Adventist HealthCare

TRAINING UPDATE

Lab Location: GEC **Department: Core lab**	**Date Distributed: 2/9/26** **Due Date: 2/23/26** **Implementation: 2/9/26**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:
AHC.QA48.5 Calibration and AMR Verification
Description of change(s):
Added details of i-STAT calibration verification including the use of hypoxic and hyperbaric QC material.

Document your compliance with this training update by taking the quiz in the MTS system.

Non-Technical SOP

Title	**Calibration and AMR Verification**	
Prepared by	Robert SanLuis	Date: 3/26/2013
Owner	Robert SanLuis	Date: 3/26/2013

Laboratory Approval		
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		
Local Issue Date:	Local Effective Date:	

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1. PURPOSE

This procedure describes the Calibration and AMR Verification process in compliance with CAP and CLIA guidelines. Both calibration and AMR can be verified at the same time if the calibrators used are at or near the bottom and top of the measurement range. If this is not the case, then the AMR must be verified separately from the calibration verification.

Calibration and AMR Verification evaluation criteria are established by the department Medical Director.

2. SCOPE

This procedure applies to assays as specified below.

Calibration and AMR verification is required at least every six months or more frequently if recommended by the manufacturer or according to the laboratories' established schedule when:

- The calibration curve is constructed using less than three calibrators or;

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- Reagent lot number changes, unless it can be demonstrated that changing reagent lot numbers does not affect the reportable range as demonstrated by acceptable Lot-to-Lot performance characteristics or;
- When there is major preventive maintenance or replacement of a critical instrument part that may affect test performance or;
- When QC results reflect an unusual trend or shift and other avenues of identifying and correcting the problem have not been successful.
- For blood gas analysis, the laboratory must perform calibration and calibration verification procedures in accordance with the manufacturer's instructions.

Note: i-STAT blood gas analyzer.
A. A multipoint calibration curve, the slope or sensitivity of which is defined by coefficients in each CLEW software, is derived for each sensor in each iStat cartridge. These calibration curves are stable over many lots and only need to be adjusted if a change in the manufacturing process affects the curve or if the relationship between results on the iStat system and other major laboratory systems drift. CLEW updates are scheduled two times per year.
B. The instrument automatically calibrates as part of the test cycle for each cartridge.
C. Calibration and/or AMR verifications are required at least every six months (or more frequently if recommended by the manufacturer) for all testing cartridges on the iStat.
D. The iStat Tri-Control Calibration verification provides five commercially prepared solutions for testing. For PO2, we utilize a hypoxic and hyperbaric QC material to assist with verifying the low and high ends of the AMR.

Calibration or AMR verification is <u>not</u> required when:

- The test being calibrated uses three or more levels of calibration materials that include low, mid and high values at least every six months, calibration performance criteria is established and achieved, the calibration verification requirement is considered met,
- For automated cell counters, if the laboratory follows the manufacturer's instructions for instrument operation, maintenance, calibration, and tests at least two levels of control materials each day of patient testing, the calibration verification requirement is met.
  Note: The control material results must meet the laboratory's criteria for acceptability.
- The method is an immunoassay using calibrators which span the reportable range,
- The method is qualitative,
  Note: For drugs of abuse screen tests, since the value of the calibrator material is not near the cutoff value, this laboratory has chosen to utilize a QC product that contains drugs of abuse and metabolites of drugs of abuse added at concentrations 20% – 25% above and below enzyme immunoassay cutoff levels.

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3. RESPONSIBILITY

The QA department is responsible for document control of this procedure and preparing the QA Recurring Calendar.

The technical supervisor is responsible for implementation and training of the staff members when using this procedure.

The Lab Management team is responsible for ensuring compliance with this policy and the QA Recurring Calendar.

The Medical Director (CLIA License holder) is responsible for establishing calibration and analytical measurement range verification processes and approval of this document.

4. DEFINITIONS

Calibration is the process of testing and adjusting a test system to provide a known relationship between the response measurement and the value of a substance measured by the procedure.

Calibration Verification is the assaying of appropriate matrix materials with known values in the same manner as patient samples to confirm that calibration of the test system has remained stable. The word "matrix" implies that materials have a matrix closely resembling that of patient test specimens, and a "matrix effect" is the influence of a component in the sample, other than the analyte, on the measurement of that analyte. When performing calibration verification procedures, the laboratory should use the correct number, type and concentration of materials specified by the manufacturer using at least a minimal (or zero value), a mid-point value, and a maximum value that covers the analytical measuring range of the test system.

Analytical Measurement Range (AMR) is the range of analyte concentration that can be measured with an undiluted and not concentrated specimen. This is verified by running at least 3 separate levels with one at or near the lowest and highest limit of the measurement range.

Allowable Total Error (TEa): The amount of error that meets the laboratory's stated quality goals or quality requirement for that analyte.

Recurring Calendar: A tool utilized to organize and track regularly occurring tasks related to quality and safety via Smartsheet (software application for collaboration and work management).

5. PROCEDURE

1. Ensure the test system is well maintained, prior to performing Calibration and AMR Verification. Verify all routine maintenance and system function checks are acceptable and documented.

2. Perform calibration verification on freshly prepared reagent; ensure adequate volume of reagent for the number of tests and replicates.

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3. Obtain and prepare the appropriate calibration material. Ideally calibration verification material should be of similar matrix to patient material. These may include in-house pools, commercially prepared samples, quality controls, or calibrators of known concentration.

4. **Include a set of at least three levels (low, medium and high) spanning the analytical measuring range deemed appropriate to verify the manufacturers stated AMR.** At a minimum each level should be tested in duplicate.

   - For systems with autodiluting systems, i.e. the Dimension, **program the samples with the autodilution system turned off**. Dimension **EXL** users will program the assays as *XQC* and *Serum QC3*, then select the assay three consecutive times (i.e. TSH, TSH, TSH, FT4, FT4, FT4).

5. The Medical Director approves the AMR and calibration acceptability criteria for each point for each assay, TEa unless otherwise stated.

6. Evaluate the results for each point and for each assay against the TEa or established criteria for the assay. Maine Standards, Validate, and material provided by the manufacturer or the College of American Pathologists (CAP) are manufactured such that a linear relationship exists among the levels. Material that is prepared internally should have an equal delta between consecutive levels. The dilution scheme is consistent with the CLSI EP6 recommendation for preparing linearity sets. The delta between two consecutive points, within the known linear range, can be used to calculate the theoretical values. Linear regression should be interpreted using standard statistical analysis, with results compared to the manufacturers' claims for linearity. In addition, replicates are evaluated against CLIA total allowable error as well as optional peer data comparison.

7. If the result is outside the established criteria, troubleshoot and document any appropriate corrective actions taken.
   a. Document the issue: TEa, calibration, or AMR verification failure.
   b. Ensure there was appropriate sample volume for scheduled testing.
   c. Verify the QC is in range and the test system is functioning properly.
   d. If precision is suspect, pull the method package insert and verify precision at the identified levels.
   e. Ensure the samples where programmed with the autodilution function turned off.
   f. If instrument problems are identified, call service and resolve prior to retesting.

8. After appropriate corrective action, repeat Calibration and AMR Verification process.

9. All corrective actions will be coordinated and reviewed by the Technical Director (or designee) and approved by the Medical Director. **The degree of acceptable non-linearity is an individual judgment based on methodology, clinical significance and medical decision levels of the test analyte as deemed acceptable by the Medical Director.**

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6. RELATED DOCUMENTS

1. CLSI *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline - Third Edition.* CLSI document EP05-A3. Wayne, PA: Clinical and Laboratory Standards Institute, 2014
2. CLSI *Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline.* CLSI document EP6-A. Wayne, PA: Clinical and Laboratory Standards Institute, 2003
3. Atellica / Chemistry Calibration Verification Summary (AG.F618)
4. EXL Calibration Verification Summary (AG.F620)

7. REFERENCES

1. Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24):3707 [42CFR493.1255]
2. Centers for Medicare and Medicaid Services; *Appendix C - Survey Procedures and Interpretative Guidelines for Laboratories and Laboratory Services*; published January 12, 2004

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
000	5/26/2015	Section 6: update titles Section 9: update test lists Footer: version # leading zeros dropped due to new EDCS in use as of 10/7/13	L Barrett	R SanLuis
1	5/31/2017	Header: add other sites App A & B: update reagent codes and AMR to match technical SOPs	L Barrett	R SanLuis
2	5/23/2019	Header: updated parent facility Section 2: moved specification from section 1 App A: added new assays, corrected MG and IPTH	L Barrett	R SanLuis
3	8/5/2021	Header: removed specific sites, added All Labs Section 4: added recurring calendar Section 6: deleted calendar, added calibration summaries Section 9: deleted summaries (added to section 6) Footer: changed prefix to AHC	L Barrett	R SanLuis, C Bowman-Gholston
4	2/9/2026	Section 2: added details of i-STAT calibration verification	R SanLuis	R SanLuis

9. ADDENDA AND APPENDICES
None

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