Vacutainer®s, Falcon® tubes, and BCS® coagulation cups. Uses Rack Lanes 5-14.

5.1.1.4 Specimen rack with blue trim holds microcentrifuge tubes.

5.1.2 Barcode Reader/Transport Mechanism

5.1.2.1 Provides loading and ejection transport for racks at the same time reading the barcodes attached to racks as well as reagents, specimens, and controls. The barcode reader mechanism is hidden to the left of the reagent cooler when not in use.

5.1.3 Processing Area

5.1.3.1 Area where samples and reagents are recognized and sampled by the BCS® XP. This area is inaccessible by the user while instrument is in use. Processing starts when reagents and samples are loaded and test requests are made.

5.1.4 Reagent Cooler

5.1.4.1 This area is cooled to 15°C when all cooler racks are on board for prolonged stability of reagents while still providing access to reagent pipetting for sampling. All racks must be inserted into the cooler for cooling to occur.

5.1.5 Transfer Arms

5.1.5.1 Two transfer arms provide level sensing and reagent/specimen pipetting. Both probes are equipped with crash sensors and shock absorbers to prevent crashes.

5.1.5.2 The left transfer arm dispenses reagents (and can heat reagents to 37°C). Will access Rack Lanes 1-4.

5.1.5.3 The right transfer arm pipettes and dispenses controls, standards, deficient plasmas, calibrators, and specimens. Will access Rack Lanes 3-14.

5.1.6 Washing Solution Stations

Three positions are used for vials of washing solution, which cleans the probe.

5.1.6.1 The left two positions are used by the Reagent arm.

5.1.6.2 The center position is used by the Specimen Transfer Arm.

5.1.6.3 Washing solution cannot be changed during a run.

5.1.7 Syringes

Two syringes are used on the instrument. The syringes are located inside the plastic cover on the left side of the instrument which provides protection but allows visibility to check proper function while pipetting.

5.1.7.1 The specimen (right) syringe pipettes a total volume of 250 ul.

5.1.7.2 The Reagent syringe (left) pipettes a total volume of 1000 ul.

5.1.7.3 Amounts less than total volume are routinely pipetted from each probe.

5.1.8 Rotor Unit

This unit provides loading, storage, and pre-warming areas for cuvette rotors. The Rotor Handler arm moves the rotors into the correct position for pre-warming, pipetting, mixing, measurement, and disposal by grasping the upper ridge of the rotor between two gripper cheeks and moving the rotor handler arm between the various stations. Rotors are added by the operator in the right rotor store and transferred to the left rotor store for pre-warming.

5.1.8.1 Pipetting, mixing and measuring all occur in this area.

5.1.8.2 This unit also disposes of used rotors.

5.1.9 Emergency Stop Button

Stops all motion by the instrument. Can be engaged in one of two ways:

5.1.9.1 Press the emergency stop button.

5.1.9.2 Open the safety cover on the front of the instrument.

5.1.10 LED Control

Alerts the operator to disposition of each rack lane. There are four possible LED signals.

5.1.10.1 No LED light- no rack in lane.

5.1.10.2 Unblinking LED-Rack is fully loaded into processing area.

5.1.10.3 Fast blinking LED- Rack is to be loaded, or is in the process of being loaded into the processing area.

5.1.10.4 Slow blinking LED- rack was ejected.

5.1.11 Waste Bin

5.1.11.1 Storage of used rotors until emptied. Amount of rotors present is continuously monitored by the instrument. The total number that the waste bin can hold is 10 rotors plus 4 held over the bin.

5.1.12 External (bulk) Reagent Containers

Three external canisters are connected to the instrument by float intake nozzles. The canisters are continually monitored for liquid levels by the instrument. If changing liquids during operation the operator must tell the instrument the canisters are being changed to avoid having the instrument try to aspirate or dispense during the time the nozzle is removed from the container.

5.1.12.1 Distilled water (green label).

5.1.12.2 Disinfectant (white label) Holds 70% isopropyl alcohol.

5.1.12.3 Waste (red label) labeled Biohazard.

5.1.13 System PC

5.1.13.1 The computer is powered by Microsoft Windows XP software which drives all analyzer functions.

5.2 Materials

5.2.1 BCS® Specimen/Reagent racks

5.2.2 Plastic BCS® Coagulation cups (Siemens) - dead space is 200ul

5.2.3 Microcentrifuge cups 1.5ml (e.g., Thermo Fisher Scientific- 05-406-16 or equivalent)

5.2.4 BCS® Sample rotors (Siemens)

5.3 Reagents.

5.3.1 CLRW

5.3.2 Washing Solution (Siemens Dade Behring #OWZC37)-contains an acidic/detergent solution in glass bottles. Used to wash pipettes. Stored at 2-25°C. Stable for 5 days on the instrument.

5.3.3 Alcohol wipes.

5.3.4 Isopropyl Alcohol, 70%

5.3.5 BCS Validation kit (Siemens Dade Behring) Store at 2-8°C. Once opened stable for 30 days.

5.3.6 Reagents for specific coagulation assays (e.g., CL SOP-10003, CL SOP-10004, or CL SOP-10005).

6 CALIBRATION

6.1 The BCS® XP will automatically request a new reference curve if:

6.1.1 At least one raw value is available and no valid reference curve is available for the reagent lot on board. When missing reagents, calibrators or deficient plasmas and assigned values are on board, calibration will commence.

6.2 Requesting curves manually.

6.2.1 Make sure all applicable lot information is on bard the BCS® XP for all calibrators, and reagents using.

6.2.1.1 Select DEFINITIONS—LOT INFO. To import a lot, click on standard or control etc. desired. Click IMPORT, enter reference number and lot number in Product Input Field. Click IMPORT. To enter reference values by hand, under Product Code choose lot number desired. Double click on assay, then enter value in the field. Click SAVE.

6.2.1.2 To enter a new lot of reagent or deficient plasma etc., click REAGENT then NEW. Enter product code and lot number (4 digit product code + 2 digit lot number) then click SAVE.

6.2.1.3 IF NEW LOTS OF CALIBRATOR ARE ENTERED, THEN REFERENCE CURVE CONCENTRATIONS MUST BE EDITED.

6.2.1.3.1 Close XP software. Close QC, Easytalk, and Autoassistant.

6.2.1.3.2 Open Data Definitions folder. Confirm dialog and enter password.

6.2.1.3.3 Choose DEFINITIONS—ASSAYS and click on desired assay. Scroll down to calibrator info. Click calibrator arrow down box and select calibrator to be used. If the desired concentrations are different than current usage, overwrite the old numbers with the new numbers by double clicking on the old number. SAVE entries.

6.2.1.3.4 Restart XP software.

6.2.1.4 Add appropriate reagents and calibrators to instrument.

6.2.1.5 Click CALIBRATION, then NEW. Choose assay to calibrate. From the pull down menus, choose lot numbers. Reagents and calibrators on board will have the BCS icon. Click MEASURE CURVE.

6.2.1.6 Individual points can be re-measured within one-half hour time period if outliers to the curve occur. Right click on point to be repeated (a green diamond will cover the point) and click REPEAT.

6.2.1.7 Check calibration curve with appropriate controls.

6.2.1.8 Once calibration is complete and valid, print curve and place in appropriate binder.

6.3 Reference curves can be entered manually.

6.3.1 Click CALIBRATION—NEW. Highlight desired assay. Instead of measure curve, click ENTER CURVE. Click NEW as many times as there are points to enter. Enter data into appropriate columns and SAVE.

6.3.2 Once a valid calibration curve is generated, check with controls.

6.3.3 Print copy of the curve and place in the appropriate binder.

7 QUALITY CONTROL AND QUALITY ASSURANCE

7.1 Controls appropriate to the specific assay will be run each shift, before patient samples are run. Refer to the end use procedures (e.g., CL SOP-10003, CL SOP-10004 and CL SOP-10005).

8 PROCEDURE/ USE

8.1 System Icons

There are 7 icons present across the top of the BCS® XP program screen which corresponds to routine screens.

8.1.1 Loading

8.1.1.1 This icon is chosen when "preloading" of specimens is necessary. Alternatively this menu is chosen by the instrument when a barcoded sample is illegible.

8.1.1.2 See Loading and Programming Patient Specimens below for use of this menu.

8.1.2 Joblist

8.1.2.1 This menu allows you to assign testing to barcoded specimens when there is no bidirectional interface or when additional testing is desired. When the instrument is loaded with specimens, their ID number appears on the Job List and tests may be assigned by clicking on the test squares listed. See Loading and Programming below.

8.1.2.2 Patient results are viewed in this menu as they become available. If results are acceptable, they may be verified in the LIS. If further action needs to be taken (See interpretation of Results) action is taken on this menu.

8.1.2.3 Results may be printed from this menu.

8.1.2.4 Result curves may be viewed from this menu:

8.1.2.4.1 Highlight result, and then click on INFO button. The computer displays the raw data and information about the kinetic curve and its errors.

8.1.2.4.2 Double click on raw data at bottom of page to display curve.

8.1.3 Reagent Overview

This menu displays the current inventory of reagents, controls and washing solution, including amounts available, amounts required for programmed testing, and length of time left for on board stability.

8.1.4 Analyzer

This menu displays the current status of the analyzer, including racks loaded, temperatures, rotor status, and canister status.

8.1.4.1 When reagents are loaded into the instrument, a circle appears at the reagent site, giving a quick inventory depending on how full the circle is. If the circle appears red, the reagent has outdated the open vial stability and it must be removed from the instrument.

8.1.4.2 When a rack is selected using the mouse, a listing appears on the right side of the screen, detailing the type of reagent and lot number or specimen ids in the case of samples. Therefore samples and reagents can be located on the instrument without removing racks.

8.1.4.3 When specimens are loaded they are signified by black dots. When tests are ordered the dot will turn blue. The dot will turn green once testing is complete.

8.1.4.4 To eject a rack, select the rack by clicking on it then click EJECT. An arrow will appear below the rack to signify that the analyzer will eject the rack at the first opportunity.

8.1.5 Calibration Menu

Allows the viewing of calibration curves, and allows the operator to request calibration.

8.1.6 Control Journal

This menu allows the programming of control runs, viewing of control results and printing hard copies of control results.

8.1.7 BCS® XP Help

This icon is color-coded, and information appears in two places on the menu screen. The icon displays three different colors:

8.1.7.1 Green-normal operation

8.1.7.2 Yellow-Instrument perceives a potential problem and may or may not proceed with operation.

8.1.7.3 Red-Instrument will not operate due to problem

8.1.7.4 Clicking on the icon, if it is displaying yellow or red, will give more information about the problem.

8.1.7.5 YELLOW AND RED MUST BE INVESTIGATED IMMEDIATELY.

8.1.7.6 In addition a short color-coded phrase is displayed immediately below the icon. The phrase should read "Instrument is Ready" when in standby mode.

8.1.8 Error (Apple) Menu

Located in the lower right side of the screen. The instrument notifies the user immediately when an error message is incurred when the error icon starts flashing green to red. This must be investigated immediately to stave off potential problems which may force the instrument to stop running.

8.1.8.1 Click on the flashing (apple) icon to bring up the error screen and follow up on errors listed.

8.1.9 File Menu

Used to shutdown the BCS® XP.

8.1.9.1 To do so, choose FILE—QUIT and confirm dialog.

8.1.9.2 Shift change screen will pop up. Deselect DISINFECT INSTRUMENT → CONTINUE.

8.1.9.3 XP software will shutdown.

8.1.10 Help Menu

This menu contains the BCS XP instruction manual and help aids.

8.2 Sample Processing Overview

8.2.1 Processing starts when specimens or controls are loaded with applicable reagents in the presence of an assigned test. The transport unit loads the reagent and sample racks into the processing area of the instrument, while simultaneously scanning barcodes into the unit memory. Barcodes of specimens are automatically written into the JOB LIST. If specimen barcodes are not used, the user must manually enter specimen identification and location.

8.2.2 If the BCS XP® is interfaced into a Host computer (LIS), the sample ID's are compared with the online request coming from the host. If the BCS® XP is not interfaced, or the LIS is down, the user must manually request tests using the JOB LIST. Reagents and controls which are barcoded, are read by the instrument and the lot-specific information is stored in the computer. If a barcode is unreadable, the rack is ejected and a diagram of that rack appears to monitor for manual ID entry. Once the unreadable barcode has been identified the rack may be reloaded.

8.2.3 If a test is ordered which requires a calibration curve, the curve must be resident on the computer for the test to be run, or a request for calibration is made automatically. Once all correct calibrators and reagents are loaded, the curve is automatically performed and the results are computed.

8.2.4 When tests are requested with applicable reagents on board a red X appears on the JOB LIST for the particular test requested. The rotor handler moves a rotor to the pipetting station of the rotor unit. One or more samples are pipetted by the right transfer arm into cuvettes of one or more rotors. The left transfer arm adds reagents. The rotor spins rapidly to combine sample and reagents. After initial incubation/activation, the final reagents are added (if necessary) and the rotor is transferred from the pipetting to the measurement position. (During incubation/activation time for one rotor, a second or third rotor may also be placed into action). The final mixing starts the reaction in the cuvette and measurements are taken while the rotor is spinning. Measurements are taken every one-half second until maximum time has been reached. When measurements are complete, results of specimens are shown in the JOB LIST and results of controls are shown in the CONTROL JOURNAL. Results remain until deleted. When results are double-clicked on by the mouse, raw data and kinetic curves become available for viewing or printing. Used rotors are disposed of into waste container as they are filled.

8.3 Loading Rotors

8.3.1 Rotors may be added at any time. Each rotor should be turned upside down and the three guides on the inner ring should be examined for chipping and breaking before loading.

8.3.2 Rotors are loaded in the right side bin. Do not load more than 10 rotors into the bin.

8.3.3 Align rotors with the indentation on the inner hub matched to the rotor handler and let them drop into position. As they drop, the instrument will scan and count them.

8.3.4 Rotor handler will pick up rotors from the right rotor store and move them to the left rotor store for pre-warming.

8.4 Loading Reagents

8.4.1 Reagents are added as needed on the instrument. However, only one bottle of reagent of each type may be loaded at one time, as the instrument does not recognize quality control assignments on reagent bottles. When a new bottle of reagent is loaded, the old bottle must be removed or pooled with the new one (dependent on expiration times-see methodology procedures for reagent specific information). When a new bottle of reagent is loaded, quality control must be performed to verify acceptability of reagent before patient testing. Coagulation QC is repeated on both levels of control whenever reagents are changed, flagging the result for the exception report with /E, and adding a comment (reagents changed).

8.4.2 Reagents may be loaded on any of the reagent/control racks, dependent on the type of reagent. Typically, reagents that are cold dependent for stability are loaded onto the Cooler racks. All other reagents are loaded onto the room temperature 5ml racks.

8.4.3 Remove cork from bottle, note date and time on bottle that reagent was opened. Also note date and time of expiration according to recommendation for open container stability.

8.4.4 Load reagent onto correct rack with barcode showing in the window area of the rack. Prior to loading, verify that no froth or bubbles are evident.

8.4.5 Insert the rack(s) into the correct open lane and push until you feel it stop. (Rack LED starts blinking fast). The rack will automatically load into position and the instrument will inventory amount present via the reagent probe.

8.4.6 When Reagent Overview is accessed, the amount accessible and type of reagent is displayed.

8.4.7 All reagents needing must be loaded before running controls, curves or patient testing.

8.5 Loading and Programming Controls

8.5.1 Place control bottles into the reagent rack with the barcode label on the bottle visible through the rack window. Verify that no froth or bubbles are evident.

8.5.2 Insert the rack in any open lane from 5-14. Push until you feel the rack stop.

8.5.3 Click on CONTROL JOURNAL icon. This shows all the controls that can be run on the XP with their corresponding lot numbers. The tests that can be performed are across the top.

8.5.4 When controls are loaded onto the instrument, a green BCS icon will be displayed next to the name. This helps to distinguish between lots of control.

8.5.5 Click the box that intersects between the control identification and the test column, then click NEW. A red X appears. The red X denotes that the control has been requested.

8.5.6 Some squares have "Do Not Enter" signs. For that particular test or dilution the control may not be run.

8.5.7 To order controls, highlight desired test(s) by clicking in box and click NEW.

8.5.8 After the control has been run, color-coding helps interpret the result:

Color	Symbol	Interpretation	Action
black	green check mark	controls within limits	verify results in LIS if implemented (if needed, release results to LIS)
red	< or >	control is out of limits	repeat and/or troubleshoot
blue	X	test requires calibration	calibrate**

** Testing performed before calibration is complete will give raw data only. When calibration is complete, a final result will be available.

8.6 Loading and Programming Patient Samples

8.6.1 Auto Host: Load barcoded samples in original tube into any sample rack with the barcode visible through the window. Use the STAT rack as needed for Priority One's and stats. Testing will automatically be ordered by LIS interface.

8.6.2 Barcoded samples without Host: Load barcoded samples as above. When fully loaded open the JOB LIST screen. Locate desired test requests and double click in box. Alternatively, click and highlight all tests desired and then click NEW.

8.6.3 Nonbarcoded samples (Preloading): Load samples into rack. Click LOADING icon. Click on rack number corresponding to loaded rack. Click SELECT RACK. Click on first position with sample loaded, then on SAMPLE ID box. If STAT sample click STAT box. Click on assays desired, then click insert or hit ENTER. Continue until all filled spaces are identified. Insert rack into any open lane.

8.6.4 Repeat Testing: If results are questionable, reflex testing should be ordered by the Autoassistant. If not, to repeat under same test mode, highlight result and click REPEAT. A red X will appear in the box, but the original result is still in the Job List.

9 RESULT INTERPRETATION.

9.1 Results are displayed on the XP as color and symbol coded. By interpreting colors and symbols displayed the operator can decide what action to take.

Color	Symbol	Interpretation	Action
purple		valid result/released to LIS	None
Dark green		valid result/not released to LIS	Release results or manually enter results into LIS
orange	?	results questionable/not released to LIS	repeat testing (use 570 method if available, if icteric, lipemic, or hemolyzed) or manually interpret curve for followup*
orange	+ or -	results valid, above or below reference range	NONE -results auto released to LIS, if implemented)
red	stop sign	INVALID	repeat testing (use regular or 570 method if specimen is icteric, lipemic or hemolyzed) /test via fibrometer if necessary
red	< or >	INVALID - beyond linearity range of test	re-test by correct method for range of results
black	⊔	no reaction	repeat test, check sample for bubbles, check bus for pipetting error, view curve to verify, and result as appropriate for procedure
blue	X	no applicable calibration curve on board. testing performed, no result generated	perform calibration. Stored patient data then computed using new curve for patient result.
blue	!	results valid, however applicable control is out-of-control	repeat control testing. If in control, release test results (to LIS, if implemented)

9.2 Manual interpretation of curve data

Each test and reagent will demonstrate a different normal curve pattern and amplitude due to density of reagent and type of curve data collected. Therefore, all curves should be judged in light of the NORMAL curve for that test using that reagent. In addition, the instrument optimally adjusts the scale of the curve. This means that the scale of the curve must also be judged as an integral factoring decisions acceptable vs. not acceptable curves. For each test, multiple factors are examined by the instrument in it's interpretation of the test curve. For this reason, it is helpful to know why the instrument questions the curve when manually interpreting it.

9.2.1 Double click on the questionable result. The specific error flags will show up in the remarks box. Double click on the single measurement in question to display the curve. Examine the curve for:

9.2.1.1 Amplitude (initial absorbance)

9.2.1.2 Shape

9.2.1.3 Height of curve

9.2.1.4 Scale (milliamps on the y axis) or change in absorbance

9.2.1.5 Pattern: Curve falls from left, curve rises from the left

9.2.2 If the curve, despite error codes appears valid, results may be released. If the curve appears valid but appears to be misread by the instrument the operator may manually read the curve and calculate the correct result.

9.2.2.1 With the curve displayed on the screen, place the mouse at the intersection point of the delta absorbance line and the correct point on the curve which demonstrates the start of clotting.

9.2.2.2 Note the time in seconds displayed on the Y line. Click on CALIBRATION and then correct curve for desired test. Click on SHOW CURVE then CALC. Enter the raw data in seconds, and recalculated final result will be displayed. This is the value entered into the computer.

9.2.3 If the curve appears invalid, it must be repeated under appropriate testing method, checked for clots, etc.

10 REPORTING

10.1 Manually print report and follow SOP CL SOP-12001 Test Result Reporting; OR

10.2 Data transmission to LIS (if implemented)

10.2.1 With Auto-release, all error free results are automatically released and sent to the host computer. NOTE: If applicable controls are out-of-control, auto-release will still occur.

10.2.2 Results may be manually released by highlighting result and clicking RELEASE if the result has not been sent, or SEND if result has been sent..

11 MAINTENANCE

11.1 Shift Maintenance (done each shift)

11.1.1 Check tubing and syringes for leaks and air bubbles.

11.1.2 Finger check valves for leaks in syringe area.

11.1.3 Empty rotor waste bin as needed.

11.2 NOTE: Contents are potentially infectious. Wear gloves and dispose of rotors in biohazard bags. Used rotors should be held in an upright position to prevent leakage.

11.2.1 Daily Maintenance (done on night shift in addition to shift maintenance)

11.2.2 Rinse tubing system once. Select SYSTEM—SYRINGE option. Confirm warning message. Enter 1 in input field "No. of rinse cycles". Click on RINSE.

11.2.3 Clean the exterior of the probes with alcohol. Select SYSTEM—PARK POSITION option. Using an alcohol pad carefully wipe down each of the probes in a single downward motion. Probe tips are very sharp and may cause injury.

11.2.4 Check the functionality of the probes. Select SYRINGE—PROBE option. Confirm warning message with CONTINUE. Click both check boxes (left and right). Select WASH INTENSITY—CHECK PROBE in the combo box. Click START button. The probes will dispense water into the relevant washing unit. The water jet must go straight down without splitting or fanning. It must not drip afterwards. If the probe fails, rinse the probe as follows:

11.2.4.1 Select WASHING INTENSITY—INTENSIVE in the combo box and click START. Repeat as necessary to clear probe.

11.3 Daily Maintenance (done at end of last shift; if one shift perform after section 11.2)

11.3.1 Perform shift change to disinfect the analyzer tubing and transfer patient data to the history log. While analyzer is in the ready mode without samples running, Select SYSTEM—SHIFT CHANGE. Click on OPTIONS. Click on "Delete sample id incl results". Close the dialog, and then click DELETE.

11.3.2 Delete control results. When in Shift Change screen, under CONTROL JOURNAL, click on DELETE RESULTS.

11.3.2.1 Minimize XP program.

11.3.2.2 Click Delete Control Results folder.

11.3.2.3 Scroll to ALL CONTROL LOTS.

11.3.2.4 Click OK. Then DELETE. Click OK again and the software will close.

11.3.2.5 Maximize XP software and continue running.

11.4 Weekly Maintenance Procedures (Performed last shift of work week).

11.4.1 Tube disinfection. Disinfects the water tubing with Terralin.

11.4.1.1 Select SYSTEM—TUBE DISINFECTION. Confirm warning with CONTINUE.

11.4.1.2 Follow the provided instructions on the screen to fill the distilled water tubing with 70% Isopropyl Alcohol. Use an extra container of distilled water to place probes when outside canisters.

11.4.1.3 Before placing the distilled water nozzle back into the water container, disinfect the distilled water canister with 70% Isopropyl Alcohol and rinse thoroughly with copious amounts of distilled water.

11.4.1.4 Remove intake nozzle from extra container and return to cleaned distilled water container. Click QUIT to complete the disinfection process.

11.4.2 Quit the BCS software to perform the remainder of the weekly maintenance.

11.4.2.1 Select FILE—QUIT. Confirm message with YES> The shift change dialog will then appear on screen. Deselect DISINFECT INSTRUMENT and CONTINUE.

11.4.2.2 On the taskbar under START, select the option marked SHUTDOWN to power off the computer. Select SHUTDOWN from the pull down menu.

11.4.2.3 Power down analyzer.

11.4.2.4 Close LIS batch, if an LIS is in use.

11.4.3 Clean the surface of the instrument with 70% Isopropyl Alcohol solution. Check for bent and dirty tubing. Do not use alcohol on the plastic shield which will lead to clouding of the shield over time.

11.4.4 Clean and disinfect the rack lanes with 70% Isopropyl Alcohol solution. Do not use alcohol as this will remove the oils from the lanes.

11.4.5 Clean and disinfect the sample racks with 70% Isopropyl Alcohol solution.

11.4.6 Power up analyzer and computer.

11.4.6.1 Default password is BCSXP_Admin to log onto BCS® XP software.

11.4.6.2 Restart LIS batch if an LIS is in use.

11.5 Monthly Maintenance (done last day shift with weekly once a month)

While the analyzer is still powered down from weekly maintenance (or power down again to perform).

11.5.1 Clean the scanner window with lint free cloth and water.

11.5.2 Clean the keyboard with 70% Isopropyl Alcohol solution

11.5.3 Clean the mousepad with 70% Isopropyl Alcohol solution

11.5.4 Clean the gripper cheeks. Reach through an open lid and move the rotor handler over the waste bin. Open the waste bin and remove the container. Clean the gripper cheeks with a lint free cloth and water by reaching upwards through the rotor waste. Return waste container to bin and close lid.

11.5.5 Power up analyzer and computer.

11.5.5.1 Default password is BCSXP_Admin to enter BCS® XP software.

11.5.5.2 Restart LIS if an LIS is in use.

11.5.6 Confirm that the analyzer meets pipetting and optical precision specifications. DO NOT PERFORM ANY OTHER TESTING WHILE PERFORMING CONFIRMATORY TESTING.

11.5.6.1 Open validation kit.

Place 10 ml CLRW into bottle labeled water.

Place 4 ml CLRW into tube labeled 101.

11.5.6.2 Verify the analyzer has a minimum of 5 unused cuvette rotors on board.

11.5.6.3 Place reagent bottle and water bottle in lane 3 or 4.

11.5.6.4 Place sample tubes 101-108 in sample rack in lanes 5-14.

11.5.6.5 Perform the following tests. Results should be <5.0 (<2.0 for calibration purposes). If not perform intensive cleaning and repeat.

Sample 105: "Prec..ple". Sample probe precision.

Sample 101: "Prec..reag". Reagent probe precision.

11.5.6.6 Perform Precision Sample Reproducibility. Results should be 0.96-1.05.

Samples 106,107,and 108: "Prec..rep"

11.5.6.7 Perform reproducibility check. Rick 2 full specimens with normal values and transfer to BCS cups. Load onto analyzer without barcodes. Perform "PT.Prec" and "APTT.Prec", one on each tube. The analyzer performs 20 of each test. The maximum allowable CV is 5%. Troubleshooting required if greater results are obtained.

11.5.6.8 Print validation and reproducibility results and place in maintenance book.

11.6 Bi-annual Preventive Maintenance (performed on day shift)

11.6.1 Oil syringe with silicon oil.

11.6.1.1 Unmount syringes.

11.6.1.2 Pull plunger out of glass barrel.

11.6.1.3 Press a drop of silicon oil into a plastic bag and oil the Teflon head of the plunger in a circular movement on all sides.

11.6.1.4 Wipe the surface of the plunger head with a lint free cloth in order to remove excess silicon oil.

11.6.1.5 Place plunger back in glass barrel and move up and down several times until moves freely.

11.6.2 Clean Mouse

11.7 Two-Year Maintenance

11.7.1 Replace syringes with lubricated new ones.

12 TROUBLESHOOTING

12.1 Refer to the online user's manual troubleshooting section 12.

13 PROCEDURAL NOTES

See specific assay end use procedures.

14 LIMITATIONS

See specific assay end use procedures.

15 SAFETY

15.1 Make sure that the instrument working area is clean and kept clear.

15.2 Promptly clean any fluid spills.

15.3 Decontaminate (not instrument) with 5% sodium hypochlorite (1 part bleach to 19 parts water) solution, if needed.

15.4 Follow local guidelines for disposal of waste material according to federal, state and local laws.

15.5 If any part of the system breaks down, contact Siemens Technical Support

16 RECORDS

16.1 Maintenance and QC records will be kept for a minimum period of three years.

17 ATTACHMENTS

17.1 CL FRM-06022-F1 BCS® XP System Maintenance Log.

18 REFERENCES

18.1 BCS® XP System Instruction Manual, version 1.2; Siemens (Dade Behring), 2008.

18.2 Operating the BCS® XP Coagulation Analyzer, Technical Procedure 1581.t, University of California, Davis, 2008, with permission.

19 REVISION HISTORY

REVISION HISTORY

Revision Level	Effective Date	Initiator	ECO Number
A	10/11/2011	A. Gelb	CL ECO-00021
B	12/5/2014	L. Gee	CL DCO-000067

Section Number	Description and Justification of Changes
ALL	Initial release
ALL	Annual Review