TRAINING UPDATE

Lab Location:	All	**Date Distributed:**	5/2/3013
Department:	Technical Supervisors & Group Leads	**Due Date:**	5/31/3013
		Implementation:	**6/1/2013**

DESCRIPTION OF PROCEDURE

Name of procedure:
Calibration and AMR Verification GEC/ SGAH/ WAH.QA48 v000
Description of change(s):
New SOP to describe our existing process to calibrate and verify AMR. (A written SOP is required by CAP) This SOP will be implemented on June 1, 2013

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

Approved draft for training all sites (version 000)

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:	

Review:		
Print Name	**Signature**	**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 is required at least every six months or more frequently if recommended by the manufacturer or according to the laboratory's established schedule when:

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

Calibration or AMR verification is not required when:

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- 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: 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% below enzyme immunoassay cutoff levels.
- For blood gas analysis, the laboratory must perform calibration and calibration verification procedures in accordance with the manufacturer's instructions.
  Note: If the blood gas analyzer performs other analytes (i.e. electrolytes, hemoglobin), calibration verification procedures are required for those analytes.

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

2. SCOPE

This procedure applies to Quest Diagnostics Incorporated at Adventist Healthcare System Laboratories

3. RESPONSIBILITY

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

The departmental 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.

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.

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 **Expand** users have the ability to program the assays as *XQC* and *Serum QC3*, then select the assay three consecutive times (i.e. TSH, TSH, TSH, FT4, FT4, FT4). The Dimension **Vista** has a calibration verification function pre-configured.
   - It is important to ensure adequate sample volume is placed on the instrument to complete all assigned testing in a single run.

5. The Medical Director approves the calibration acceptability criteria for each point for each assay.

6. Evaluate the results for each point and for each assay against the established criteria. 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.

6. RELATED DOCUMENTS

1. NCCLS Publication: Calibration Materials in Clinical Chemistry; Tentative Guideline (C22-T, 1982)
2. QA Recurring Calendar

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 January12, 2004.

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By

9. ADDENDA AND APPENDICES

A. Dimension Vista Calibration Verification Summary
B. Dimension Xpand Calibration Verification Summary

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APPENDIX A

Dimension Vista Calibration Verification Summary

Test	Calibrator	Cal. Levels	Cal. Type	Cal. Stability	Linearity Values Tested *	AMR	Units
ALC	Chem 3 Cal.	2	Linear	3 mo.		3-300	mg/dL
ALB	Chem 4 Cal.	2	Linear	3 mo.		0.0-8.0	g/dL
AMON	Chem 3 Cal.	2	Linear	3 mo.		25-1000	µmol/L
ACTM	Drug 2 Cal.	2	Linear	3 mo.		2.0-300.0	µg/mL
ALP	ALP Cal.	2	Verifier	3 mo.		4-1000	U/L
ALTI	ENZ 2 Cal.	2	Verifier	3 mo.		6-1000	U/L
AMY	ENZ 1 Cal.	2	Verifier	3 mo.		2-650	U/L
AST	ENZ 2 Cal.	2	Verifier	3 mo.		3-1000	U/L
BUN	Chem 1 Cal.	2	Linear	3 mo.		0-150	mg/dL
CA	Chem 1 Cal.	2	Linear	3 mo.		5.0-15.0	mg/dL
CREA	Chem 1 Cal.	2	Linear	3 mo.		0.1-20.0	mg/dL
Cl	Standard A & B	2	Linear	4 hrs		50-200	mmol/L
CO2	Chem 3 Cal.	2	Linear	3 mo.		1-45	mmol/L
CHOL	Chem 1 Cal.	2	Linear	3 mo.		50.0-600.0	mg/dL
CRP	PROT 2 Cal.	7	Logit	45 days		0.3-19.0	mg/dL
CRBM	Drug 2 Cal.	5	Logit	1 mo.		0.5-20.0	µg/mL
CTNI	CTNI Cal.	6	Logit	1 mo.		0.02-40.00	ng/mL
CKI	ENZ 6 Cal.	2	Verifier	3 mo.		7-1000	U/L
DGNA	Drug 4 Cal.	5	Logit	1 mo.		0.06-5.00	ng/mL
DBIL	BILI Cal.	2	Linear	3 mo.		0.1-16.0	mg/dL
FT4	LOCI 1 Cal.	5	Logit	30 days		0.10-8.00	ng/dL
GLUC	Chem 1 Cal.	2	Linear	3 mo.		1-500	mg/dL
GENT	Drug 2 Cal.	5	Logit	1 mo.		0.2-12.0	µg/mL
GGT	ENZ 1 Cal.	2	Verifier	3 mo.		3-800	U/L
HA1C	HbA1c Cal.	5	Logit	30 days		3.5-16.0	%
HDLC	LIPID Cal.	2	Linear	3 mo.		3-150	mg/dL
HCG	BHCG Cal.	6	Logit	1 mo.		1-1000	mIU/mL
K	Standard A & B	2	Linear	4 hrs		1.0-10.0	mmol/L
LA	Chem 1 Cal.	2	Linear	3 mo.		0.1-15.0	mmol/L
LDI	ENZ 5 Cal.	2	Verifier	3 mo.		6-1000	U/L
LIPL	ENZ 1 Cal.	2	Linear	45 days		10-1500	U/L
LI	Drug 1 Cal.	5	Logit	2 mo.		0.2-5.0	mmol/L
MMB	MMB Cal.	6	Logit	1 mo.		0.5-300.0	ng/mL
MYO	MYO Cal.	6	Logit	1 mo.		1-1000	ng/mL
MG	Chem 1 Cal.	2	Linear	3 mo.		0.2-20.0	mg/dL
Na	Standard A & B	2	Linear	4 hrs		50-200	mmol/L
PHOS	Chem 2 Cal.	2	Linear	3 mo.		0.1-9.0	mg/dL
PHNO	Drug 1 Cal.	5	Logit	1 mo.		2.1-80.8	µg/mL
PTN	Drug 1 Cal.	5	Logit	1 mo.		0.4-40.0	ug/mL
SAL	Chem 2 Cal.	2	Linear	3 mo.		1.7-100	mg/dL
TBIL	BILI Cal.	2	Linear	3 mo.		0.1-25.0	mg/dL

* Values are specific to the lot of calibration material and are added prior to testing

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APPENDIX A

Dimension Vista Calibration Verification Summary (Continued)

Test	Calibrator	Cal. Levels	Cal. Type	Cal. Stability	Linearity Values Tested *	AMR	Units
TP	Chem 4 Cal.	2	Linear	3 mo.		0.0-12.0	g/dL
TGL	Chem 2 Cal.	2	Linear	3 mo.		2-1000	mg/dL
TOBR	Drug 2 Cal.	5	Logit	1 mo.		0.3-12.0	µg/mL
THEO	Drug 1 Cal.	5	Logit	1 mo.		2.0-40.0	ug/mL
TSH	LOCI 1 Cal.	5	Logit	30 days		0.01-100.00	µIU/mL
UCFP	UCFP Cal.	5	Logit	2 mo.		5-250	mg/dL
URCA	Chem 1 Cal.	2	Linear	3 mo.		0.2-15.0	mg/dL
U. Creat.	Chem 1 Cal.	2	Linear	3 mo.		0.1-200.0	mmol/L
Urine K	Standard A & B	2	Linear	4 hours		1.0-300.0	mmol/L
Urine Na	Standard A & B	2	Linear	4 hours		5-300	mmol/L
Urine TP	Chem 4 Cal.	2	Linear	3 mo.		5-250	mg/dL
VALP	Drug 2 Cal.	5	Logit	1 mo.		3.0-150.0	µg/mL
VANC	Drug 2 Cal.	5	Logit	1 mo.		0.8-50.0	µg/mL
AMPH	UDAT Cal.	5	Logit	1 mo.		N/A	N/A
BARB	UDAT Cal.	5	Logit	1 mo.		N/A	N/A
BENZ	UDAT Cal.	5	Logit	1 mo.		N/A	N/A
COC	UDAT Cal.	5	Logit	1 mo.		N/A	N/A
OPI	UDAT Cal.	5	Logit	1 mo.		N/A	N/A
PCP	UDAT Cal.	5	Logit	1 mo.		N/A	N/A
THC	UDAT Cal.	5	Logit	1 mo.		N/A	N/A
OSMO	OSMO Cal.	5	Logit	3 mo.		50-2000	mOsm/Kg
BNP	BNP Cal.	5	Logit	42 days		2.0-5000.0	pg/mL
iPTH	iPTH Cal.	5	Logit	14 days		2.5-1900	pg/mL

* Values are specific to the lot of calibration material and are added prior to testing

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APPENDIX B

Dimension Xpand Calibration Verification Summary

Test	Calibrator	Cal. Levels	Cal. Type	Cal. Stability	Linearity Values Tested *	AMR	Units
ALC	ALC Cal.	3	Linear	3 mo.		0-300	mg/dL
ALB	TP/ALB Cal.	3	Linear	3 mo.		0.6-8.0	g/dL
ACTM	Drug II Cal.	3	Linear	3 mo.		1.7-300.0	µg/mL
ALP	ENZ VER Cal.	3	Verifier	3 mo.		11-1000	U/L
ALT	ENZ VER Cal.	3	Verifier	3 mo.		0-1000	U/L
AMY	ENZ VER Cal.	3	Verifier	3 mo.		0-650	U/L
AST	ENZ VER Cal.	3	Verifier	3 mo.		0-1000	U/L
BUN	Chem I Cal.	3	Linear	1 mo.		0-150	mg/dL
CA	Chem I Cal.	3	Linear	3 mo.		5-15	mg/dL
CREA	Chem I Cal.	3	Linear	3 mo.		0-20	mg/dL
CK	CK VER Cal.	3	Verifier	3 mo.		7-1000	U/L
CTNI	CTNI Cal.	5	Logit	2 mo.		0.04-40	ng/mL
CRP	CRP Cal.	5	Logit	2 mo.		0.2-12	mg/dL
Cl	IMT	2	Linear	2 hrs		50-200	mmol/L
DBIL	TBIL/DBIL Cal.	3	Linear	3 mo.		0-20	mg/dL
ECO2	ECO2 Cal.	3	Linear	3 mo.		5-45	mmol/L
GLUC	Chem I Cal.	3	Linear	3 mo.		0-500	mg/dL
HCG	HCG Cal.	5	Logit	2 mo.		1-1000	mIU/mL
K	IMT	2	Linear	2 hrs		1-10	mmol/L
LIPL	LIPL Cal.	3	Linear	45 days		50-1500	U/L
LA	Chem I Cal.	3	Linear	3 mo.		0.3 - 15	mmol/L
MG	Chem II Cal.	3	Linear	3 mo.		0-20	mg/dL
MMB	MMB Cal.	5	Logit	2 mo.		0.5-300	ng/mL
Na	IMT	2	Linear	2 hrs		50-200	mmol/L
SAL	SAL Cal.	3	Linear	3 mo.		0.2-100	mg/dL
TBIL	TBIL/DBIL Cal.	3	Linear	3 mo.		0-25	mg/dL
TP	TP/ALB Cal.	3	Linear	3 mo.		2-12	g/dL
TSH	THY Cal.	5	Logit	2 mo.		0.01-50.0	µIU/mL

* Values are specific to the lot of calibration material and are added prior to testing

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