Beaumont HEALTH

Beaumont Laboratory
Clinical Pathology
Royal Oak

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Related Documents:

QC PROCEDURES AND POLICIES FOR AUTOMATED CHEMISTRY

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Introduction
All methods in the Automated Chemistry section are subject to the following guidelines for quality control. The appropriate Chemistry faculty member must approve all protocols.

Purpose
This document defines Quality Control procedures for the analytical phases of testing and reporting in the Automated Chemistry Lab.

Definitions
Unassayed Controls = QC material that is not supplied with pre-determined SD, Mean and ranges for the analytes contained within. Each Lab is expected to assay the material to determine these statistical parameters. Unassayed QC is generally used to routinely monitor precision. Statistics are submitted for peer group comparison. Example: BioRad Multiqual Chemistry Controls

Assayed Controls = QC material that is received with pre-determined SD, Mean and ranges for specific analytes. Some assayed QC are specialty controls used on a daily basis. Others are available for method evaluation, troubleshooting, or for backup in the event of a question about performance of unassayed QC.

LIS = Laboratory Information System

BioRad Unity and/or LIS QC = Software used for monitoring QC performance.

Equipment Calibration and Maintenance
All laboratory instruments should be well-maintained and calibrated appropriately prior to running QC materials and patient specimens.

Quality Control Requirements
For quantitative methods, at least two levels of quality control material must be included in each analytical run or batch, as run or batch are defined within each area of the Chemistry Section. The definition of a run may not exceed a 24-hour period unless the method is performed less frequently than daily. Immunoassays, or other methods which deviate from a linear response, require at least three levels of quality control material to be evaluated within each 24-hour period as described above.

For qualitative methods without an IQCP in place, a positive and a negative control must be included in each analytical run or batch as previously described.

Quality controls for both quantitative and qualitative methods must be included in the analytical run, treated in the same fashion, and tested by the same personnel as patient samples. Tests for which calibration and control materials are not available must have established guidelines for verifying the accuracy of patient results.

See QC Stability Tables for list of QC materials currently used in Automated Chemistry and their appropriate storage/expiration dates.

Special Safety Precautions
All QC materials should be handled with the same Standard Precautions used for biological specimens.

Procedure

A. QC Preparation

1. Commercial lyophilized control materials are reconstituted with Clinical Laboratory Reagent Water (CLRW, formerly known as Type 1 water) or other diluents as specified in the manufacturer's instructions using Class A volumetric pipettes and appropriate techniques. Reconstituted materials is adequately mixed according to manufacturer's guidelines or until complete dissolution. Controls are maintained stoppered and refrigerated except when in use, or unless specified differently by the manufacturer.

2. Controls stored frozen must be permitted to thaw and then should be mixed to achieve complete dissolution before use. Liquid controls, when not in use, should be stored, stoppered and refrigerated.

3. All QC is labeled with appropriate "Open" and "Expires" information. See QC Stability Tables for list of QC materials currently used in Automated Chemistry and their appropriate storage/expiration dates.

B. Control Ranges

1. Primary control material, also known as unassayed control material, should be evaluated to determine a mean and standard deviation for each quantitative method supported by the control. These materials may or may not have a manufacturers' stated range provided with the material. Controls should be evaluated on each analyzer, over at least 10 analytical runs up to a maximum of 20 runs unless directed by a Chemistry Faculty member.

2. Secondary control material, previously known as assayed controls, may be used for troubleshooting purposes and to release patient results when primary controls are out of range only. Secondary controls will be evaluated using the manufacturers' stated ranges. Assayed controls are not to be used on a routine basis without consulting with a Chemistry Faculty member.

C. Evaluation Criteria

1. Routine control results must be recorded and evaluated before release of patient results. Tolerance Limits or suitable control rules must be established for each method. Control results that exceed tolerance limits must be noted and corrective action recorded. Release of patient results is not permitted if tolerance limits are exceeded unless authorized by a section supervisor or Clinical Pathology Faculty member. In the absence of specific control rules or tolerance limits, the default control rule is 1-2S. Results outside ± 2 SD are rejected and require corrective action.

D. Automated Chemistry QC Documentation

1. Most QC results for Automated Chemistry and Urinalysis are documented and reviewed in the LIS or Biorad Unity. QC results for the Hematology and Coagulation instruments in Stat Lab are documented and reviewed in the analyzer.
2. QC sheets are posted, for all instruments and analytes, with mean, SD and 2SD ranges, or expected results for qualitative testing.
3. QC from interfaced instruments is entered through the interface.
4. All QC results, even those out of posted QC range, should be documented. This is our record of corrective action for QC.
5. You must evaluate across QC levels for any 1 of 1 2SD warning, or for any QC violation. You may choose to view Levy Jennings plots for both levels of QC, if that is helpful.
6. You must troubleshoot all QC failures (violations).
7. Choose an appropriate action anticipating your troubleshooting and corrective action. You may choose action CHEM: See comment, and free text your action (eg. will recalibrate, will re-verify with assayed controls etc.) in the Comments field.
8. After troubleshooting and problem resolution, report QC that is within posted range.

E. Resolving QC warnings and violations

1. Respond to QC results that are out of control as you encounter them.
2. The LIS QC or Biorad Unity will alert you for the following QC warnings or violations:

Automated Chemistry QUALITY CONTROL Rules

QC Rule Violation	Description	Responses/ Corrective Action
1 of 1 2 SD	Single result is greater than 2 times the SD, above or below the defined mean.	Review Levy Jennings graph and evaluate QC across levels. Other QC in run and the previous run must be within 2 SD range.
7T	7 consecutive runs are trending progressively higher or lower than the defined mean.	Review Levy Jennings graph and evaluate QC across levels. Calibrate if necessary.
2 of 2 2SD or 1 of 1 3SD	Two consecutive results of a QC item are greater than 2 times the SD, above or below the defined mean. Results can be within the same run or across runs. A single result is greater than 3 times the SD, above or below the defined mean.	1. The QC will be repeated. Repeat QC is expected to be within acceptable range. 2. Will verify with assay QC if available. The procedure will be verified with assayed controls that are expected to be within specified ranges for method. 3. Will recalibrate. The method/instrument will be recalibrated and controls/patients (if any) will be repeated. Repeat QC is expected to be within acceptable range. 4. Will put on fresh reagent. The reagents will be replaced. Controls/patients (if any) will be repeated. Repeat QC is expected to be within

		acceptable range. 5. Patients will be repeated. After troubleshooting, the method or instrument controls are expected to be within acceptable range. Controls and patients (if any) will be repeated. Description of problem/correction will be logged. 6. Patients will be selectively repeated. Patient results will be selectively repeated by the same or a different method. Results will be compared. QC is expected to be within acceptable range. Comparisons, description of problem and corrections will be logged. 7. Patient results were not reported. 8. Reverse controls. QC must be repeated. 9. Will repeat with fresh QC. Repeat QC is expected to be within acceptable range. 10. Evaluating new lot QC.

F. To view trend in LIS QC

1. QC warning or violation requiring Action ID presents LJ for review.
2. View expected result and SD at the top of the screen.
3. Toggle QC history and rules for review by using check boxes in the Graph lines selection area on the top left side of the screen.
4. View previous results by choosing Result Points tab.
5. To view LJ and previous QC points without QC failure, from QC result entry field, use arrow on the right side of the Verify row, choose Result Graph.

G. Result Manual QC from Non-interfaced Instruments from LIS Lab Module

1. Go into a result field on any Result Workslist.
2. Right Click and choose Add QC order.
3. Delete Workstation if you are in proper Location/Department, otherwise change Location to ROLB, and Department to RCHEM or RTOX.
4. Find will bring up the list of QC IDs to choose from.
5. Click on desired QC and OK, you will bridge to LIS QC module to order and enter QC result.
6. Check boxes of QC items you wish to result, select Save from top of screen, click Yes, Save changes.
7. Close window with QC Order number.
8. Wait for resulting field, if you have already used the LIS QC it will be minimized at the bottom of your screen, click on it to open.
9. Close Print Labels tab, if it appears.
10. If you selected to order more than 1 QC instrument choose one of the QC options to result, then Open, or if only 1 QC instrument was ordered you will open directly into the result field.
11. Enter QC results. Failures will bridge to LJ information and Action Result tab.

H. Automated Chemistry QC Documentation in Biorad Unity

1. All QC warnings must have comments documented in BioRad Unity.
2. All QC violations must have actions and comments documented in BioRad Unity.
3. No patients will be assayed for tests with QC violations until the failure can be resolved.
4. Assays with QC failures may be disabled for troubleshooting so that patients are not run.

I. Procedure When Both QC Levels are High or Low w/ Respect to the Means

1. Review previous QC trends
2. Consider appropriate actions
3. Repeat QC
4. Verify with assayed QC to see if they also follow low/high pattern.
5. Recalibrate method/instrument and repeat QC
6. Replace reagent(s), calibrate and repeat QC.
7. Consider previous maintenance performed. Was a problem introduced?

8. Selectively repeat patients by same or different method to compare results.
9. Continue troubleshooting until problem is resolved.

J. Corrective Action and "Lookback" Policy When QC Fails (Violations)

1. Immediately suspend reporting of patient results.
   - Repeat failed QC and run assayed QC if available.
   - If feasible, process patients on another analyzer or by backup method.
   - NOTE: With supervisory approval, you may release results based on acceptable assayed QC. However, you must continue to troubleshoot until unassayed QC is again within acceptable range.
2. Investigate and resolve the problem:
   - Recalibrate, use a different calibrator, change reagents, check instrument operating parameters, notify supervisor, call for service, etc.
   - You may proceed with processing additional specimens once the procedure is verified (eg. assayed QC is acceptable) or the method/instrument problem has been resolved and repeat QC is within acceptable range.
3. Determine when the failure started, and consult with supervisor, Pathologist, or Technical Director for the appropriate course of action for specimens already processed or results released during the failure period.
   - Look back for the last valid QC results for the parameter(s) in question, review operations for prior reagent changes, calibrations, etc. that may have impacted operations.
   - If assayed QC was acceptable prior to troubleshooting, it may be used to validate patients already run/reported.
   - If assayed QC was not within posted 2SD range, then QC has failed and specimens must be repeated.
   - Repeat patients back to the last acceptable QC, using the same method (if now verified as acceptable) or a different method. If only a few patients are involved, repeat all. If the batch is small, repeat the ten patients prior to the failed QC. Proceed backwards in groups of ten until you find the group of ten whose repeat results match the original results for the out-of-control parameter(s).
   - If the batch is large, tens or a few hundred patient specimens may have been processed. In this case, Chart Review in the LIS all results between the last valid QC and the failed QC. Samples with significantly different results (ie. changed from normal to abnormal or vice versa) along with those with no previous value for comparison must be retested.
4. Correct results as warranted in the LIS. Notify appropriate personnel (eg. EC or Inpatient Nursing, Outpatient Physician, BRL Client Services) of any corrected reports. Notify the Medical Director of Automated Chemistry or Pathologist Assistant whenever multiple patient results must be corrected.
5. Document a description of the problem, patient comparisons and the resolution.
6. If the problem is systematic, the supervisor will institute appropriate procedural modifications or in-service training of personnel.

K. Supervisory Review of QC

1. Section assistant supervisors for the Core Lab, Stat Lab and Urinalysis will regularly review QC.
2. Tech is notified for clarification whenever QC failure is inappropriately documented or there is no evidence of corrective action.
3. Outliers are cancelled so they are not included in monthly statistics.
4. In Biorad Unity and LIS QC, previous QC and comments can be viewed.
5. Section assistant supervisors compile monthly means and SD reports for review by Technical Directors. Data is submitted monthly for peer comparisons. (eg. with BioRad, Radiometer, etc.)
6. Bioscientific Staff review monthly peer comparison statistics reports.
7. Should monthly mean and precision data change significantly, the assistant supervisor will investigate (eg. initiate precision studies, check method accuracy with assayed QC, CAP proficiency samples, patient comparisons with another method, verify calibrator value assignments, check reagent lot # stability, consult with manufacturer/field service/Bioscientific staff etc.).
8. Significant adjustments to mean or SD for a method must be signed by a Bioscientific Staff member.

Expected Values

See posted QC ranges for analytes by specific instrument/method and current QC lot. Acceptable QC ranges are also defined in LIS QC and Biorad Unity.

Proficiency Testing

External proficiency testing should be performed for each test in the laboratory at least twice annually. Subscription to CAP, AACC, UKNEQAS or other commercially available programs satisfies this requirement. In the absence of commercial or professionally based programs**,** proficiency testing requirements can be satisfied by alternative means, such as assayed controls, samples shared with other laboratories, analysis by other in-house methods, clinical chart review or another method as defined by the Laboratory Director. Tolerance limits for acceptability of proficiency test results must be defined by the Chemistry section if not specified by government or professional bodies. Results that exceed tolerance limits require duplicate analysis if possible and corrective action (including report of investigation) by supervisory staff with signed approval of the Chemistry faculty. Laboratory sections should treat all proficiency samples as blind and independent. Lyophilized materials must be reconstituted with CLRW or other diluents as specified in the manufacturers' instructions using Class A pipettes and appropriate techniques.

Water Checks

Readings should be recorded for each deionizing unit on each day of use. Resistance should exceed 10 Mohms for CLRW. If readings fall below 15 Mohms supervisory staff should be alerted. If readings fall below 10 Mohms deionizing cartridges should be replaced or other appropriate corrective action taken.

Microbiological cultures should be performed each quarter on each water system. Acceptable limits are < 10 cfu/mL for CLRW. If results exceed the acceptable limit

contamination should be ruled out by confirmation with repeat cultures. If confirmed the water system should be sanitized as needed. Maintenance sheets are to be reviewed monthly by supervisory staff.

Temperature Checks

All incubators, heating baths, ovens, refrigerators and freezers must be checked for temperature each day of use. Each device must be assigned a specific tolerance limit. If tolerance limits are exceeded supervisory staff must be noted and corrective action taken and documented.

If acceptable temperature ranges are exceeded for refrigerators and /or freezers, reagents, controls, calibrators, etc. must be evaluated for possible adverse effects, with documentation of results. Maintenance sheets are to be reviewed monthly by supervisory staff.

References

Tietz, Textbook of Clinical Chemistry, 4th Ed, Burtis, Ashwood and Bruns, Eds, Elsevier/Saunders, 2006, Ch. 19.

Authorized Reviewers

Medical or Technical Director

QC Procedures and Policies for Automated Chemistry

Document Control

Location of Master: Master electronic file stored on the Clinical Pathology server under S:/Automated Chemistry/Document Control Library/RC/CH/LOP/Master Files
Master printed document stored- Chemistry General Policy & Procedure Manual, Core Lab
Number of Controlled Copies posted for educational purposes: 0
Number of circulating Controlled Copies: 1
Location of circulating Controlled Copies:
Chemistry General Policy and Procedure Manual, Stat Lab

Document History

Signature			
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