

CALIBRATION VERIFICATION

Purpose To define the policy for Calibration verification and to ensure compliance with applicable JCAHO, COLA, CAP, Centers for Medicare and Medicaid (CMS) and the California Department of Health and Services regulations/requirements.

Policy Calibration verification is performed based on the following criteria:

For Coagulation:

- Change of reagent lots for chemically or physically active or critical components.

For all analytes:

- If QC materials reflect an unusual trend or shift or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct problem.
 - After major preventive maintenance or change of critical instrument component
 - At least every 6 months.
1. Commercial calibration verification material and commercial calibrators will be used to assess calibration verification.
 2. Calibration materials used by the laboratory include the following;
 - a) the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and
 - b) at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system.
 3. All calibration verification reagents/kits will be ordered and stored by the main laboratory.
 4. Calibration verification data must be submitted for data crunching no later than one week after the calibration verification procedure has been completed.
 5. Calibration verification review completed by appropriate Manager and submitted to Quality Assistant Director. Quality Assistant Director to submit to Laboratory Operations Director for final approval.
 6. All reviews and corrective actions must be completed within 2 weeks from the time calibration verification was performed.
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Calibration verification will be performed for the following analytes:

ALB	BUN	Calcium	Chloride	Creatinine
Glucose	Potassium	Lactate	Magnesium	Sodium
Phosphorus	Total Protein	Uric Acid	CO2	ETOH
Ammonia	Lithium	Acetaminophen	Carbamazepine	Digoxin
Gentamicin	Phenobarbital	Phenytoin	Salicylate	Theophylline
Tobramycin	Valproic Acid	Vancomycin	Urine OSMO	Serum OSMO
Urine Sodium	Urine Potassium	Urine Chloride	Urine Total Protein	Urine Creatinine
CKMB	BNP	Troponin	HCG	iPTH
Anti-Xa	DDimer			

Controlled Documents

The table below lists the controlled documents for this policy.

Document #	Title
LGM 2042	How to Interpret Evaluation Report for Calibration Verification
LGM 2044	Linearity/Calibration Verification Remedial Action Form - LAMC
	Calibration Verification Review Form

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Calibration/Verification Review Form – Medical Centers and Medical Offices

TESTING DEPARTMENT

RESPONSIBLE INDIVIDUAL	REQUIRED ACTION(S)	COMMENTS	SIGNATURE	DATE SUBMITTED
Manager, Area Laboratory	<ul style="list-style-type: none"> Review statistical analysis. Add comments as needed. Document any corrective action for failed calibration. Resolves any corrective action in a timely manner. 			
Quality Review, if applicable	<ul style="list-style-type: none"> Verify that all statistical analysis are acceptable Verify all corrective actions for failed calibration are documented and resolved in a timely manner Add comments as needed. 			
Operations Director, Area Laboratory	<ul style="list-style-type: none"> Review reports and follow up actions to date. Add comments as needed. 			

CALIBRATION VERIFICATION, Continued

HISTORY PAGE

Change type: New, major, minor	Changes made to SOP - describe	Signature responsible person/date	Laboratory Director review/date	Laboratory Manager review/date	Date change implemented
New			JAC 7/27/04	JAC 7/27/04	06/28/04
Minor	add cal schedule, main lab to order and store cal reagents/kits, and deadline to submit cal data for analysis	10/26/10	JAC 10/28/10	JAC 10/27/10	10/29/10
		wt			
Minor	updated management title	wt 5/22/12	JAC 7/10/12	JAC 7/10/12	7/10/12
Minor	Remove 150f	N 11/4/14	JAC 12/1/14	JAC 12/1/14	12/8/14
Minor	Update policy. Added list of analytes for calibration verification and added calibration verification Review form	Atteyari 9/15/15	JAC 9/21/15	JAC 9/15/15	