CALIBRATION AND CALIBRATION VERIFICATION

Safety Message

Use universal precautions when handling patient samples or human source derived calibration verification material.

Purpose

To define Calibration, Calibration Verification and performance frequency.

Introduction

Calibration and calibration verification procedures are required to substantiate the continued accuracy of the test method throughout the laboratory's reportable range for patient test results.

Definitions

CALIBRATION is the set of operations that establish, under specified conditions, the relationship between reagent system/instrument response and the corresponding concentration/activity values of analyte.

CALIBRATION VERIFICATION denotes the process of confirming that the current calibration settings remain valid for a method.

Policy

Calibration is performed:

- When a change of reagent lots for chemically or physically active or critical components occurs, unless the laboratory can demonstrate that the use of different lots does not affect the accuracy of patient/client test data.
- If QC fails to meet established criteria.
- After all maintenance or service.
- When recommended by the manufacturer.
- Using manufacturer specified calibration material.
- And instrument systems automatically perform checks on the calibration and produce data at the end of the calibration. In the event of a failed calibration the data will be printed with error codes and the system will alert the operator of the failure.

Calibration Verification is performed:

- Every six months for assays with less than 3 levels of calibrators (spanning low, mid-point, high of AMR).
- When recommended by the manufacturer.
- And accepted when results of study fall within total allowable error for the assay.
- Using materials that have a matrix appropriate for the clinical specimens assayed by that method and target values appropriate for the measurement system. Suitable materials may include, but are not limited to:
    - Calibrators used to calibrate the analytical system
    - Materials provided by the analytical measurement system vendor for the purpose of calibration verification.
    - Previously tested unaltered patient specimens
    - Primary or secondary standards or reference materials with matrix characteristics and target values appropriate for the method.
    - Proficiency testing material or proficiency testing validated material with matrix characteristics and target values appropriate for the method.
- If results do not fall within acceptable limits, calibration of assay is performed.

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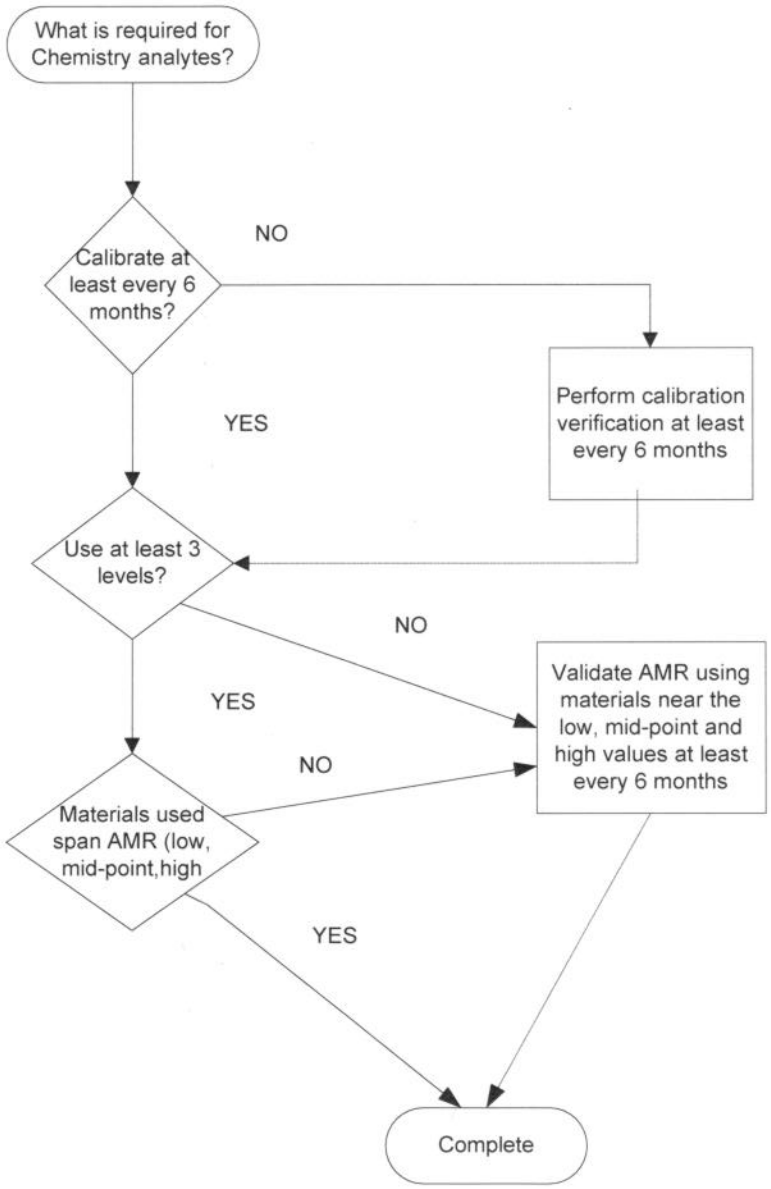
Flowsheet



CALIBRATION AND CALIBRATION VERIFICATION

ATTACHMENT A

CHEMISTRY CALIBRATION VERIFICATION

	Instrument	Assay	Product	
1	DXC800	CRPH	Maine Stds	CM2
2	DXC800	CSF PROTEIN	Maine Stds	Body Fluid
3	DXC800	Albumin	Maine Stds	GC1
4	DXC800	BUN	Maine Stds	GC1
4	DXC800	Calcium	Maine Stds	GC1
5	DXC800	Chloride	Maine Stds	GC1
6	DXC800	Creatinine	Maine Stds	GC1
7	DXC800	Glucose	Maine Stds	GC1
8	DXC800	Lactic Acid	Maine Stds	GC1
9	DXC800	Magnesium	Maine Stds	GC1
10	DXC800	Phophorus	Maine Stds	GC1
11	DXC800	T Protein	Maine Stds	GC1
12	DXC800	Uric Acid	Maine Stds	GC1
13	DXC800	Alcohol	Maine Stds	GC2
14	DXC800	Ammonia	Maine Stds	GC2
15	DXC800	CO2	Maine Stds	GC2
16	DXC800	ALP	Maine Stds	GC3
17	DXC800	ALT	Maine Stds	GC3
18	DXC800	AST	Maine Stds	GC3
19	DXC800	CK	Maine Stds	GC3
20	DXC800	LDH	Maine Stds	GC3
21	DXC800	Lipase	Maine Stds	GC3
22	DXC800	D Bili	Maine Stds	GC4
23	DXC800	T Bili	Maine Stds	GC4
24	DXC800	UR CL	Maine Stds	UC1
25	DXC800	UR CREAT	Maine Stds	UC4
26	Model 3320 Osmometer	UR OSM	Maine Stds	OSMO
27	Model 3320 Osmometer	OSMOs	Maine Stds	OSMO
28	DXC800	SAL	Maine Stds	TDM 1
29	Roche AVL 9180	I-CA	Verichem	9200

CALIBRATION AND CALIBRATION VERIFICATION

References

- CAP Chemistry and Toxicology Checklist, 01-04-2012.
- Chemistry Information Sheets, Synchron DxC analyzer, Beckman Coulter.
- Chemistry Information Sheets, Access Immunoassay Systems, Beckman Coulter.
- 9180 Electrolyte Analyzer, Roche Diagnostics, Rev. 5.0, March 2008.
- The Advanced® Micro-Osmometer, Model 3320, User's Guide, Advanced Instruments, Rev 6, 2005.

Attachment

- Attachment A: Table of Analytes requiring Calibration Verification at least every 6 months and appropriate Calibration Verification Material

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Document History Page

Effective Date: 09/04/92

Change type: New, Major, Minor etc.	Changes Made to SOP – describe	Signature responsible person/date	Lab Manager reviewed/ date	Med. Director Reviewed/ Date	Date change implemented
Minor	New format.	A. Dabir 2-16-04	N. Muneno 2-17-04	R.H. Doshi, MD 02-18-04	N/A
Major	• Updated table to reflect current assays.	M.Acosta 09-25-12	N.Muneno 09-25-12	S.Wirio M.D. 09-25-12	09-25-12
Major	• Updated table Attachment "A" to reflect current products.	7/16/18	7.19.18	7/22/18	