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| **DOCUMENT NOTES:** | |

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| **DOC TYPE:** RIV PPP | **STATUS:** Draft |

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| **RELEASE DATE:** | **EXPIRATION DATE:** |

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| **AUTHOR:** | **PREVIOUS NUMBER:** LCHS-5000 |
| **OWNER:** RIV Chemistry Mgr | **CHANGE NUMBER:** RIV-CR-0584 |

# GENERAL POLICY STATEMENTS

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| **Lot Numbers** | Lot numbers of controls, reagents, and calibrators currently in use must be recorded or filed on Bio-Rad Unity RealTime®, reagent log, or reagent/calibrator status log in chemistry. |
| **Quality Control Graphs – Levy - Jennings** | Quality control must be performed, recorded and reviewed on Bio-Rad Unity RealTime® quality control graphs or on the Beckman DXC800 and Access2 computer QC files on all performed procedures per manufacturers or regulatory requirements. Each procedure outlines the number of controls, and when they need to be run. |
| **Preventive Maintenance** | Preventive maintenance must be performed on all instruments in the laboratory, per manufacturer recommendations. This could be daily, weekly, monthly, etc., and is outlined in the maintenance log book. |
| **Critical Values** | See Critical Values in Lab Net |
| **Reagents/QC/ Calibrators** | All reagents must be dated when opened or reconstituted and initialed. A new expiration date must be recorded if opening the container changes the expiration date, storage requirement, etc. Store all reagents per manufacturers' recommendations.<br>No mixing of reagent lot # for DXC reagents with kits. |
| **Reference Range** | See reference range per test in Lab Net |

## GENERAL POLICY STATEMENTS, *Continued*

**Criteria for Unsatisfactory Specimens**

Unsatisfactory specimens will not be processed and will be recollected. The following conditions constitute un-acceptability and must be documented in the CERNER system as not being acceptable along with date, time, and nurse/physician notified.

A. Unlabeled specimen

B. Incorrectly labeled - name on specimen container different than name on requisition or not according to Blood Bank policy and procedure.

C. Incorrectly collected - wrong preservative or anticoagulant, no preservative.

D. Incorrectly submitted - not on ice, too old.

E. Incorrectly stored - not refrigerated, not frozen.

F. Lipemic - If slight, specimen may be processed. Consult with Supervisor. If run, report must indicate nature of specimen.

G. Icteric - If slight, specimen may be processed. Consult with Supervisor. If run, report must indicate nature of specimen.

H. Hemolyzed - If slight, specimen may be processed. If run, report must indicate nature of specimen as being slightly hemolyzed.

I. Clotted - When whole blood is required, body fluid when cell count required.

J. Insufficient quantity - Short specimen, e.g.: PTT or Protime, not enough serum, whole blood, urine, etc., to provide reliable results.

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## GENERAL POLICY STATEMENTS, *Continued*

**Quality Control**

A. To obtain data for statistical treatment and to establish limits of acceptability for all control material whether assayed or unassayed.

1. 10-20 analysis are performed or as many necessary to obtain a stable cumulative mean.
2. Calculate the **mean**.
3. Calculate the 3 **standard deviation**.
4. Calculate the **acceptable limits** at (2) standard deviation.

B. Acceptable Quality Control:

When 1 out of 2 controls is outside 2 S.D., but within 3 S.D., the run is acceptable. This is used as a flag to monitor a possible trend or shift that may be starting with that level of control. Random error without a real pattern could be the cause of a result between 2 S.D. and 3 S.D. a one-time event. A pattern of continuous error is systematic and could affect all results, resulting in a shift or trend. Systematic errors should be investigated to identify their causes.

C. Definition of Out-of-Control:

1. **"Acceptable limit of error"** - the permissible range by which the obtained results may vary from the specified result. Repeated analysis of the control or an unknown specimen should give results within this limit.
2. **"Out-of-control"** - if a result outside of these limits is obtained.

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## GENERAL POLICY STATEMENTS, *Continued*

**Quality Control, Cont...**

D. Identification of Shift or Trends:

1. Trends: A gradual change in quality control that can be recognized by the values for the reference control that continues in one direction. Trends may occur as the result of the deterioration of one or more of the reagents, controls, protein degradation, poor sampling techniques, equipment malfunction and deterioration.

2. Shift: An abrupt change in the mean that becomes continuous on one side of the mean value, maintaining a constant level. The usual causes are change in lot number of reagents, calibrators or controls. Instrument maintenance and malfunction can also be a cause as well.

E. Interpreting Results and Course of Action:

1. See protocol included with each procedure as well as the manufacturer's technical manuals.

2. If values are outside the acceptable range, the data must be carefully evaluated before any results are reported.

   If the source of error cannot be found, a new control(s) along with secondary controls and/or previously tested patients are tested.

   If the control(s) and previously tested patient results gives an appropriate value, the values are reported. If not, the data is held back and the reagents and procedure steps checked one by one until the cause of the error is determined.

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# GENERAL POLICY STATEMENTS, *Continued*

**Quality Control, Cont..**

F. Controls:

1. **Bio-Rad Liquichek Unassayed Chemistry Control**
   Level I and Level II. Ready to use. Store unopened at -20 to -70°C. Once the material is thawed and opened; material is to be used within 6 days. Stored between 2-8°C after opening.

   **TESTING FREQUENCY: 1X EVERY 24 HRS AND AFTER CALIBRATION**

2. **Bio-Rad Liquichek Ethanol/Ammonia Control** Levels I & III. Assayed, liquid ready to use. Once the material opened, analytes will be stable for 20 days when stored tightly capped at 2 to 8 °C.

   **TESTING FREQUENCY: 1X EVERY 24 HRS AND AFTER CALIBRATION**

3. **Bio-Rad Liquichek Spinal Fluid Control** Levels I & II.
   Liquid, assayed ready to use. Once opened, analytes will be stable for 14 days when stored capped at 2 to 8 °C.

   **TESTING FREQUENCY: 1X EVERY 24 HRS AND AFTER CALIBRATION**

4. **Bio-Rad Liquichek Immunoassay Plus Control** Level I and III.
   Liquid assayed ready to use. Once opened, analytes will be stable for 14 days when stored capped at 2 to 8 °C.

   **TESTING FREQUENCY: 1X EVERY 24 HRS AND AFTER CALIBRATION**

5. **Bio-Rad Liquichek Bilirubin Pediatric Control** Level II.
   Liquid ready to use. Store unopened at -20 to -70 °C. Once the material is thawed and opened; all analytes will be stable for 14 days when stored tightly capped at 2 to 8 °C. Do not refreeze the control.

   **TESTING FREQUENCY: 1X EVERY 24 HRS AND AFTER CALIBRATION**

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# GENERAL POLICY STATEMENTS, *Continued*

6. **Bio-Rad Liquichek Cardiac Marker Plus LT Controls**
   Level 1B and 3. Store unopened at -20 to -70. °C. Thaw to room temperature 30 min prior to use. Once the material is thawed and opened; analytes will be stable for 5 days when stored tightly capped at 2 to 8 °C.

   **TESTING FREQUENCY: 1X EVERY 24 HRS AND AFTER CALIBRATION**

7. **Bio-Rad Liquichek Urine Chemistry Control** Level I and II.
   Liquid, ready to use. Once opened, analytes are stable for 30 days when stored at 2 to 8 °C.

   **TESTING FREQUENCY: 1X EVERY 24 HRS AND AFTER CALIBRATION**

8. **Bio-Rad Specialty Immunoassay** Level I and III.
   Liquid, ready to use. Store unopened bottles at -20 to -70°C. Once opened, analytes are stable for 7 days when stored at 2 to 8 °C.

   **TESTING FREQUENCY: 1X EVERY 24 HRS AND AFTER CALIBRATION**

9. **Bio-Rad Specialty Immunoassay Plus** Level I and III.
   Liquid, ready to use. Store unopened bottles at -20 to -70 °C. Once opened, analytes are stable for 14 days when stored at 2 to 8 °C.

   **TESTING FREQUENCY: 1X EVERY 24 HRS AND AFTER CALIBRATION**

10. **Toxicology Urine Control:** MEDTOX Scan High 2X Positive and Medtox Negative. Stored unopened bottle at 8° to -20°C. Once opened, analytes are stable for 30 days when stored at 2 to 8 °C.

    **TESTING FREQUENCY: 1X EVERY 24 HRS AND AFTER CALIBRATION**

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# GENERAL POLICY STATEMENTS, *Continued*

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| | 11. **Fentanyl Urine:** Calibrator 1 and Calibrator 3.<br>Stored unopened bottle at 2° to 8°C. Once opened, analytes are stable for labeled expiration date.<br><br>**TESTING FREQUENCY: 1X EVERY 24 HRS AND AFTER CALIBRATION** |

**Precision Testing**

Linearity will be performed as necessary on the chemistry analyzers to show instrument precision and accuracy or to check reagent integrity on new lot numbers of chemistry reagents.

**Evaluation of Measuring Equipment**

Pipettors must be calibrated and recorded annually or whenever a part has been changed.

**Proficiency Testing**

Our Laboratory subscribes to the College of American Pathologists (CAP) proficiency testing service. As a result, we receive 3 kits annually for analysis in Chemistry. These reports are reported to the State Department of Health and HCFA to meet CLIA regulations. This is rotated among all the staff.

We also perform CAP Quality Cross Check testing in chemistry and therapeutic drugs. All proficiency testing is rotated within the staff of CLS to ensure all staff, regardless of shift and employment status perform such testing.

**Comparison Studies**

Comparison studies are done bi-annually. See General Lab Policy for allowable total error.

**Cal/Ver**

Calibration Verification performed to verify Analytical Measurement Range (AMR) semi-annual. See General Lab Policy for details.

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## GENERAL POLICY STATEMENTS, *Continued*

**TDM** Therapeutic Drug Monitoring – Refer to Labnet for specimen collection. Criteria.

**References**

Clinical Chemistry Concepts and Applications, S. Anderson and S. Cockayne; Saunders, 1993.

Liquichek Unassayed Chemistry Control Product insert, Bio-Rad Laboratories Diagnostics Group, October 2025.

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MedTox Toxicology Urine controls package Insert, MedTox Diagnostic, INC April 2014

Immunalysis Fentanyl Urine Calibrator/Control Product Insert. Immunalysis corporation, Sept 2021

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SCPMG Murrieta Medical Office Laboratory

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## GENERAL POLICY STATEMENTS, *Continued*

Reviewed and approved by:

| SIGNATURE | DATE |
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| | |
| **Annaleah L. Raymond, MHA, CLS**<br>**Director, Clinical Laboratory – Riverside Medical Center** | |
| | |
| **Mark Taira, M.D.**<br>**Medical Director, Clinical Laboratory – Riverside Medical Center** | |

# GENERAL POLICY STATEMENTS, *Continued*

## HISTORY PAGE

Effective Date: 12/17/13

| Change type: New, major, minor | Changes made to SOP - describe | Signature responsible person/date | Medical Director review/date | Laboratory Director review/date | Date change implemented |
|---|---|---|---|---|---|
| New | | B. Salas 11/07/13 | D. Quach 12/16/13 | D. Topliff 11/07/13 | 12/17/13 |
| Minor | New Directorship | B. Salas 02/24/14 | M. Taira 02/24/14 | D. Topliff 03/14/14 | 03/14/14 |
| Minor | New Directorship, removed Stago and coagulation information, updated BioRad Controls, and updated References | N. Corpuz | M. Taira | A. Raymond | |
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