**TITLE: Chemistry Quality Control**

**PRINCIPLE:**

The Chemistry department requires a comprehensive Quality Control program to ensure quality test results as well as meet guidelines and requirements assigned by various regulatory agencies. Quality Control serves to verify the accuracy and precision of reported test values by checking instrument performance, reagent performance and human performance. Quality control issues are detected by embedding select Westgard rules into quality control software such as Unity Bio-Rad Real-Time QC program. The Bio-Rad software creates Levy-Jennings charts that help the technologist visualize the quality control performance. The results of controls are verified for acceptability before reporting patient results and require appropriate action if results are unacceptable.

**Westgard rule definitions:**

**1-2S Rule:** One control value exceeds either +2 Standard Deviations (SD). This is considered a warning rule and requires additional inspection of the control data and monitoring. Approximately one in twenty control values will fall outside the +2 SD rules.

**1-3S Rule:** Control value exceeds + 3SDs. This should occur less than 3 times in 1000 determinations. This is a rejection error indicating the QC run has failed; this could be due to a random and/or systemic error.

**2-2S Rule:** Two consecutivecontrol values either exceed+2 SDs or both controls on the same day exceed either +2 SDs. This is a rejection error indicating the QC run has failed. Errors of this type are generally systematic in nature and they may be due to problems with standards, calibration, reagents or diluents.

**R-4S Rule:** This type of error occurs when the difference between two control values within the run exceeds 4SDs of each other in the opposite direction.

**12X Rule:** This rule looks for the presence of 12 consecutive control values on the same side of the mean, either as 12 values from a single level of control or 12 values over a five-day period from both levels. This error is warning and may be an indication of systematic error.

**2/3-2s:** This is a variation of the 2-2s rule and detects systematic errors. It is triggered when any 2 of 3 levels of QC exceed 2SD on the same side of the mean. This is a rejection error indicating the QC run has failed.

**EQUIPMENT**

Abbott Architect ci4100; SN: i1SR61063 and C402455

**CALIBRATION:**

Refer to the individual analyzer and test procedures.

**REAGENTS AND SUPPLY REQUIREMENTS:**

1. All reagents and quality control material must be labeled properly and contain the following information as applicable.
   1. Identity of reagent or quality control product
   2. Lot number
   3. Date when the control is thawed if applicable
   4. Date when the control is opened
   5. Preparation date and technologist initials (if prepared by the laboratory)
   6. Expiration date (update if dates changes when diluted, thawed or opened)
   7. Note: date must include Month/Date/Year
2. Reagents used for Quality Control procedures should be the same reagents used for patient testing
3. Quality Control testing is to be performed by the same personnel who performs testing on patient samples, using the same testing methods as used to report patient results.
4. Equipment used for quality control procedures must be maintained, cleaned, and calibrated according to manufacturer’s specifications.
5. The control material which most closely resembles the patient sample being tested is to be run for the indicated test.
6. Discard any control material that appears to be contaminated with bacteria or any other possible contaminant.
7. When reconstituting control material (if required) use only Class A volumetric glassware or automatic MLA pipettes.
8. Specific individual assay calibrators can also be used as a back-up to the existing Quality Control Program. A single calibrator or the set of calibrators for all ranges can be used as needed.
9. Manufacturer’s assayed controls can also be used as a back-up to QC for troubleshooting.
10. Previously run Proficiency survey specimens may be thawed and used as an alternative for QC troubleshooting as well. Expected results can be found in the completed PT binders.

**PROCEDURE:**

1. Quality Control must be included in all aspects of chemistry testing and is to be tested in the same manner as patient samples.
2. All control material should be treated as a bio-hazardous material and discarded properly.
3. The Architect control material is preprogrammed into the Abbott Architect analyzer. See 7180-CH-255 Abbott Architect ci4100 Operating Instructions for more information. To run QC select the correct barcoded tube, place a clean sample cup into the tube, add the stated amount of QC (located on the bar code label) into the cup and load on the analyzer. Once all the tests are completed, review the results to make sure there were not any aspiration errors or outliers. If the run is acceptable, press Select All and Release. This will transmit the results to the Unity Bio-Rad Real Time Unity QC program.
4. Follow manufacturer’s recommendations for control frequency; Chemistry QC must be run as follows:
   1. Once every 24 hours when patient testing is ordered
   2. After each calibration
   3. After major maintenance or part replacement
   4. When a new lot of reagent is put into use
   5. Every 8 hours for Na+, K+ and Chloride.
   6. Ketone QC is required when opening a new bottle of Ketone reagent tablets and every 24 hours when patient testing is performed.
5. For tests that report qualitative results based on a quantitative measurement using a threshold (cut-off) to discriminate between a positive and negative clinical interpretation, the pos and neg controls must have values appropriately near the cut-off value.
6. Test all new incoming lots of **QC** prior to putting them into use- See attached instructions for setting up lot correlations by “Running New Lot of QC with Barcodes”.
   1. During the QC lot change period for assayed controls, test the new lot of QC along with current lot. Compare the mean and SD to the manufacturer’s ranges and the Laboratory Comparison Evaluation in the Bio-Rad evaluation report.
   2. For Unassayed controls, the laboratory must establish a valid acceptable range by repetitive analysis in runs that include previously tested control material. For assayed controls, the laboratory must verify the acceptability ranges supplies by the manufacturer.
   3. Enter the new lot of QC into the Unity Bio-Rad Real-Time QC program by duplicating the new lot of QC under the lot tab. Select the new lot from the drop-down box when prompted.
7. Test all new incoming lots of reagents before use for patient testing. Mark with red dot on each new lot. Then compare quality control results as well as random patient samples to those obtained with prior reagent lots –see SOP 7180- CH-330 “Reagent Handling and Validation”. Once verified new lot place a green dot on reagent indicating ready for use.
8. Review and save all control data in the Bio-Rad Unity QC program (manual tests should be entered into TQC program- see SOP 7180-G-310 Total Quality Control in SOFT-TQC).
9. The results of controls are reviewed for acceptability before reporting patient results.

**Quality Control Products and Instructions for Use:**

**See Attachment for Control List Chart**

1. **Bio-Rad Multiqual Level 1 and Level 3 Unassayed Controls:**
2. Store the controls at -20 to -70 degrees C until they are ready to be thawed.
3. Allow the control to stand at room temperature (18-25ºC) for 1 hour or until completely thawed. A precipitate may be present that dissolves upon mixing.
4. Invert the vials 10-15 times before use.
5. Remove the cap/stopper and dispense the volume required for testing.
6. Replace the cap/stopper. Store at 2-8ºC.
7. Frozen control is stable until the expiration date on the box and the individual vials. NOTE: Direct Bilirubin, ALT, HDL, and ALP levels may gradually decrease during the product shelf life
8. Thawed and Unopened: When the control material is thawed and stored unopened at 2 to 8 ºC, all analytes will be stable for 30 days with the following exceptions: Direct Bilirubin will be stable for 11, Triglycerides, HDL, will be stable for 7 days. Total Bilirubin and Direct Bilirubin values may decrease, ALP activity may rise.

Thawed and Opened: Once the control material is thawed and opened, it will be stable for 7 days at 2 to 8 ºC or until the manufacture expiration date, whatever comes first.

1. **Bio-Rad Liquichek Cardiac Markers Plus Control LT levels 1 and 3:**
2. Store the controls at -20 to -70ºC until they are ready to be thawed.
3. Thaw the controls at room temperature prior to use.
4. Invert the vials 10-15 times then swirl contents until homogeneous before use.
5. Remove the cap/stopper and dispense the sample volume required for testing.
6. Replace the cap/stopper.
7. Frozen control is stable until the expiration date on the box and the individual vials.
8. Thawed and Opened: Once thawed, opened, and stored tightly capped at 2 to 8º C, will be stable for 5 days.

1. **Bio-Rad Liquichek Immunology Control Levels 1 and 3:**
2. Stable until the expiration date when stored unopened at -20 to -70 ºC
3. Thawed Unopened: When thawed and stored at 2 to 8 ºC, this product will be stable for 45 days

Thawed Opened: Once thawed, opened, and stored tightly capped at 2 to 8 ºC, this product will be stable for 30 days.

1. **Bio-Rad Liquichek Immunoassay Plus Control Levels 1, 2, and 3:**

1. Store the controls at -20º C until they are ready to be thawed.

2. Allow the control to stand at room temperature for 1 hour or until completely thawed.

3. Invert the vials 10-15 times before use.

4. Once thawed stored unopened at 2 to 8º C, the control is stable for 30 days- Note the date that the control was thawed on the label.

5. Thawed Opened: Once thawed, opened, and stored tightly capped at 2 to 8 ºC, this product will be stable for 14 days.

1. **Bio-Rad Spinal Fluid Control Levels 1 and 2**
2. No preparation is required.
3. Controls that are stored unopened at 2 to 8º C are stable until the expiration date on the box and the individual bottle labels.
4. Once opened, the control set is stable for 30 days or until the printed expiration date, whatever comes first.

1. **Bio-Rad Liquichek Ethanol/Ammonia Control Levels 1 and 3**
2. No preparation is required.
3. Controls that are stored unopened at 2 to 8º C are stable until the expiration date on the box and the individual bottle labels.
4. Once opened, the control set is stable for 20 days or until the printed expiration date, whatever comes first.
5. **Liquichek Urine Toxicology Control- Level S10 and S20 Low Opiate**
6. The control is stable until the expiration date when stored unopened at 2 to 8ºC .
7. Once opened, the control is stable for 30 days when stored tightly capped at

2 to 8ºC

J. **Alta Diagnostics, Inc. Urine Control - Positive** (Ketones)

1. No preparation is required.
2. Store at 2 to 8º C.
3. Stable until the expiration on the bottle.
4. **Abbott Architect THC 60 Control**
5. The control is stable until the expiration date when stored unopened at 2 to 8ºC
6. The control is stable at 2 to 8ºC until the expiration date printed on the individual bottle labels.

**RESULTS:**

1. If QC is flagged as out of control:
   * 1. **Do not run or report any patient tests until the issue is resolved.**
     2. Use available information to aide in troubleshooting such as reagent and calibration history, QC expiration, instrument maintenance records, review of CAP surveys and review of Levy-Jennings charts to look for QC shifts or trends.

3. To view the Levy-Jennings charts: open Bio-Rad Unity QC program and the QC product you are investigating, select the specific analyte then in the menu bar select LJ to view the graph.

4. Review all levels of QC to determine how the analyte QC has been trending over the entire AMR .

5. Previously graded CAP survey material may be used to assist in troubleshooting unresolved issues.

1. Once the QC issue is resolved, determine if a retrospective review of samples is required.
   * 1. If QC failure is due to quality control material only, no further follow up is required.
     2. If QC failure is solved by changing any system component used for patient testing, a retrospective review is required.
2. Retrospective review of samples involves looking back at results reported back to the last successful control run.
   * 1. Select and rerun up to a 10 random selection of patient specimens from the last time controls were acceptable.
     2. If the comparison of the random patient specimen results fall within the evaluation criteria for comparison of analytes, no corrections are required.
     3. If comparison of the random patient’s results fall outside the evaluation criteria notify Lead Tech or Manager.
     4. The Lead or Manager will consult with the Medical Director to determine if all reported results need to be rerun and corrected.
3. Document the cause for any out of control situations in the Bio-Rad Unity Real-Time QC program.

**QC REVIEW:**

**Daily Quality control Review in Bio-Rad Unity Software**

* 1. Daily quality control review is to be performed by the testing personnel.
  2. All Control results are to be reviewed immediately by the operator for trends, shifts, or values that exceed acceptable limits.
     1. Log into the Bio-Rad Unity software program.
     2. Under the review tab, select Bench Review. All QC pending review will be highlighted in green font.
     3. Select pending QC by the specific analyzer, then by QC product
     4. Review all data points: pay close attention to the outliers (QC failure will be highlighted in a red/pink color, warnings are highlighted in yellow).
     5. All QC failures must have an action comment attached. To attach a comment, right click in the action box and enter the appropriate action then select apply. Make sure failed QC is rejected and the QC which is acceptable is marked as reviewed.
     6. When QC has been deemed acceptable, select the review check box in the upper left corner of the screen and select save.
  3. Review Levy Jennings charts for shifts or trends.
     1. Levy-Jennings charts can be found in the Bio-Rad Unity software by selecting the QC product then select the specific analyte. Once selected in the menu bar select LJ to view the chart. You can change the date range to see all data entered for the lot number.
  4. Observe the effect of new reagent lots and instrument elements by running new lot validation testing.
  5. Be observant of delta failures, critical values and technical limits when running patients.
  6. An additional Supervisor Review in the Bio-Rad Unity QC program will be performed by the Lead Tech or designee at least monthly.

**Monthly Quality Control Review**

A. QC data will automatically be submitted to the Bio-Rad QC program on the 5th day of each month. This submission includes all accepted data from the previous month.

B. On Receipt of Peer Group Evaluation Reports

* + 1. Review data reports for outliers due to errors in data entry.
    2. Correct prospective control values; if erroneous data was submitted for evaluation, data can be re-evaluated based on the correct statistics.
    3. Compare means for each analyte to the mean of other laboratories using your method and the selected method. If significant bias is present, study and revise the procedure, or adjust the means to match the peer group.
    4. Compare the Standard Deviations (SD) to the average SD of peer laboratories, using your method and coefficient of variation (CV) compare values to the CV summary data for each analyte.
    5. Follow up on all evaluation reports that show evidence of bias, imprecision or potential instrument malfunctions.
    6. Previously run Proficiency Survey specimens, linearity or another manufacturer’s Quality Control may be used as a reference tool for troubleshooting QC exceptions and outliers.
    7. Sign and date the Bio-Rad Monthly Evaluation reports, addressing any QC issues found and follow up action performed.
    8. File the reports in the IQAP Arch Binder.
    9. QC reports and charts will be stored for two full years then discarded at the end of the two-year period.

**REFERENCES:**

1. Bio-Rad Control package inserts
2. Reagent kit and product package inserts
3. CLIA 88’ Regulations
4. CAP Checklist
5. Manufacturer’s Procedure Manuals
6. Unity Real Time

**MultiQual levels 1, 3 (MQUAL 1, 3) (ICTMQ1, 3 for ICT)**

Stable until expiration date stored unopened at –20 to –70 degrees C

Thawed and Unopened: 2 to 8 degrees C for **7 days**

Thawed and Opened: Tightly capped at 2 to 8 degrees C for **7 days**

1 hour thaw time at room temperature

**CRP/Immuno levels 1, 3 (IMMUNO 1, 3)**

Stable until expiration date stored unopened at –20 to –70 degrees C

Thawed and Unopened: 2 to 8 degrees C for **45 days**

Thawed and Opened: Tightly capped at 2 to 8 degrees C for **30 days**

Allow control to reach room temperature before sampling

**CSF Control Levels 1,2 (CSF 1, 2)**

Stable until expiration date when stored unopened at 2 to 8 degrees C

Opened: Tightly capped at 2 to 8 degrees C for **30 days**

Allow control to reach room temperature before sampling

**ETOH/Ammonia Levels 1,3 (ETOH/AMM 2, 3)**

Stable until expiration date when stored unopened at 2 to 8 degrees C

Opened: Tightly capped at 2 to 8 degrees C for **20 days**

Allow control to reach room temperature before sampling

**Immunoassay Plus Levels 1, 2, 3 (IA PLUS 1, 2, 3)**

Stable until expiration date when stored unopened at -20 to -70 degrees C

Thawed Unopened: 2 to 8°C, this product will be stable for **30 days**

Thawed and Opened: Tightly capped at 2 to 8°C for **14 days**

**Cardiac Markers Plus Levels 1, 3 (CARD 1, 3)**

Stable until expiration date when stored unopened at -20 to -70°C

Thawed and Opened: 2 to 8°C, this product will be stable for **5 days**

**Urine Toxicology S10, S20 Low Opiate (DOA S10, S20)**

Stable until expiration date when stored unopened at 2 to 8°C

Opened: 2 to 8°C, this product will be stable for **30 days**

**Abbott Architect THC 60 Control (THC 60)**

The control is stable until the expiration date when stored unopened at 2 to 8ºC

Opened: The control is stable at 2 to 8 ºC until the **expiration date** printed on the individual

bottle labels.