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Quality Control		

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The medical/laboratory director or the director's designee should review all copies of this procedure at least once a year. The director should keep a log of the copies being maintained.

Reviewed By:	Date:	Comments:
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1 PURPOSE

The purpose of quality control (QC) is to ensure that the analytical values reported by the laboratory correspond to the clinically correct values. This SOP establishes the procedures to follow to ensure the quality and reliability of laboratory results. The goal is to assess the laboratory's performance in relation to expected values, to identify significant problems as they arise, to implement and document corrective actions, and to ensure that patient test results are accurate and that any problems are corrected in a systematic manner.

2 SCOPE

This protocol covers QC in the chemistry area as performed by all testing personnel, analyzed by supervisors, and reviewed by the Quality Assurance / Quality Control Manager or designee and the Laboratory Director in the CLIA Laboratory.

3 DEFINITIONS AND ABBREVIATIONS

3.1 QC: Quality control refers to activities that ensure basic functions and specific processes meet acceptable parameters.

3.2 Internal (intralaboratory) QC is the system where controls with determined values (assayed or unassayed) are run, prior to patient samples, to determine whether the analytical test system is producing analytically reliable results for that particular analyte (test).

3.3 Qualitative controls yield a positive or negative result based upon an interpretation, e.g., some pregnancy test controls.

3.4 Quantitative controls yield a numerical result

3.4.1 Assayed controls are commercial controls where the analytes have been assigned a mean value and standard deviation by the vendor and are "traceable".

3.4.2 In unassayed controls the analytes are of unknown values. Each analyte must be tested and, based upon the results, a mean and standard deviation may be derived.

3.4.3 Accuracy controls are utilized to determine whether a test system is reporting accurate results as compared with the previously determined "known values" of the tested analytes.

3.4.4 Precision controls are utilized throughout the operation of a test system to verify the precision of the test system for a given analyte.

3.4.5 A shift is defined as 6 or more consecutive data points on one side of the established mean.

3.4.6 A trend is defined as a gradual drift of 6 or more consecutive data points in the same direction. A trend can start on either side of or at the mean and may or may not go beyond 2 standard deviations.

4 RESPONSIBILITIES

4.1 Testing personnel are responsible for following QC procedures in this protocol and those specified for instrument use and in the individual test methods.

4.2 Supervisors are responsible for analyzing the results of all QC procedures and taking any appropriate

corrective actions.

4.3 The Quality Manager or designee along with the Laboratory Director are responsible for reviewing the results of QC monthly to identify any trends (i.e., as found from examination of Levey-Jennings charts/logs), or sooner if any problems have been discovered. These evaluations will be documented in a summary of QC findings prepared by the QA/QC Manager, designee or Laboratory Director.

5 MATERIALS AND REAGENTS

Two, three or four level controls appropriate to the assays being run (see individual technical methods) for the particular analyzer(s).

6 PROCEDURE

6.1 General Guidelines

6.1.1 Continued education of laboratory personnel.

6.1.2 Preventative maintenance procedures.

6.1.3 Proper preanalytical, analytical and postanalytical processing of samples and results. This includes proper identification of samples and results.

6.1.4 Confirming that the instructions in reagent package inserts for specific tests are being followed, especially when there is a new lot.

6.1.5 Use only reagents and disposables recommended for use by the manufacturer.

6.1.6 Document the daily performance of QC control materials.

6.1.7 Document monthly QC record review.

6.2 Running QC Controls Materials (e.g., QC sera)

6.2.1 Careful handling and preparation of the control materials (e.g., control sera) is required.

6.2.2 Controls are run in the same way as regular samples.

6.2.3 Unless three or four levels are required for a particular assay, run two levels of controls (high and low) for each analyte each day the test is run, and always before any patient results are being reported.

6.2.4 Controls are also run whenever a new container of reagent is loaded or recalibration is performed.

6.2.5 A report of the day's QC shall be analyzed before any results are released and documented by the method appropriate for the analyzer.

6.3 Control Rules

The laboratory uses various control rules based upon specifics of each individual test system or analyte

tested. See the individual SOPs for each test system or analyte for the rules used and control tolerance limits. See sections 6.3.1.9 below if a particular manufacturer does not provide pass / fail for QC.

6.3.1 Daily QC should include all of the following:

6.3.1.1 Perform daily QC according to the SOP for the assay being performed.

6.3.1.2 Documenting all daily QC results and ensure they are initialed by a CLS or Supervisor.

6.3.1.3 Careful handling and preparation of the control materials (e.g., control sera) is required.

6.3.1.4 Controls run in the same way as regular samples.

6.3.1.5 Unless three or four levels are required for a particular assay, run two levels of controls (high and low) for each analyte each day the test is run, and always before any patient results are being reported.

6.3.1.6 Controls are also run whenever a new container of reagent is loaded or recalibration is performed.

6.3.1.7 DAILY QC IS DEEMED TO HAVE PASSED WHEN:

6.3.1.7.1 All QC levels fall within the assay range specified for the testing system, regardless of the number of QC levels used for the assay.

6.3.1.7.2 Westgard rules have not been violated (see following monthly QC section 6.3.2).

6.3.1.8 If Daily QC failed for the first trial, check the analyzer, all reagents and the process, repeat the QC test for second time. If fails again, report to supervisor.

6.3.1.9 Ensuring that all QC levels are within QC acceptable ranges. If no manufacturing guidance provided for daily QC, pass if ≤ 2SD.

6.3.1.9.1 If failed, then follow guidance in Section 6.5 and repeat QC test. If all ≤2SD, controls passed. Continue to run patient specimens.

6.3.1.9.2 If two levels of controls are ran and one level is >2SD, run fails and follow guidance in Section 6.3.1.8.

6.3.1.9.3 If three levels of controls are ran and 2 levels are ≤2SD and one level is >2SD but <3SD, the run passed for the day. Notify supervisor to initiate monitoring of following days QCs.

6.3.1.9.4 If four levels of controls are ran and 3 levels are ≤2SD and one level is >2SD but <3SD, the run passed for the day. Notify supervisor to initiate monitoring of following days QCs.

6.3.1.10 NO PATIENT RESULTS CAN BE RELEASED UNTIL DAILY QC PASSES

6.3.2 MONTHLY QC: Should be monitored for any of the following failures (control rules):

6.3.2.1 1_{2S}: If one control is greater than +/- 2SDs is used as a warning rule that initiates testing of control data by the other control rules

6.3.2.2 1_{3S}: QC "Flyers": One control exceeding +/-3SD results in QC failure for that control: such failures are usually the result of random error

6.3.2.3 2_{2S} Two (2) consecutive control observations exceeding +/-2SD results in QC failure for that control observation: such failures may indicate systematic error

6.3.2.4 R_{4S} One observation exceeding the mean +2SD and another exceeding the mean -2SD is a rejection rule. Observations can come from the same QC run with different control levels. Such a failure usually indicates random error.

6.3.2.5 10_x Ten consecutive observations on the same side of the mean line.

For a detailed description of the application of Westgard rules, refer to Tietz. Et. al. (4th Edition), pgs 504-506 Control Rejection Criteria.

6.4 Levey-Jennings Control Chart

6.4.1 The QA/QC Manager or designee will review Levy-Jennings Control Charts monthly to determine if a trend or shift is occurring.

6.4.2 Ten consecutive observations on the same side of the mean line will be evaluated using the following techniques:

6.4.2.1 If the ten consecutive observations are within one SD of the mean – no corrective action is necessary.

6.4.2.2 If the ten consecutive observations are not within one SD of the mean, corrective actions may involve adjusting mean and range with manufacture's peer data or in-house's.

6.5 Procedure to take when Controls are out

Follow the particular procedure specified for a particular test system. The following is a generalized procedure to resolve control problems. Follow these steps sequentially. If values are still out of control, inform your supervisor.

6.5.1 Step 1. Rerun the controls. Verify expiration date, properly prepared, proper storage, contamination and control range. If repeated results fall within the control range, the patient results for the run where the controls are in range may be reported.

6.5.2 Step 2. If the rerun of controls failed in step 6.5.1, repeat with fresh controls. If repeated results fall within the control range, the patient results for the run where the controls are in range may be reported.

6.5.3 Step 3. If the rerun of controls failed in step 6.5.2, check the operation of the instrument, ensuring that it is clean, functioning, and has sufficient reagents and disposables. Ensure all instrument lines are in the appropriate receptacle where applicable. Perform recalibration, any adjustments and repeat with fresh controls. If repeated results fall within the control range, the patient results for the run where the controls are in range may be reported.

6.5.4 Step 4. If the rerun of controls failed in step 6.5.3, repeat using a new reagent kit, recalibrate and repeat with fresh controls. If repeated results fall within the control range, the patient results for the run where the controls are in range may be reported.

6.5.5 Step 5. If the rerun of controls failed in step 6.5.4, call instrument support and inform supervisor.

6.5.6 DO NOT report test results for a run where the controls are out of range.

6.5.7 On a monthly basis, the Quality Assurance / Quality Control Manager will analyze the QC data for the Instruments and review and discuss with Laboratory Director and supervisors.

7 RECORDS

QC and maintenance records will be maintained for 3 years.

8 ATTACHMENTS

None

9 REFERENCES

9.1 Valenstein, Paul, MD (Editor); Quality Management in Clinical Laboratories, Promoting Patient Safety Through Risk Reduction and Continuous Improvement. Northfield, Illinois: College of American Pathologists; 2005.

9.2 Burtis CA, Ashwood, ER, Bruns DE. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 4th Edition, 2006. Elsevier.

10 REVISION HISTORY

REVISION HISTORY			
Revision Level	**Effective Date**	**Initiator**	**ECO or DCO Number**
A	06/09/2011	A. Gelb	CL ECO-00001
B	6/13/2011	A. Gelb	CL ECO-00016
C	01/27/2014	L. Gee	CL ECO-0135
D	03/17/2014	L. Gee	CL DCO-0003
E	03/25/2015	L. Gee	CL DCO-00081
F	04/23/2015	L. Gee	CL DCO-00085
Section Number	**Description and Justification of Changes**		
6	Updated QC rules and added Levey-Jennings control chart.		
6	Updated QC rules		
6	Updated QC rules		
6	Updated QC rules to incorporate the use of four levels of controls		
6	Updated logo, add 10x resolutions, update QC failure rules		