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Kaiser Permanente Medical Center, San Francisco
Northern California Region
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Work Instruction

Title: Chem Quality Assurance Plan		**WI Number** SFOWI-0218 **Revision:** 19
Department: Chemistry **Area:** 2425 Geary Blvd SFO Hospital Lab	***Approved & Released Work Instruction***	**Implementation Date:** 07/15/2019
Type of Document: Work Instruction		**Review Period -** 340 **Days**

I. PURPOSE

The laboratory is committed to providing the highest quality of patient results in a timely manner. The Chemistry Quality Assurance Plan provides an ongoing monitoring and evaluation of all phases of the testing process. To guarantee this, the following guidelines are established to evaluate the policies and procedures for continuous quality and service improvement.

II. OBJECTIVES

To establish and evaluate an ongoing system to monitor policies and procedures in the Chemistry Department in order to identify, evaluate, and improve all phases of the testing process.

III. SCOPE

All testing personnel working in chemistry department.

IV. QUALITY ASSURANCE GUIDLINES:

A. Personnel

All testing personnel working in the chemistry department are licensed Clinical Laboratory Scientist.

B. Patient Identification

1. All specimens must be labelled with the patients name and medical record number when submitted to the laboratory. All tubes must have the collection date, time, and NUID or name/initials of the person who drew the blood.
2. The specimen-specific, barcoded, Lab Information (LIS) or RILIS labels should be affixed to the tubes in a lengthwise fashion (without masking the original 2 patient identifiers, if a generic label was used). The LIS label is placed lengthwise, with the left side of the label immediately adjacent to the cap, so that the instruments can read the barcode label and download patient information from the system. If a second label (placing barcoded label over a generic label) is affixed to the sample, verify that the name and medical record number match before proceeding.
3. All secondary/transfer specimen vials/aliquots must be labeled with the LIS accession aliquot label (with medical record number – MRN) or permanent marker with the Julian date and the last 5 digits of the accession number.
4. Unlabeled specimens received in the lab or mislabeled specimens must be discarded. The laboratory does not allow unlabeled specimens to be labeled and mislabeled specimens to be relabeled. Notify unit that patient would have to be redrawn.
5. Refer to Specimen Collection Manual for further instructions.

C. Specimen

1. Refer to individual work instructions for specimen requirements. Refer to Specimen Collection Manual for additional information.

2. Collection:
   a. Care is taken to preserve the integrity of the specimen.
   b. Anti-coagulated tubes are mixed well prior to running.
   c. Chemistry specimens are brought to the lab in a timely manner, e.g. blood gas.

3. Specimen Rejection Criteria
   a. Mislabeled or unlabeled specimens.
   b. Incorrect (wrong anticoagulant, no anticoagulant, etc.), or improperly filled container.
   c. Insufficient samples or QNS.
   d. Specimens that exceed the stability requirement or sub-optimal specimen.
   e. Visibly contaminated containers.
   f. Clotted specimen for ABG or clotted specimen when whole blood is required.
   g. CSF, body fluids, or blood gases received thru the pneumatic tube; it should be brought down to the lab and hand delivered to the lab assistant or CLS for immediate processing.
   h. Documentation:
      1. If the specimen was rejected because it did not meet the specimen requirement, notify the nurse or physician and request another sample if applicable. Ensure that the test is canceled and enter a reason for the cancelation in the LIS. The person notified (name and title or NUID), extension # called, date/time and caller's NUID should be included in the comment.

2. Any lipemia, icterus, or hemolysis will be qualitatively noted. If the specimen cannot be run, i.e., hemolysis affects certain tests, notify the nurse or physician for another sample. Cancel the test and affix the reason for the cancelation. The person notified (name and title or NUID), extension # called, date/time and caller's NUID should be included in the comment. Refer to SFOFCD-0411 for AU680 comment codes for reporting interfering substances.
3. If a test is part of a panel, do not cancel the test (Example: K test in Chem 7 panel) instead, in Accession Result Entry (ARE), enter TND as the result and attach a result comment with "TND" template. Enter the reason for the TND, the person notified (name and title or NUID), extension # called, date/time and caller's NUID should be included in the comment. Refer to SFOFCD-0411 for AU680 comment codes for reporting interfering substances.
4. If the test is run on a sub-optimal specimen at the request of the physician, enter a comment, "Test run at request of Dr. _____". Include the person notified (name and title or NUID), extension # called, date/time and caller's NUID should be included in the comment.
5. Clotted specimens are not acceptable for blood gas samples. If clotted, notify the nurse or physician, and request another sample. Ensure that the test is canceled and affix a reason for the cancelation. The person notified (name and title or NUID), extension # called, date/time and caller's NUID should be included in the comment.

4. Aliquots
   a. The original specimen collection tube must be properly labelled. Label the aliquot tube with an aliquot RILIS label, if available, or with the use of a permanent marker label the cup with the Julian date and the last 5 digit of the patient's accession number. Confirm positive patient identification by verifying that the label on the aliquot tube/cup matches that of the original tube of the patient's specimen.
   b. To prevent cross contamination, use transfer pipettes only once to transfer sample from tube to cup. Aliquot the amount needed for testing. Save the rest for add-ons and additional testing. Do not pour back the sample after testing is completed.
   c. Conserve specimen in original tube by only aliquoting the amount needed for testing. Aliquoting from previous aliquot sample is only permissible if no specimen is left in the original tube. Confirm positive patient identification by verifying that the label on the aliquot tube/cup matches that on the original tube of the desired patient's specimen. Follow steps on how to prevent cross contamination above.

D. Maintenance

1. Instruments:
   a. Equipment performance is first validated upon installation, and thereafter, after major maintenance or repairs to ensure that they are working according to

manufacturer's claims. CAP standard requirements such as correlation, linearity, etc.… are performed according to regulation.

b. Maintenance is performed as defined by the manufacturer's recommendation.
c. Routine maintenance and troubleshooting is performed by licensed personnel. Additional preventive maintenance and advanced troubleshooting requiring specialized equipment will be performed by either Clinical Technology (formerly Biomedical Engineering), or the manufacturer's Field Service Engineer (FSE).
d. Function checks are performed as defined by the manufacturer. The frequency of the checks are in accordance with manufacturer's recommendations.
e. Maintenance, function checks, and repairs must be logged and reviewed monthly by the Supervisor or designee. If additional documentation for instrument problem is needed, document it into the "Corrective Action" section of the maintenance logs.
f. Additional maintenance, part and supply replacement, and function checks are performed on an as-needed basis are also documented.
g. Maintenance, function checks, and repair records are retained for the life of the instrument. In the event that the instrument is moved, all records are transferred as well.
h. All logs are reviewed monthly by the department Supervisor or designee.

2. Refrigerators and Freezers:
   a. Reagents are stored according to manufacturer's recommendations. The refrigerators and freezers used for reagent storage are monitored continuously with Check Point temperature monitoring system. A daily review of temperature is performed by the CLS staff and reviewed weekly by Operations Supervisor or designee.
   b. When the temperature is outside acceptable limits (<2º or >8ºC for refrigerators and higher than -20ºC for freezers) due to power outage or malfunction, and the recovery time is expected to be more than 2 hours, contents are relocated to another unit ASAP.
   c. When there is a major power outage due to a disaster, and no back up unit can be found to transfer the contents, do the following corrective action procedure:
      1. Evaluate contents for adverse effects by randomly selecting a minimum of 5 units stored in that refrigerator or freezer. (Units should be representative of different types of reagents, controls, etc. stored in that refrigerator/freezer.)
      2. Perform routine QC testing on the selected units. Record data and maintain documentation in the PM binder.
      3. Based on QC testing results, Supervisor will determine whether to:
         a. Use the contents with a continuous monitoring for future performance problems.
         b. Consult with manufacturer of contents for more specific handling guidelines.
         c. Discard the contents.

3. Thermometers:
   All thermometers in use in the chemistry section are checked against a traceable NIST standard thermometer before being placed in service and annually thereafter.

4. Centrifuges:
   Daily and as-needed cleaning is performed by staff working in chemistry area. The calibration of centrifuges is performed by Clinical Technology, usually on a biannual schedule.

5. Volumetric Pipettes and Glassware:
   Class A volumetric glassware is used for quantitative procedures in the chemistry section when specified by the vendor. Serological pipettes may be used in non-quantitative procedures. Pipettes will be segregated by size, and they are discarded when the tips become broken, blurred, or lose marking's.

6. Automatic Pipettes:
   The fixed volume adjustable and/or Micropipettes are checked for accuracy and reproducibility before being placed in service and every six months thereafter. Altar is the contracted vendor to perform calibration.

7. Materials and Supplies
   a. Reagents:
      1. All reagents are placed/stored at appropriate temperature as recommended by manufacturer.
      2. Expired reagents are not used.
      3. All reagents in current usage are properly labelled with the following:
         a. Contents and original volume
         b. Storage requirements
         c. In-use date or date prepared/ reconstituted (**Note:** In-use date starts when the reagent or material is thawed, not the day it was opened for use).
         d. Expiration date. (**Note:** A new expiration date must be recorded if opening the container changes the expiration date, storage requirement, etc.)
      4. New lots of reagents are calibrated and QC must pass prior to use. Lot to lot verification of reagents is also performed with appropriate patient samples (minimum of 10 patients for initial calibration and 5 patient samples for recalibration).
      5. Reagents with multiple components should not be combined with another kit for any reason.

   b. Calibrators and Standards:
      1. All calibrators and standards are placed/stored at appropriate temperature, as recommended by manufacturer.
      2. Expired reagents are not used.

3. Calibration materials establish the relationship between method/instrument response and the corresponding concentration/activities of an analyte. They have defined analyte target values and appropriate matrix characteristics for the clinical specimens and specific assay method.
4. Only Calibration materials recommended by manufacturer are used. These are assay specific with system-specific target values to produce accurate results for clinical specimens. Calibrators are prepared and handled according to manufacturer's specifications.
5. All calibrators and standards in current usage are properly labelled with the following:
    a. Content and original volume.
    b. Storage requirements
    c. In-use date or date prepared/ reconstituted (**Note:** In-use date starts when the reagent or material is thawed, not the day it was opened for use).
    d. Expiration date. (**Note:** A new expiration date is recorded if opening the container changes the expiration date, storage requirement, etc.)
6. Calibration, Recalibration, or Cal verification is performed under, but not limited to the following conditions:
    a. New reagent lot numbers.
    b. QC has a shift, trend, or is outside the acceptable range.
    c. After major preventive maintenance or change of a critical instrument component. Routine and "as-needed" maintenance does not constitute major maintenance. Acceptable QC following maintenance including change of components, is the first check of instrument performance. If there is a question regarding a component replacement, the Laboratory Director/designee is consulted to determine if AMR validation is required.
    d. Recommended by the manufacturer.
    e. At least every 6 months.
    f. Proficiency Testing Exception Survey (PTES) investigation.
    g. Failed calibration verification.
7. Calibration is documented and worksheet includes the information listed below.
    a. Calibrator lot number and expiration date.
    b. Date calibration was performed.
    c. Control lot number and expiration date.
    d. Control results and control ranges.
    e. CLS performing calibration.
    f. Date that the reagent was put in use.
    g. Attach the calibration print-out with the worksheet.
8. Methods that are re-calibrated more frequently than every 6 months do not require a separate calibration verification procedure.
9. If the calibrator material has more than 3 points that include low, mid, and high values that are near the stated Analytical Measurement Range (AMR) and the calibration frequency is more often than every 6 months, no

additional AMR validation is required, provided that the calibration data are within the laboratory's acceptance criteria.

c. Quality Control Materials
    1. All quality control (QC) materials are placed/stored at appropriate temperature recommended by manufacturer.
    2. Expired QC materials are not used.
    3. All QC materials in current usage are properly labelled with the following:
        a. Content and original volume
        b. Storage requirements
        c. In-use date or Date prepared/ reconstituted (**Note:** In-use date starts when the reagent or material is thawed, not the day it was opened for use).
        d. Expiration date. (**Note:** A new expiration date must be recorded if opening the container changes the expiration date, storage requirement, etc.).
    4. A new lot study (unassayed quality control materials) should be done prior to usage of the new lot. It should include but not limited to a 20-point precision study per level. Study should span a minimum of 5 days and run at least 4 hours apart unless otherwise indicated. Preferably, run control once every 8 hours or once a shift for 10 days totaling 30 data points. When new lot of assayed control is used, the laboratory must verify the acceptability ranges supplied by the manufacturer. The manufacturer suggested mean and range maybe used initially. After 20 data points has been collected, the mean and tolerance limit is reviewed and range is adjusted as needed.

8. Inventory Management
    a. The laboratory will maintain sufficient inventory to continue operation without interruption and concomitantly conserves resources by limiting reserves on site. Orders will be limited to the approved product standard any deviation must be submitted for approval.
    b. Contents of the shipments received are examined for the following:
        1. Product and amount ordered are precise.
        2. Product is not defective.
        3. All the products listed in the packing slip are correct.
        4. Any discrepancy should be reported and resolved immediately.
    c. All back-orders is followed-up.
    d. Received date and stickers or labels such as New lot/ Not-in-use affixed to the product received.
    e. All packing slips should be kept for records.

9. Quality Control
    Defined control procedures are in placed to detect immediate errors that occur due to test system failure, environmental conditions, and operator performance. QC

precision and accuracy is monitored over time. All QC samples are tested in the same manner as patient samples.

a. Materials
    1. Quality Control testing for each instrument is performed daily to monitor analytical variations of the instrument.
    2. Commercial assayed and unassayed controls are the materials used.
    3. All controls are used within their expiration date and monitored for open vial stability.
    4. Control materials are carefully selected to reflect patient sample matrix and to reflect both normal and medically significant levels.
    5. All unassayed control materials used for routine analysis are assayed to determine mean and standard deviation values before being put into use.
    6. New lots of unassayed control material are assayed in parallel with the current lot before the current lot of control is depleted or expired.
    7. A new lot study should be done prior to usage. It should include a minimum but not limited to a 20-point precision study per level. Study should span a minimum of 5 days and run at least 4 hours apart unless otherwise indicated. Preferably run control once every 8 hours or once a shift for 10 days totaling 30 data points.
    8. Control materials are prepared or handled according to manufacturer's specifications.
    9. When new lots of unassayed controls are initially put into use, the calculated mean of the new lot and the historical (working) tolerance limit are used. After the new lot has been in use, the mean will be updated and tolerance limit will be reviewed. When new lot of assayed control is used, the laboratory must verify the acceptability ranges supplied by the manufacturer. The manufacturer suggested mean and range maybe used initially. After 20 data points has been collected, the mean and tolerance limit is reviewed and range is adjusted as needed.

b. Control System
    1. Qualitative Procedures: Positive and Negative Controls
    2. Semi-Quantitative Procedures or graded result test: negative control and a positive control with graded activity
    3. Quantitative Procedures: multiple levels of control

c. Control Set-up
    1. Proper maintenance and standardization should be performed before running quality control samples and patient’s samples. All level of controls should be run within a 24-hr. period. Refer to Table 1.1 and Table 1.2 for Control Guidelines.
    2. If patient results were in process when quality control was performed, delay reporting results until control results have been evaluated. **DO NOT REPORT PATIENT RESULTS IF CONTROL RESULTS EXCEED ACCEPTABLE LIMITS**.

3. All QC run must be reviewed and verified in URT or RILIS before running any patient samples. The Quality Control programs in the machine only serves as a preliminary/ intermediate approach for reviewing QC. As a precaution, patients should not be tested unless all QC run has been reviewed and verified in BioRad URT or RILIS.

Table 1.1 Quantitative Assays:

System	Test	Control Material	Levels	Frequency
AU680	AMM, ETOH	BioRad ETOH/ AMM	1 and 3	Once every 24 hours
	CSF GLU and CSF PROT	BioRad Spinal Fluid	1 and 2	Once every 24 hours
	SERUM: ACET, ALB, ALKP, ALT, AMYL, AST, BILI-D, BUN, CA, CK, CL, CREAT, ECO2, GLUC, K, LIP, LDH, MG, NA, TP, PHOS, TBIL, URIC,	BioRad Unassayed Chem	1 and 2	Once every 24 hours Na, K, CL and CREAT: once every 8 hours
	PEDIATRIC DBILI and TBIL	BioRad Pediatric Control	1 and 2	Once every 24 hours
	CRP	BioRad Elevated CRP	1 and 2	Once every 24 hours
	DIG, GENT, PHYTN, SALI, and VANCO	Biorad Immunoassay Plus	1 and 3	Once every 24 hours
	URINE: NA, K, CREAT, U-TP	BioRad Urine Chemistry	1 and 2	Once every 8 hours U-TP: Once every 24 hours
ACCESS2	CKMB, TROPI	BioRad Cardiac Markers	1 and 2	Once every 24 hours
	BNP	BioRad Cardiac Markers	1, 2, & 3	Once every 24 hours
	BHCG	Biorad Immunoassay Plus	1 and 3	Once every 24 hours
		BioRad Fertility	3	Once every 24 hours
	PTHiO (For Access2-2 only or when Access2-1 is used)	BioRad Specialty IA	1, 2, & 3	Once every 24 hours
ABL	pH, PCO2, PO2, SO2, ctHB, FCOHB, FMethB, LAC, CA++	AutoCheck 5+	1, 2, 3 & 4	Levels 1 & 3 night shift Levels 1 & 2 Day shift Levels 2 & 3 PM shift
OSMO	Osmolality	BioRad Unassayed Chem- Serum BioRad Urine Chemistry	1 and 2	Once every 24 hours

		290 Standard Control		Once per shift
pH	pH	pH Indicator Strips	Fisher Scientific Certified Buffer Solution: pH 4.00 pH 7.00 pH 10.0	Once every 24 hours

Table 1.2 Semi-Quantitative/ Qualitative Assays:

System	Test	Control Material	Levels	Frequency
Med Tox	AMP, BAR, BZO, COC, mAMP, MTD, OPI, OXY, PCP, THC	MedTox QC Test Device MedTox External QC	Neg and Pos	Once a week Once every 24 hours Each new lot of MedTox Test Device

d. Determining/Evaluating Q.C. Mean and Tolerance Limits (CV):
   1. Assay all levels of the new control lot as patient samples.
   2. A minimum 20-point precision study per level.
   3. Study should span a minimum of 5 days and run at least 4 hours apart unless otherwise indicated. Preferably run control once every 8 hours or once a shift for 10 days totaling 30 data points.
   4. Calculate the mean of each level and use historical (working) tolerance limit to calculate for the SD.
   5. This limit is set:
      a. So that it does not exceed HCFA/CAP proficiency limit of that analyte.
      b. To conform with the manufacturer's claims of precision for that analyte.
      c. To correlate well with the past performance limits.
   6. After the new lot has been in use, the mean and tolerance limit will be reviewed in comparison to PEER group or any Inter-Laboratory Quality Control Data Evaluation and will be updated as necessary.

e. QC Rules, Terminologies, and Definitions
   1. The following rules are in placed: 1-2s, 1-3s, 2-2s. **Refer to SFOSOP-0288 for more details.**
   2. Document problems and corrective actions taken.
   3. Record in URT or RILIS.
   4. Common Terminologies and Definitions
      a. *Shift*:

- An abrupt change in the control mean representing a sudden and dramatic positive or negative change in the test system performance
- usually brought about by a known event such as reagent change, calibration, temperature change, or major analyzer maintenance
- QC data observed in this situation remains stable over time. Depending on the magnitude of the shift (in general, greater than one tolerance limit or displacing test values in a clinically significant manner) the supervisor will determine if the mean value should be reassessed

b. *Trend:*
   - An error where control results continue to either increase or decrease over a period
   - Represents a change in the system due to systematic error brought about by progressive changes such as reagent stability, calibration stability or control stability
   - If the data from imprecision statistics change significantly from previous data, depending on the magnitude of the trend, the supervisor will determine the type of action needed i.e. change reagents, recalibrate, or service the analyzer

c. *Random Error:*
   - An error defined by positive or negative deviation away from the calculated mean
   - Errors with no predictable pattern; Due to the presence of variables, there will always be some deviation from the true value in measurement.
   - Affects precision
   - Some possible reasons are bubbles in reagents, inadequately mixed reagents, temperatures change in control materials used, pipetting, or operator

d. *Systematic Error:*
   - Errors with predictable magnitude and is always in one direction
   - Avoidable if materials or substances used are handled properly
   - Affects accuracy
   - Often related to bad calibrations materials, improper mixing or preparation of reagents, misaligned probes, contaminated solutions, deterioration of reagents, improper storage of reagents and calibrators, etc.…

f. Criteria for Accepting Q.C. Values:
   1. Accept QC results if:
      a. Both controls are within 2 tolerance limit.
   2. Reject QC results if:
      a. Both levels of control have a rule violation
      b. One control is outside 2 tolerance limit
      c. An erroneous Z score is observed, discard or delete QC result

3. Troubleshooting Rejected Runs **(See SFOSOP-0288 for more information)**
   Actions to be taken but not limited to the following:
   a. Repeat QC run
   b. Change reagents (run both levels of control)
   c. Use a new set of control materials
   d. Recalibrate analyte and run both levels of control
   e. Review LJ chart and assess how the analyte has been performing
      1. If a sudden shift if observed, inspect the reagent, calibration, and maintenance records. Verify the lot numbers in use are correct and not expired and proper maintenance has been performed.
      2. If a trend is observed, inspect reagent stability or QC shift after calibration. Consider changing reagents or performing calibration.

NOTE: Do not reflexively do any of the following as a first course of action without careful analysis of the problem.

4. Factors and Variables to consider:
   - Was there any major preventive maintenance done?
   - Were there any parts change?
   - Were there any reagent lot changes?
   - Were there any recent calibrations performed?
   - Were there any new lot of controls in place?

If control is still out, CLS must inform the supervisor, shift supervisor or designee. They will decide and take appropriate action. All corrective action steps taken should be documented in BioRad URT or RILIS. DO NOT RUN OR RELEASE ANY PATIENT RESULTS UNLESS QC FOR BOTH LEVELS ARE DEEMED ACCEPTABLE. In the event that the problem is not resolved, discontinue patient testing and use the other analyzer for testing. Document in URT or RILIS that QC is out and instrument is not used for patient testing.

g. Documentation of Quality Control:
   1. Bench CLS's responsibility:
      a. Enter QC data values on QC forms for the following: Osmometer, MedTox, and pH. Verify Osmometer results in RILIS prior to running patient samples.
      b. AU 680, Access-2 and ABL QC's are automatically stored in the analyzer's QC file. Verify in URT or RILIS prior to running patient samples.
      c. Each technologist working the bench is responsible for verifying and reviewing QC results performed in BioRad Unity Realtime QC software or Cerner Millennium RILIS Quality Control review.
      d. All QC results that are out of control require an Action or Comment in Biorad Unity Realtime QC software or Cerner Millennium QC file.
      e. Additional comments such as loading of new reagent packs or bottles, recalibrations, part or supply changes, major or additional maintenance

performed and other pertinent information for QC review should also be documented in URT or RILIS.

2. Supervisor, Shift Supervisor, or In-Charge CLS's responsibility:
   a. Daily
      - Ensure that maintenance and QC has been performed, reviewed, and documented in log book
      - Review out of control results and confirm that all documentation is correct, complete and all out of control results has been resolved
      - Communicate any issues or problems experienced during the shift
   b. Weekly- Department Supervisor, Shift Supervisor, In-Charge CLS or Designee
      - Review LJ charts for shifts and trends
      - Document or note any observations made in URT or RILIS
      - Troubleshoot as needed
   c. Monthly- Department Supervisor or Designee
      - Print and review monthly QC report
      - Document or note any observations made in URT or RILIS
      - Submit to ALAD for review

10. Proficiency Testing:
    Chemistry section of the laboratory participate in internal and external proficiency testing program. Guidelines for these procedures are followed from the total Quality management policy on proficiency testing. The following external surveys are subscribed:

    a. AL2 - AACC/CAP Serum Alcohol
    b. AQ- Aqueous Blood Gas
    c. BNP - BNP
    d. CZX - Chemistry and TDM
    e. CAR - Cardiac Marker
    f. M - Cerebrospinal Fluid Chemistry
    g. NB - Bilirubin, Total (Neonatal)
    h. S - Diagnostic Immunology (CRP)
    i. SO - Blood Oximetry
    j. U - Urine Chemistry-Series 1
    k. Y ING - Ligand
    l. UDS-Urine Drug Screening

V. REFERENCE:

1. Tietz, NW (Ed): Fundamental of Clinical Chemistry, WB Saunders Co., Philadelphia, pp 60 - 102, 1976.
2. "Quality Control Concepts - definitions and interpretations" by Fisher Diagnostics - Chemistry QC Computer Service Center, 1980.
3. Statistical QC for Quantitative Measurement C24-A3, 2006 from Clinical Laboratory Standards and Institute

4. Westgard, J.O., et al. Basic QC Practices: Training in Statistical Quality Control for Healthcare Laboratories, 2nd Edition. Westgard QC, Inc. Madison, Wisconsin, 2002
5. Regulatory Compliance and Quality Control Practice Workshop. Sponsored by Laboratory Science Labor and Management Committee

Associated Documents:

External Documents

Associated Documents:

SFOSOP-0288 -- TPMG SFO Laboratory Quality Control Policy – Quantitative Assays

Click to Open an Associated Document

Documents Generated:

Document Revision History:

Revision: 19	**Date Created:** 04/04/2006 **Date of Last Revision:** 07/15/2019	**Last Approval Date:** 07/15/2019

Document Author: Kevin W LUI/CA/KAIPERM	

Reason for Change:

Revision:	Sec/Para Changed	Change Made:	Date
1	N/A	Initial Issue of Document	
2	N/A	Change of Medical Director	11/17/06
3	2.III.2 and 2.IV.1 and E	Nova CCX and Sweat chloride test discontinued .PT samples for Sweat analysis and Kaiser inter laboratory comparison samples deleted . Change of Medical Director	8/13/07
4	C. 5. 2 C. 6. C.7.1.g	Rejecting QC results Patient results reviewing before verification of results. QC result verification on Biorad Unity Realtime	12/16/08
5	C.2.iv.1 and 2 Sec C. 7 E	Reflect changes associated with instrument change in Coag section Added 2 levels of serum and urine controls for Osmo Deleted KC 4 section Stago added, deleted CA 1500 and 560. Changed ABL 705 to 825. Added SO - Blood oximetry	1/11/09
6	3 6 B C	Daily review of temp Daily cleaning of centrifuges Specimen acceptance and rejection criteria Aliquot procedure	9/19/11
7	Through out the document	Changes to reflect current test menu and instruments and PT	11/18/11
8	Sec 8.4,5	Added cal verification not required for frequently calibrated methods Deleted cal verification established criteria part of this sentence	3/14/12
9	N/A	Version changed from 8 to 9	2/23/13
10	Sec II,A,8,6 and Sec C, 6, j Approver list	Added AMR verification not required for frequently calibrated methods Added Max dilution Change CLIA Director	2/26/13
11	Sec II A.8., IID.	Add instruction to handle calibrators according to manufacturer's instructions. Add UDS to list of CAP Surveys	4/23/13
12	Sec II A.4. Sec II A.7.a. Sec II A.8.2 Sec II B.10 Sec II B.11 Sec II D.	Add Instruction "when specified by the vendor" Delete concentration or titer Add elements of calibration log Changed annually to at least annually Add condition for adding thrombin to sample Delete Ketone, Add Urine Drug Screen	12/3/2013
13	Sec II.7.5 Sec II B.11	For acceptable criteria for lot validation on patient samples, refer to SFO WI - 0243 (Acceptability criteria for repeat test values) procedure. Add specimen to another tube of FDP	1/30/14
14	Throughout the document Sec II A.3 .Refrigerator and freezers Sec II c 2 QC	Deleted information regarding coag section Corrective action PTH IO QC daily Mon-Fri	10/3/14
15.	Title and Instrument Maintenance.	Performance of equipment is verified upon installation and after repair or reconditioning to ensure that they run according to expectations	2/19/2015

16	Throughout document II.A.3. Refrigerators and freezers II.A.8.c Calibration/Cal Ver II.C2.ii Q.C. Setup II.C.2.Note II.C.7.1.a. Documentation II.C.7.3 II.D. Proficiency Testing Approvers	Delete "Coagulation" Delete ±5ºC and±10ºC differences as criteria for removing contents. Expand to include QC as first check. Change "A"and "B" to "1" an "2" Add Document number, SFOFCD-0119 Delete Radiometer, add MedTox Delete review by CLIA director Delete FLD survey, add S (CRP) survey Delete A.Tiong, add V.Ruikar	2/4/2016
17	C. Quality Control	Changed FS to AU680, Changed CLIA Director	10/12/2016
18	C. Quality Control	Added BioRad URT/RILIS QC review. Added QC Rules, QC Frequency...	06/15/17
19	Quality Control Associated Documents Approver	Added U-TP QC Intervals Removed Table 1.3 Associated SFOSOP-0288 Changed Lab Director to Dr. Elizabeth Hosfield.	7/12/19

Approvals:

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Jul 15, 2019 09:06:19 AM PDT - Approved by: Vaiju Ruikar/CA/KAIPERM

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Jul 15, 2019 09:07:20 AM PDT - Approved by: Elizabeth M Hosfield/CA/KAIPERM