



KAISER PERMANENTE®

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QUALITY CONTROL POLICIES

Purpose To provide a general summary of the quality control process in the Chemistry Department.

Policy

- A. All control samples are tested in the same manner as patient specimens.
- B. Perform and document control procedures using at minimum two (2) levels of controls at least daily or at defined intervals of patient testing.
- C. It is the responsibility of the CLS or MLT assigned in the department to ensure that quality controls are run and meet the acceptable criteria prior to releasing patient results.

Reagents **Bio-Rad Unassayed Chemistry Control**

Bio-Rad Liquichek Unassayed Chemistry Controls are designed for use in monitoring the reliability of the overall system performance in the clinical laboratory. The use of controls at the lower and higher ranges of the linearity of the analyzers allow the laboratory to monitor changes in calibration and linearity along with analytical error and imprecision. The controls are unassayed, liquid ready to use. The raw materials used in these products are from human serum to which purified biochemical material (tissue extracts of human and animal origin), chemicals, drugs, preservatives and stabilizers have been added. The product is human, and has been tested for HBsAg, HIV, and HCV to ensure the material is not infective.

| Bio-Rad Unassayed Chemistry Control | | |
|--|---------------|--------------------|
| Albumin | CO2 | Phenytoin |
| ALP | Carbamazepine | Phosphorous |
| ALT | Digoxin | Potassium |
| AST | Glucose | Salicylate |
| Acetaminophen | Gentamycin | Sodium |
| Total Bilirubin | Lactic Acid | Theophylline |
| Direct Bilirubin | LDH | Total Protein |
| BUN | Lipase | Uric Acid |
| Calcium | Lithium | Vancomycin |
| Chloride | Magnesium | Valproic Acid |
| Creatinine | Phenobarbital | Osmolality - Serum |
| Ionized Calcium | | |

QUALITY CONTROL POLICIES

Reagents,
Cont..

Bio-Rad Liquichek Urine Chemistry Control

Bio-Rad Liquichek Urine Chemistry Control is intended for use as an assayed quality control urine to monitor the precision of laboratory testing procedures. This product is prepared from human urine with added constituents of human and animal origin, pure chemicals, preservatives and stabilizers. The control is provided in liquid form for convenience.

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| Bio-Rad Liquichek Urine Chemistry Control |
| Creatinine, Urine |
| Chloride, Urine |
| Total Protein, Urine |
| Potassium, Urine |
| Sodium, Urine |
| Osmolality, Urine |

Bio-Rad Liquichek Cardiac Markers Plus Control LT

Bio-Rad Liquichek Cardiac Markers Plus Control is prepared from human serum with added constituents of human and animal origin, stabilizers and preservatives. This product is provided in liquid form for convenience.

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| Bio-Rad Liquichek Cardiac Markers Plus Control LT |
| hCRP |
| Troponin |
| BNP |

Bio-Rad Liquichek Ethanol/Ammonia Control

Bio-Rad Ethanol/Ammonia Control is prepared from bovine serum albumin with pure chemicals, stabilizers and preservatives added. The control is provided in liquid form for convenience.

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| Bio-Rad Liquichek Ethanol/Ammonia Control |
| Alcohol |
| Ammonia |

QUALITY CONTROL POLICIES

**Reagents,
Cont..**

Bio-Rad Liquichek Immunoassay Plus Control

Bio-Rad Liquichek Immunoassay Plus Control is prepared from human serum with added chemicals, constituents of human and animal origin, therapeutic drug, stabilizers and preservatives. The control is provided in liquid form for convenience.

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| Bio-Rad Liquichek Immunoassay Plus Control |
| HCG |
| Ferritin |

Bio-Rad Liquichek Spinal Fluid Control

Bio-Rad Liquichek Spinal Fluid Control is a human based control with added constituents of human origin and pure chemicals. The control is provided in liquid form for convenience. The control contains 0.1% Sodium azide as a preservative. The control is used to monitor the reliability of the overall system performance of the laboratory.

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| Bio-Rad Liquichek Spinal Fluid Control |
| Glucose, CSF |
| Lactic Acid, CSF |
| Total Protein - CSF |

Bio-Rad Liquichek Pediatric Control

Bio-Rad Liquichek Pediatric Control is prepared from bovine serum with added pure chemicals, therapeutic drugs, preservatives and stabilizers. The control is provided in liquid form for convenience. The control is used to monitor the reliability of the overall system performance of the laboratory.

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| Bio-Rad Liquichek Pediatric Control |
| Direct Bilirubin |
| Total Bilirubin |

QUALITY CONTROL POLICIES

Reagents,
Cont..

Bio-Rad Liquichek Specialty Immunoassay

Bio-Rad Liquichek Specialty Immunoassay Control is prepared from defibrinated human plasma with added chemicals, constituents of human origin, therapeutic drug, stabilizers and preservatives. The control is provided in liquid form for convenience.

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| Bio-Rad Liquichek Specialty Immunoassay Control |
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| iPTH |
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MEDTOX Toxicology Urine Control

The MEDTOX product line of controls is manufactured using a human based matrix that has been stabilized to ensure that the product will be viable until the date of expiration. Positive controls are spiked with reference drug standards and/or appropriate metabolites that have been obtained from ISO certified manufacturers. Standards are certified by the manufacturers to be at least 98% minimum purity. Specific gravity, pH, and creatinine fall within the limits of normal human urine.

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| MEDTOX Toxicology Urine Control, Positive and Negative |
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| MEDTOX Urine Drugs of Abuse Test Kit (AMP, mAMP, BAR, BZO, COC, OPI, PCP, THC, and TCA) |
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Mission Control

Mission Control is a buffered solution of electrolytes (Na^+ , K^+ , Cl^- , Ca^{++} , Li^+ , HCO_2^- , $/\text{CO}_3\text{-}2$). It has been equilibrated with specific levels of CO_2 , O_2 and N_2 . This control contains no human-based material.

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| Mission Control |
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|-----------------|
| Ionized Calcium |
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Fentanyl Urine Calibrator 1 &3

Fentanyl Urine Calibrator 1 and 3 is used as Negative and Positive control respectively. Fentanyl Urine enzyme Immunoassay is used for the determination of Fentanyl in urine on automated clinical chemistry analyzer. Each vial contains synthetic urine with calibrated amount of fentanyl with stabilizer and sodium azide as a preservative.

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| Fentanyl Urine Calibrator 1 &3 |
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| Fentanyl |
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QUALITY CONTROL POLICIES

Reagents, Cont..

SYNCHRON® Multilevel Control

Synchron Multilevel Control is a comprehensive Chemistry Control serum is human based serum designed for Synchron systems. Level 1, 2, and 3 are manufacture assayed QC used for troubleshooting.

| SYNCHRON® MultiLevel Comprehensive Chemistry Control | | |
|---|---------------|-----------------|
| Albumin | CO2 | Phenytoin |
| ALP | Carbamazepine | Phosphorous |
| ALT | Digoxin | Potassium |
| AST | Glucose | Salicylate |
| Acetaminophen | Gentamycin | Sodium |
| Total Bilirubin | LDH | Theophylline |
| BUN | Lipase | Total Protein |
| Calcium | Lithium | Uric Acid |
| Chloride | Magnesium | Vancomycin |
| Creatinine | Phenobarbital | Creatine Kinase |

Storage and Stability

Unassayed Chemistry Control

Bio-Rad Liquichek Unassayed Chemistry Control will be stable until the expiration date when stored unopened at -20°C to -70°C. For optimum performance, avoid storage in a frost-free freezer. Once the control is thawed, all analytes will be stable for 15 days when sorted tightly capped at 2-8°C; do not refreeze the control. Bilirubin is stable for 6 days only.

Urine Chemistry Control

Bio-Rad Liquichek Urine Control will be stable until the expiration date when stored unopened at 2-8°C. Once the control is opened, all analytes will be stable for 30 days when stored tightly capped at 2-8°C.

Ethanol/Ammonia Control

Bio-Rad Liquichek Ethanol/Ammonia Control will be stable until the expiration date when stored unopened at 2-8°C. Once opened, the control will be stable for 20 days when stored tightly capped at 2-8°C

Spinal Fluid Control

Bio-Rad Liquichek Spinal Fluid Control will be stable until the expiration date when stored unopened at 2-8°C. Once the control is opened, all analytes will be stable for 30 days when stored tightly capped at 2-8°C.

QUALITY CONTROL POLICIES

Storage and Stability Cont..

Pediatric Control

Bio-Rad Liquichek Pediatric Control will be stable until the expiration date when stored unopened at -20°C to -70°C. The control may be stored unopened at 2-8°C for 6 months, but should not be used past the expiration date (note when storage of 2-8°C begins). Once the control is opened, all analytes will be stable for 14 days when stored tightly capped at 2-8°C. Once thawed, do not refreeze the control.

Cardiac Markers Plus Control LT

Bio-Rad Liquichek Cardiac Marker Plus Control LT will be stable until the expiration date when stored unopened at -20 to -70°C. Once the control is thawed and opened, all analytes will be stable for 5 days at 2-8°C. Once thawed, do not refreeze control.

Immunoassay Plus Control

Bio-Rad Liquichek Cardiac Marker Plus Control LT will be stable until the expiration date when stored unopened at -20 to -70°C. Once thawed and stored unopened at 2-8°C, this liquid product will be stable for 30 days.

Specialty Immunoassay Control

Bio-Rad Liquichek Specialty Immunoassay Control will be stable until the expiration date when stored unopened at -20 to -70°C. Once thawed, opened, and stored tightly capped at 2-8°C, product is stable for 7 days.

MEDTOX Toxicology Urine Control

Protect product from exposure to direct sunlight. The controls are stable until the expiration date when stored unopened at -10 to -20°C and protected from light. Once opened, controls are stable for six months or until the expiration date, whichever comes first, when stored at -10 to -20°C. Once opened, controls are stable for 31 days or until the expiration date, whichever comes first, when stored tightly capped at 2-8°C.

Mission Control

Mission control should be stored at 18-25°C.

Do not freeze. Once opened, ampules are stable for 7 days when stored capped tightly at room temperature.

QUALITY CONTROL POLICIES

Storage and Stability Cont..

Fentanyl Urine Calibrator 1 &3

Calibrator is provided ready to use and may be used directly from refrigerator. Bottle should remain closed when not in use with screw caps tightly closed. Store refrigerated at 2-8°C. When stored and handled as directed, the unopened bottle is stable until expiration date listed on the label. The opened bottles are stable for 60 days or the printed expiration date, whichever comes first. Do not use bottle beyond their expiration dates.

SYNCHRON® Multilevel Control

Synchron control will be stable until the expiration date when stored unopened at -15 to -20°C. Product is used at room temperature then promptly returned to freezer when done.

Reagent Handling

Unassayed Chemistry Control

1. Bio-Rad Liquicheck Unassayed Chemistry Control should be treated the same as patient specimens and run in accordance with the analyzer instructions for running patient samples.
2. Before sampling, allow the control to thaw completely at room temperature for 15 to 20 minutes. Once thawed, gently invert the vial 4-5 times to ensure homogeneity and use immediately. Do not use a mechanical mixer!
3. Promptly replace the stopper and return to 2-8°C after each use.

Urine Chemistry Control

1. Bio-Rad Liquicheck Urine Chemistry Control should be treated the same as patient specimens and run in accordance with the analyzer instructions for running patient samples.
2. Before sampling, allow the control to reach room temperature and swirl gently to ensure homogeneity.
3. Promptly replace the stopper and return to 2-8°C after each use.

QUALITY CONTROL POLICIES

Reagent Handling Cont..

Ethanol/Ammonia Control

1. Bio-Rad Liquichek Ethanol/Ammonia Control should be treated the same as patient specimens and run in accordance with the analyzer instructions for running patient samples.
2. Before sampling, allow the control to reach room temperature and swirl gently to ensure homogeneity.
3. Promptly replace the stopper and return to 2-8°C after each use.

Spinal Fluid Control

1. Bio-Rad Liquichek Spinal Fluid Chemistry Control should be treated the same as patient specimens and run in accordance with the analyzer instructions for running patient samples.
2. Before sampling, allow the control to reach room temperature and swirl gently to ensure homogeneity.
3. Promptly replace the stopper and return to 2-8°C after each use.

Pediatric Control

1. Bio-Rad Pediatric Control should be treated the same as patient specimens and run in accordance with the analyzer instructions for running patient samples.
2. Allow the frozen product to thaw at room temperature 18-25°C prior to use. Before sampling, swirl gently to ensure homogeneity.
3. Promptly replace the stopper and return to 2-8°C after each use.

Cardiac Markers Plus Control LT

1. Bio-Rad Liquichek Cardiac Marker Plus Control LT should be treated the same as patient specimens and run in accordance with the analyzer instructions for running patient samples.
2. Allow the frozen product to thaw at room temperature 18-25°C for approximately 30 minutes or until completely thawed prior to use.
3. Once thawed gently swirl to ensure homogeneity prior to use.

QUALITY CONTROL POLICIES

Reagent Handling Cont..

4. Promptly replace the stopper and return to 2-8°C after each use.

Immunoassay Plus Control

1. Bio-Rad Liquichek Immunoassay Plus Control should be treated the same as patient specimens and run in accordance with the analyzer instructions for running patient samples.
2. If the product has been stored frozen, allow it to stand at room temperature 18-25° until it is completely thawed.
3. Before sampling, allow the control to reach room temperature and swirl gently to ensure homogeneity.
4. Promptly replace the stopper and return to 2-8°C after each use.

Specialty Immunoassay Control

1. Bio-Rad Liquichek Immunoassay Plus Control should be treated the same as patient specimens and run in accordance with the analyzer instructions for running patient samples.
2. If the product has been stored frozen, allow it to stand at room temperature 18-25° until it is completely thawed.
3. Before sampling, allow the control to reach room temperature and swirl gently to ensure homogeneity with no visible signs of precipitate. Any precipitate present after thawing should dissolve upon mixing.
4. Promptly replace the stopper and return to 2-8°C after each use.

MEDTOX Toxicology Urine Control

1. The controls should be treated the same as patient specimens and run in accordance with the analyzer instructions for running patient samples.
2. If the product has been stored frozen, allot it to stand at room temperature 18-25° until it is completely thawed.

QUALITY CONTROL POLICIES

Reagent Handling Cont..

3. Before sampling, allow the controls to reach room temperature followed by gentle swirling or inversion before use. DO NOT SHAKE.
4. Promptly replace the stopper and return to 2-8°C after each use.

Mission Control

1. Mission Controls should be treated the same as patient specimens and run in accordance with the analyzer instructions for running patient samples.
2. Prior to use gently invert the ampule a few times to mix the contents and release any trapped liquid droplets. Do not shake! Avoid localized heating of ampules.
3. Protect fingers with gauze or tissue and carefully snap the neck of the ampule.
4. Aspirate liquid from the ampule within one minute after opening, following the sampling procedure of the analyzer.

Fentanyl Calibrator 1 & 3

1. The controls should be treated the same as patient specimens and run in accordance with the analyzer instructions for running patient samples.
2. Prior to use gently invert the bottle a few times to mix the contents.
3. Promptly tightly recap bottle and return to 2° to 8°C after use.

SYNCHRON[®] Multilevel Control

1. The controls should be treated the same as patient specimens and run in accordance with the analyzer instructions for running patient samples.
2. Product must come to Room Temperature prior to use.
3. Gently invert the bottle a few times to mix the contents prior to use.
4. Promptly tightly recap bottle and return to -15° to -20°C after use.

QUALITY CONTROL POLICIES

Limitations

Unassayed Chemistry Control

1. Bio-Rad Liquichek Unassayed Chemistry Control should not be used past the expiration date.
2. Erroneous results may be obtained if the control is improperly stored or inadequately mixed.
3. **Total Bilirubin** levels may **gradually decrease** during the product shelf life.
4. If there is evidence of microbial contamination or excessive turbidity in the control, discard the vial.
5. Bio-Rad Liquichek Unassayed Chemistry Control is not intended for use as a standard.

Urine Control

1. Bio-Rad Liquichek Urine Chemistry Control should not be used past the expiration date.
2. If there is evidence of microbial contamination or excessive turbidity in the control, discard the vial.
3. Bio-Rad Liquichek Urine Chemistry Control is not intended for use as a standard.
4. **Creatinine** values may **gradually decrease** over the product shelf life, individual laboratory means may eventually fall outside of the corresponding ranges printed in the insert.

Ethanol/Ammonia Control

1. Bio-Rad Liquichek Ethanol/Ammonia Control should not be used past the expiration date.
2. If there is evidence of microbial contamination or excessive turbidity in the control, discard the vial.

QUALITY CONTROL POLICIES

Limitations Cont..

3. Bio-Rad Liquichek Ethanol/Ammonia Control is not intended for use as a standard.

Spinal Fluid Control

1. Bio-Rad Liquichek Spinal Fluid Control should not be used past the expiration date.
2. If there is evidence of microbial contamination or excessive turbidity in the control, discard the vial.
3. Bio-Rad Liquichek Spinal Fluid Control is not intended for use as a standard.

Pediatric Control

1. Bio-Rad Liquichek Pediatric Control should not be used past the expiration date.
2. If there is evidence of microbial contamination or excessive turbidity in the control, discard the vial.
3. Bio-Rad Liquichek Pediatric Control is not intended for use as a standard.

Cardiac Markers Plus Control LT

1. Bio-Rad Liquicheck Cardiac Marker Plus Control should not be used past the expiration date.
2. If there is evidence of microbial contamination or excessive turbidity in the thawed control, discard the vial.
3. Bio-Rad Liquichek Cardiac Marker Plus Control is not intended for use as a standard.

Immunoassay Plus Control

1. Bio-Rad Liquichek Immunoassay Plus Control should not be used past the expiration date.
2. If there is evidence of microbial contamination or excessive turbidity in the thawed control, discard the vial.

QUALITY CONTROL POLICIES

Limitations

Cont..

3. This product is not intended for use as a standard.

Specialty Immunoassay Control

1. Bio-Rad Liquichek Specialty Immunoassay Control should not be used past the expiration date.
2. If there is evidence of microbial contamination or excessive turbidity in the thawed control, discard the vial.
3. This product is not intended for use as a standard.

MEDTOX Toxicology Urine Control

1. MEDTOX Toxicology Urine Controls should not be used past the expiration date.
2. This product is not meant to be used as a standard or calibrator.

Mission Controls

1. Mission Controls should not be used past the expiration.
2. These controls do not contain red blood cells, and thus may not detect any system malfunctions that can cause lysis of red blood cells leading to erroneous results.
3. These products are intended for use as quality controls and cannot be used as calibration standards.
4. These controls are used to aid in evaluation of the performance of electrolyte instrumentation and should not be considered as a substitute for other aspects of total quality control.

Fentanyl Calibrator 1 & 3

1. Fentanyl Calibrator 1&3 should not be used past their expiration date.
2. These products are not meant to be used as calibrator or standards
3. These products should not be frozen. Proper temperature storage is critical to the performance of the assay.

QUALITY CONTROL POLICIES

Limitations

Cont..

4. These products must not be mixed with different lots, and caps should not be interchanged between levels or lots.

SYNCHRON® Multilevel Control

1. Synchron Control should not be used past its expiration date
2. This Product is not intended as Calibrator or Standards
3. These Products must not be mixed with different levels
4. Product must be recapped when done and returned to -15 to -20°C

Procedure

DxC 800 and Access2

Control levels to be run are in the following table:

| Control | Level 1 | Level 2 | Level 3 |
|------------------------|---------|---------|---------|
| Unassayed Chemistry | X | X | |
| Ethanol/Ammonia | X | | X |
| Urine Chemistry | X | X | |
| Spinal Fluid | X | X | |
| Pediatric | | X | |
| Cardiac Marker Plus LT | X | | X |
| Immunoassay Plus | X | | X |
| Specialty Immunoassay | X | | X |
| Mission Control | X | X | X |
| Fentanyl Control | X | | X |
| SYNCHRON Control | X | X | X |

Procedure

Quantitative Tests

1. Prior to reporting results, establish assay performance using the following Westard Rules:

QUALITY CONTROL POLICIES

- a) 1-2Ss: This is a warning rule by itself, however, if it is preceded by the rules following, then it is a rejection rule.
 - b) 2-2s: Reject run when 2 consequent control measurements exceed the same mean +2SD or the mean minus 2 SD limit.
 - c) 1-3s: The run is considered rejected when one of the control results exceeds +3SDs.
 - d) R-4s: Reject run when 1 control measurement in a group exceeds the mean + 2SD and another exceeds the mean minus 2SD.
 - e) 10x (optional): Reject run when 10 consecutive control measurements fall on one side of the mean.
2. Quality control values are entered into the Unity Real Time[®] via Unity Connect interface. If the analyte is flagged as being out of control limits, remedial action is completed and documented on Unity Real Time[®] action log.

Qualitative Tests

1. For each qualitative assay, include a positive/detected and negative/non-detected control.
2. Evaluate both the controls for proper reactivity before evaluating patient samples. If controls results are unacceptable, remedial action is completed and documented on the Unity Real Time[®].

Quality Control Review

1. **Daily** – Controls are reviewed by a CLS or MLT after each designated run. Each analyte is checked for acceptability.
2. **Monthly**
 - a) Quality control cumulative monthly data and Levey Jennings Charts are printed and reviewed monthly by the section manager or designee. Monthly data is sent to Bio-Rad Unity for peer group comparison. Peer group reports

QUALITY CONTROL POLICIES

- b) Peer Group reports received from Bio-Rad each month are a comparison of our laboratory to all other laboratories performing the same analyte using the same reagents and the same analyzer. Any analyte flagged by Bio-Rad monthly report will be analyzed for a determination if adjustments are appropriate or remedial action is necessary.

Remedial Actions

1. Verify that the correct controls are used, i.e. current lot numbers and levels.
2. Check for adequate and proper mixing of reagents.
3. Check the age of the control. If beyond stability, open a new/fresh control material and rerun.
4. Check the age of the assay reagent and replace with fresh reagent pack if necessary and rerun.
5. Check the analyzer maintenance records to assure it is up to date. If not perform the maintenance and rerun the controls.
6. Check to see if probes are plugged.
7. Review calibration and recalibrate, if necessary. Check that the correct calibrator disk has been loaded.
8. Review testing technique.
9. Review manufacturer's troubleshooting guidelines,
10. Consult the manager.

New Control Reagent Lot Verification

1. Any control out of limits will have remedial action performed and documented on Unity RealTime[®] action log.

QUALITY CONTROL POLICIES

2. Quality control values are entered into Unity RealTime[®]. If any analyte is flagged as being out of control, remedial action is completed and documented on Unity Real Time[®] action log. QC monitoring by CLS is done daily from the Unity Real Time[®]. Manager or designee reviews are done monthly.
3. The mean may be determined by the analyzer in Unity RealTime[®]. Unity RealTime[®] data will be automatically submitted to Bio-Rad for monthly peer review evaluation. The Quality Control charts are reviewed for any shifts and trends on a weekly basis or as soon as possible.
4. The mean of the new lot number is determined in the laboratory by running 20 values within 10 days during the last month of the previous lot number. The Unity RealTime[®] calculates the mean and standard deviation. The values are determined by Unity RealTime[®] after 20 QC values have been entered. The values determined by Unity Real Time[®]: the Mean, and 1 SD.
5. The Peer Group reports received from Bio-Rad each month are a comparison of our laboratory to all other laboratories performing the same analyte using the same reagents and the same analyzer.
6. Any analyte flagged by Bio-Rad monthly report will be analyzed for a determination if adjustments are appropriate or remedial action is necessary.
7. The controls on all analyzers are run at least once every 24 hours. The printouts are saved for a period consistent with regulatory agencies.
8. The control limits are +/- 2 SD from a calculation of at least 10 days of results.
9. Use the following procedure for any controls which are not acceptable.
 - a. Check to see if probes are plugged.
 - b. Check the age of the control.
 - c. If greater than stability, open another control and rerun.
 - d. Check the age of the reagent, if greater than 30 days on the analyzer, place a fresh bottle on the analyzer.

QUALITY CONTROL POLICIES

- e. Check the analyzer maintenance to assure it is up to date. If not perform the maintenance and rerun the controls.
- f. Check the calibration to make sure the calibration is current and recalibrate if the controls continue to be out of control.
- g. Write action taken on the quality control printout from the analyzer.
- h. Consult manager.

**Checking New
Reagent Lot
Number
Confirmation
of
Acceptability**

With new lot numbers of reagents, including calibrators, the controls are to verify that the new lot numbers of reagents are acceptable for use. The controls for both new and old reagent lot numbers must be within the established acceptable range for the analyte, or the reagent will be rejected. QC materials have peer group established means. In case the results are unacceptable, notify the manager and vendor for the reagent for replacement of the entire lot number of reagents.

References

Liquichek Unassayed Chemistry Control Product insert, Bio-Rad Laboratories Diagnostics Group, October 2020.

Liquichek Urine Chemistry Control Product Insert, Bio-Rad Laboratories Diagnostics Group, August 2020.

Liquichek Ethanol/Ammonia Control Product Insert, Bio-Rad Laboratories Diagnostic Group, August 2019.

Liquichek Spinal Fluid Control Product Insert, Bio-Rad Laboratories Diagnostic Group, July 2020.

Liquichek Pediatric Control Product Insert, Bio-Rad Laboratories Diagnostic Group, June 2016.

Liquichek Cardiac Markers Plus Control LT Product Insert, Bio-Rad Laboratories Diagnostic Group, April 2020

Liquichek Immunoassay Plus Control Product Insert, Bio-Rad Laboratories Diagnostic Group, November 2020.

Liquichek Specialty Immunoassay Control Product Insert, Bio-Rad Laboratories

QUALITY CONTROL POLICIES

Diagnostic Group, December 2019.

MEDTOX Toxicology Urine Controls Package Insert, MEDTOX Diagnostics, Inc., April 2014

Mission Control™ Blood Gas and Electrolyte Control Package insert, Diamond Smart Lab Solutions., April 2023

SYNCHRON® Multilevel Control Package Insert, UniCel DxC Synchron systems., 2021

Author Alexandro Gomez MHA, CLS

Distributions Kaiser Permanente Riverside Medical Center Laboratory

End

QUALITY CONTROL POLICIES

Reviewed and approved by:

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

QUALITY CONTROL POLICIES

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 |
|--------------------------------------|--|---|------------------------------------|---------------------------------------|----------------------------|
| Minor | New format | Ben Salas 11/07/13 | Mark Taira 12/16/13 | Denise Topliff 11/07/13 | 12/17/13 |
| Minor | New directorship | Ben Salas 2/24/14 | Mark Taira 2/24/14 | Denise Topliff 3/14/14 | 3/14/14 |
| Minor | Urine control – assayed quality control Procedure – mean new lot 10 values within 10 days | A. Raymond 06/28/18 | M. Taira 06/28/18 | D. Topliff 06/28/18 | 6/28/18 |
| Minor | 1) Updated Cardiac Markers Control 2) Added Medtox Controls and Cobas Isetrol Controls 3) Added analytes tested 4) Updated References | N. Corpuz | M. Taira | A. Raymond | |
| Minor | 1) Added mission control QC. 2) Replaced QC action log with Unity Realtime Action log 3) Added Ionized CA++ 4) Added Synchron Control | A. Gomez | M. Taira | A. Raymond | |
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QUALITY CONTROL POLICIES

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