CHEMISTRY CONTROLS

POLICY The following controls are currently in use in the MOB Chemistry Department:

1) BioRad Unassayed Chemistry Control, Levels 1 and 2

Stable for 6 days at 2 to 8 degrees after thawing.

Alkaline Phosphatase
ALT
AST
Direct Bilirubin
Total Bilirubin
Calcium
Chloride
CO2
Creatinine
Glucose
Lactic Acid
Lipase
Potassium
Sodium
BUN

2) BioRad Cardiac Markers Plus LT, Levels 1 and 3

Stable for 5 days at 2 to 10 degrees after opening.

High Sensitivity Troponin
BNP

3) BioRad Immunoassay Plus TDM Control Serum, Levels 1 and 3

Once the control material is thawed and opened, stable for 14 days at 2 to 8 degrees.

HCG

4) BioRad Liquichek Pediatric Control, Levels 1 and 2

Stability: Thawed and Unopened: When the control material is thawed and stored unopened at 2 to 8 degrees, all analytes will be stable for 3 months, but should not be used past the expiration date.
Stability: Thawed and Opened: Once the control material is thawed and opened, all analytes will be stable for 14 days when stored at 2 to 8 degrees.

Total Bilirubin
Direct Bilirubin

CHEMISTRY CONTROLS, Continued

POLICY

GENERAL CHEMISTRY QUALITY CONTROL

Run two levels of controls or standards after calibration, a change of reagents and with each run of chemistries. Each run of chemistries is defined as:

DXC 600/MC: every 8 hours/once each shift,
DXC 600 CC: every 24 hours/AM shift
Access 2: every 24 hours
Unistat Bilirubinometer: each day of use
iSTAT: each day of use

DXC 600 and Access 2 controls will be recorded automatically on the DXC 600 and Access 2 computer files as well as instrument printouts.

iSTAT and Unistat Bilirubinometer controls will be recorded on corresponding logs when used.

a. Daily QC printouts will be kept in a designated binder in the chemistry department for one month.
b. CLS who performs QC will check off the QC Audit Log attesting that they have reviewed and accepted the QC run. Any QC corrective action that has to be made will be documented on the QC Quality Control Action Log.
c. Each shift must review and initial the current QC printouts in the binder to ensure that the QC was run as expected according to the schedule for that particular instrument and that no QC failures were overlooked and not acted upon.
d. If it is determined that a QC failure occurred, it must be corrected before patient testing can resume on the affected analyzer.
e. QC ranges are indicated on the instrument printouts. All Chemistry QC records will be stored by month and retained for 3 years.
f. QC plotting charts from the DXC 600 and Access will be printed monthly, reviewed by a supervisor and stored in the department.

Use the following rules to determine if your control is “OUT”.

1. One value outside 3 SD.
2. Two values between 2 SD and 3 SD (either both levels or consecutive values)
3. Four consecutive values on one side of the mean further than 1 SD from the mean with at least one value outside 2SD.
4. Ten consecutive values on one side of the mean with at least one value outside 2SD.

- If any of the above conditions exist; the controls should be rerun or corrective action taken to correct the problem. Record action taken on the action logs. Significant shifts and trends should be addressed through recalibration or other corrective action as necessary to resolve the issue.

- A QC failure that is the result of **both** levels of QC producing values that are greater than 3 SD and is not corrected by running new QC material, may require a retrospective review of patient results since the last known acceptable QC event. Most likely causes for this type of QC failure are reagent degradation and/or instrument malfunction. The technical supervisor will review the issue and determine if retrospective review of results is indicated based on clinical significance and the affected analyte.

- If the problem is not corrected, DO NOT REPORT PATIENT RESULTS. Use alternate analyzer, if available.

- Each shift is responsible to review the QC that has been run so far that day. The day shift will review the ISE controls that the PM shift performs on the DxC. The PM shift will review the Access controls as well as the ISE controls run by the day shift. Each shift will sign off on the QC sheets that the results have been reviewed and are acceptable.

- The Clinical Laboratory Scientist assigned to the department is responsible for reviewing and documenting review of instrument QC charts for shifts and trends following assigned control runs.

POLICY **ENZYME CHEMISTRY QUALITY CONTROL**

Run two levels of controls daily and after a change of reagents.

- Control results will automatically be recorded on the DXC 600 logs.

- Enzymes are verified, not calibrated since reference standards are not available. Thus, control values may shift when a new lot number of reagents or reagent packs is used. These shifts must remain within the acceptable range of the control in order to maintain an insignificant clinical effect upon patient values.

The following QC rules will be applied to enzymes to determine if controls are out of control.

1. One value outside 3 SD
2. Two values between 2 SD and 3 SD (either both levels or consecutive values)

- If any of the above conditions exist; the controls should be rerun or corrective action taken to correct the problem. Record action taken on the action log.

- If the problem is not corrected, DO NOT REPORT PATIENT RESULTS. Perform testing on alternate analyzer if available.

POLICY **BIO-RAD QUALITY CONTROL**

Quality control results for the DxC600 and Access 2 are submitted monthly via the internet to BioRad for evaluation and comparison with other DxC600 and Access2 analyzers. The name of the program is Unity interlab (IQAP).

Follow the steps below to enter in control values for levels 1 and 3 BioRad Unassayed Chemistry Controls, levels 1 and 3 Biorad Cardiac Markers LT plus, levels 1 and 3 Biorad Immunoassay Plus and levels 1 and 2 Biorad Liquicheck Pediatric Controls for all runs falling within the laboratory's Westgard Rules. Out of control results are not to be entered into Unity web. Document the result on daily QC log and follow protocol.

Step	Action
1.	Using internet Explorer, find website www.QCnet.com.
2.	Log in using MOB login and password.
3.	Click on tabs Unity Interlab, Unity web 2.0
4.	Select data entry, "multi test point data entry"
5.	Enter values for 2 levels for each analyte.
6.	Click on Evaluate SPC rules tab.
7.	Click Save.
8.	After data is entered for the entire month, review the data for errors/omissions. There should be at least one entry for each day of operation. Go to Tools –Unity Interlab-Send Data to Biorad.

- On a monthly basis, Bio-Rad Unity quality control reports are submitted, printed and reviewed by the Lab Manager. Review of QC is documented on the cumulative QC report. Issues identified are noted. Corrective action is taken as needed and documented.
- This review includes inspection for trends and small shifts that indicate systematic errors or potential accuracy problems. Monthly standard deviations and CV's are examined for changes in random errors or precision. Corrective action is implemented and documented as needed.

REVIEWING CAP PROFICIENCY TESTING – ADDITIONAL INFORMATION REGARDING EVALUATION OF BIAS

1. An acceptable level of bias is inherent in the chemistry analyzers in use in the laboratory. Bias will be investigated if the following condition is met:
    a. 10 consecutive survey results for an analyte falling on one side of the mean with all values exceeding 1.0 SDI and at least one value exceeding 2.0 SDI.

CHEMISTRY CONTROLS, Continued

Document History Page

Change type: New, Major, Minor etc.	Changes Made to SOP – describe	Name of responsible person/date	Med. Dir. Reviewed/ Date	Director of Lab Ops. reviewed/ date	Date change Implemented
Major	Change open date stability of Biorad Cardiac Markers Level 1 and 2 from 10 days to 8 days.	Sam Ibe 03/31/2015			
Minor	Added Ca,AST and D. Bilirubin in Biorad Unassayed Chemistry Controls, level 1 and level 2	Sam Ibe 03/11/2016			
Minor	Added D.Bilirubin in Biorad Liquicheck Pediatric Controls Level 1 and Level 2	Sam Ibe 03/11/2016			
Minor	1.Regional Template Update 2. Consolidated Chemistry controls, out of control MOB QC and QAP policies. 3. Updated index number 4. Updated Cardiac Markers Control for HS Troponin	Yvette Lingat 4/19//2021		Mary Lou Beaumont	