QUALITY CONTROL STATEMENT-CHEMISTRY

Safety Message

Use universal precautions and appropriate PPE when handling patient or control samples.

Policy

Quality control materials are periodically processed with patient samples to verify acceptable performance of the reagent-instrument-operator system and insure accurate determination and reporting of patient results

Testing Frequency

Quality Control is performed:

1. Once every shift for:
    - ISE analytes
    - Trop-I
    - Coagulation Assays:
        - PT/INR
        - APTT
        - Fibrinogen
        - Anti-Xa
        - D-Dimer
2. At least once per day for non-ISE or Trop-I
3. On day patient sample is tested for:
    a. Fetal Fibronectin
4. After instrument calibration.
5. After instrument maintenance.
6. When new reagent is loaded on:
    - Beckman Synchron DXC800
    - Beckman DXI 600
    - Sta-R Evolution
    - Roche AVL 9180

Testing Guidelines

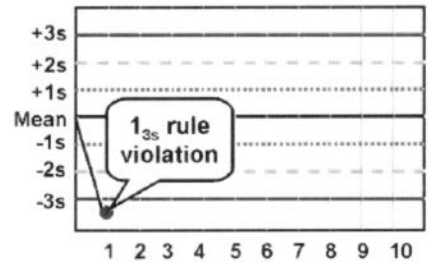
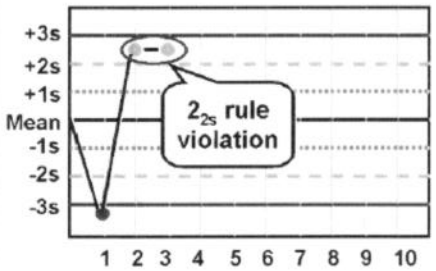
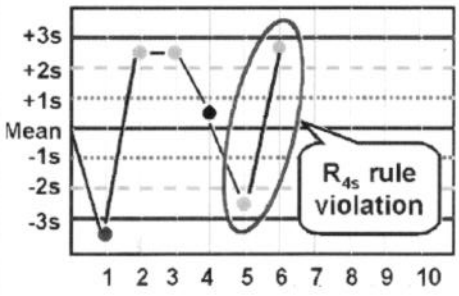
To meet the above objective, quality controls must be evaluated for accuracy shifts and trends. All quality control Westgard rule failures identified must be addressed, corrected, and appropriately documented prior to reporting of patient results.

- For the DXC800s, and the DXI 600s the on board QC program Westgard Rules evaluation and Remisol EQC (Extended Quality Control) program is utilized.
- QC results for the Advanced Instruments Osmometer and Roche AVL 9180 ionized Calcium is entered into the Remisol EQC system.
- For the Sta-R Evolutions #1 & #2, the on board QC program is utilized.

It is the responsibility of the CLS or MLT to evaluate the Westgard rule violation(s) and take appropriate action to correct the out-of-control situation and to establish the system is reporting accurate results prior to reporting patient results. Documentation of such action is required in EQC as well as the Chemistry QC Action Log.

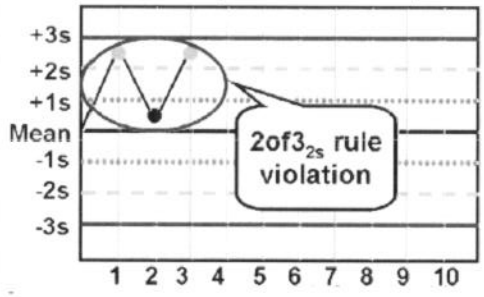
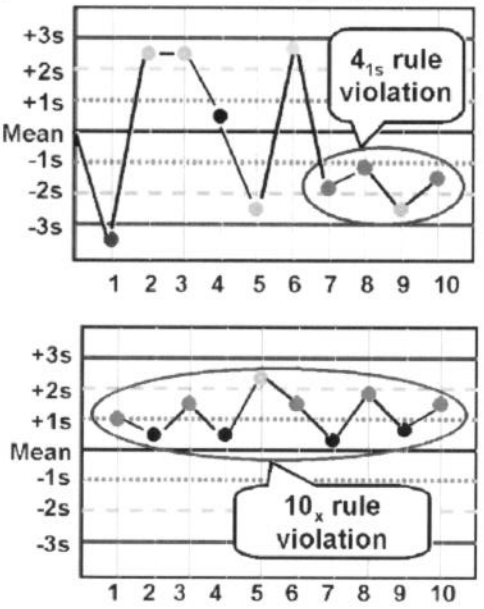
QUALITY CONTROL STATEMENT-CHEMISTRY

Patient Result Reporting

IF	THEN
TRI-Level: All three levels read within 2 SD of the established mean.	Report patient results.
TWO-Level: Both controls read within 2 SD of the established mean.	Report patient results
TWO-Level: One control reads within 2 SD, the other control between 2-3 SD (once, not in consecutive occurrence). When this occurs, indicate on the Corrective Action Log, "1_{2S} rule warning noted".	Report patient results
One control is >3SD from the mean (1_{3S}). 	Reject the run and do not report patient results prior to further investigation.
Two controls are >2SD from the mean (2_{2s} and R_{4s} violations).  	Reject the run and do not report patient results prior to further investigation.

QUALITY CONTROL STATEMENT-CHEMISTRY

Patient Result Reporting

IF	THEN
One control is between 2-3 SD on two consecutive runs (2 of 3_{2s} violation) 	Reject the run and do not report patient results prior to further investigation.
4_{1S} or 10_x rule violations occur which indicate a shift or trend. This rule takes effect when there is also a 1_{2S} violation. 	Report patient results but examine procedure and notify supervisor.

If the CLS or MLT cannot resolve the problem, they should seek Area Lab manager assistance or designee, assistance and approval prior to reporting patient results.

Corrective Action to be Taken and Documented

- Verify the correct control lot number and control material has been tested.
- Check open expiration of control.
- Check the other components of the procedure and the instrumentation (precision check if indicated).
- Check or verify the instrument calibration (linearity standards and recalibration is necessary).

QUALITY CONTROL STATEMENT-CHEMISTRY

Area Lab Manager or Designee Review of Action Log

- Check laboratory mean and SD range against interlaboratory quality assurance data and CAP proficiency survey values. Recalculate mean and SD intervals if the current ranges are inappropriate. All supervisory corrective actions are documented in the Supervisory Review section of the Corrective Action Log.
- QC periodic reports will be reviewed, signed and dated at the end of each month by Chemistry Area Laboratory Manager or designee.

Monthly Submission of Cumulative Mean and SD to Peer InterLab Programs

- BioRad Unity Program (Chemistry & Immunoassay Tests):
  - At the end of each month cumulative data (mean, sd & # of data points) is extracted.
  - The data is entered into BioRad Unity Program between the 1st to the 7th of following month.
  - Report is generated approximately around the 15th of the month.
- Clarity Peer Group Program:
  - At the end of each month cumulative data (mean, sd & # data points) is extracted.
  - The data is entered into Clarity website.
  - Report is generated immediately.

Area Lab Manager or Designee Review of InterLab Reports

- Review the current month's mean to verify that it has not changed significantly from the cumulative mean. A significant shift may indicate a performance issue. Compare the current month's mean to the peer group mean.
- Review the SD. The standard deviation is related to the spread or distribution about the expected Mean. Whereas the mean is an indicator of central tendency and therefore related to accuracy or systematic error, the standard deviation is a measure of the width of the distribution and is related to imprecision or random error. The wider the standard deviation range is, the poorer the precision of the method and vice versa.
- Review the CV of all levels of control analyzed. The CVs should be within the same relative range each month. A CV of 5.0% or less is an acceptable level of variation indicating a well-functioning system.
- CV of the cumulative data is the best indication of the long-term performance of the analyzer.
- Review the SDI calculated for the month. An SDI between -2.0 and +2.0 indicates good correlation within the peer group. A negative sign indicates that your laboratory mean is below the peer group mean, a positive sign indicates that your laboratory mean is above the peer group mean.
- Individual instrument Mean should be between 2 SD of the peer group for best correlation.
- Peer group SD and CV may be higher than the individual instrument statistics because of the variations in instrument operating condition.
- The CVI (stago) and CVR (BioRad) is the relative CV of the individual instrument compared to the peer group CV. Value should be less than 1.0.
- QC periodic reports will be reviewed, signed and dated each month by Chemistry Area Laboratory Manager or designee.

QUALITY CONTROL STATEMENT-CHEMISTRY

New QC Lot

- Run the new controls 1-3 times per day for a minimum of 7 days to obtain 20 data points. If values meet criteria below, controls are ready for use.
  - For assayed controls, the results must fall within 2 SD of manufacturer's reported mean for each analyte tested.
  - For unassayed controls, the results must fall within 3 SD of the manufacturer's target mean.
  - For assayed coagulation controls, run QC to verify the acceptability ranges supplied by the manufacturer.

Reference

- Basic QC Practices, 3rd Edition, Westgard Rules and Multirules-Westgard QC,2010.
- Clarity Peer Group Program Guide for Stago Customers.09-2013.
- CAP Hematology and Coagulation Checklist, 08-21-17

Attachment

- Attachment A: Chemistry QC Action Log
- Attachment B: Clarity Peer Group Program Guide for Stago Customers

Authors

Ardavan Dabir, BS, MT, CLS
Mina Acosta, CLS, MT(ASCP)
Jay Raymund Castaneto, CLS, BSMT

QUALITY CONTROL STATEMENT-CHEMISTRY

Document History Page

Effective Date: 09/01/93

Change type: New, Major, Minor etc.	Changes Made to SOP – describe	Signature responsible person/date	Lab Manager reviewed/ date	Med. Director Reviewed/ Date	Date change implemented
Minor	New format.	A. Dabir 4-28-04	N. Muneno 5-4-2004	R.H. Doshi, MD 5-4-2004	5-4-2004
Minor	Additional review step	A. Dabir 4-28-04	N. Muneno 5-4-2004	R.H. Doshi, MD 5-4-2004	
Major	• Deleted instruments no longer in use. • Added new instruments. • Added Chemistry QC Action Log Attachment	M. Acosta 09-11-12	M. Muneno 9-12-12	S. Wirio, MD 9-12-12	9-12-12
Major	• Removed Stago-Compact and AccessII instruments. • Added Sta-R Evolution. • Added Clarity Peer Program Guide for Stago Customers Attachment • Added data submission to InterLab QC Program • Added Area Lab Manager or Designee Review section guidelines • Replaced Supervisor with Area Lab Manager designation	M. Acosta 09-29-14	J. Wolf 09-29-14	S. Wirio, MD 09-29-14	09-29-14
Minor	• Corrected list for testing frequency once per shift to include Coag assays. • Added Thrombin Time and Fetal Fibronectin to testing frequency schedule of when patient sample is tested as stated in respective assay procedure.		N/A	N/A	02-09-16

QUALITY CONTROL STATEMENT-CHEMISTRY

Major	• Changed LMS Westgard Rules Evaluation for Advanced Osmometer to utilize Remisol EQC and Sta-R Evolution #1 & 2 to use onboard QC program. • Removed running Thrombin Time QC on day of patient testing-assay discontinued	R.Castaneto 10-26-16	J. Wolf 10-28-16	S.Wirio M.D. 11/02/16	12-01-16
Major	• Added New QC Lot statement.	7/16/18	7.19.18	7/22/18	

QUALITY CONTROL STATEMENT-CHEMISTRY

Attachment

CHEMISTRY QC ACTION LOG

ALL ITEMS MUST BE COMPLETED

DATE:_____
TEST:_____

RESULT OBTAINED:_____
Hi or Low

WESTGARD RULE FAILURE:_____
INSTRUMENT:_____
CONTROL NAME:_____
CONTROL LOT#:_____
TECH INITIALS:_____

NOTE: Please paperclip QC print-outs to this form and once completed place into QC review bin.

CORRECTIVE ACTIONS:

_____ 1. Check for alarms on the instrument print-out or monitor.
_____ 2. Reanalyze fresh aliquot of the same control. If result is in range continue patient testing.
_____ 3. Repeat test using a freshly reconstituted (or thawed) vial of control. **REPEAT Results:**
_____ 4. Repeat the test using a a different control, e.g. Beckman Synchron. **Synchron Results:**
_____ 5. Repeat daily maintenance, checking for problems with the sample probe, sample valve, pinched tubing, dirty tubing, light source, contaminated reagents, outdated reagents, reagents preparation, etc.
_____ 6. Recalibrate and rerun the controls. **QC Run Results Post-CAL:**
_____ 7. Call instrument repair or manufacturer hot-line.
_____ 8. If unable to resolve the problem, patient specimens are run on in-control instrument or sent out to Sherman Way Regional Reference Laboratory.
_____ 9. All specimens run since the last acceptable QC need to be rechecked and verfified.

CORRECTIVE ACTION TAKEN: (Describe solution; mechnical, reagents, calibrator, control, etc.)

_____

_____

_____

_____

PATIENTS RESULTS REPORTED: YES / NO

Supervisor's Review:_____ Date:_____

SUPERVISOR'S COMMENT:_____

_____

_____

_____

Chemistry QC Action Log LCS 1231-A

QUALITY CONTROL STATEMENT-CHEMISTRY

Attachment B

Stago

CLARITY

Peer Group Program Guide for
Stago Customers

We Coag