TRAINING UPDATE

Lab Location:	All	**Date Distributed:**	7/1/2015
Department:	Mgmt (technical) & QA	**Due Date:**	7/29/2015
		Implementation:	**7/29/2015**

DESCRIPTION OF REVISION

Name of procedure:
Calibration and AMR Verification GEC /SGAH /WAH.QA48 v1
Description of change(s):
Section 6: update titles Section 9: update test lists This revised SOP will be implemented on July 29, 2015.

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

Approved draft for training (version 1)

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**

Form revised 3/31/00

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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 procedure 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 **Xpand** 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. 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. 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 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 zero's dropped due to new EDCS in use as of 10/7/13	L Barrett	R SanLuis

9. ADDENDA AND APPENDICES

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

APPENDIX A

Dimension Vista / Chemistry Calibration Verification Summary

Test Code	Reagent / Flex	Calibrator	Cal. Levels	Cal. Type	Cal. Stability	Linearity Values *	AMR	Units
ACTMP	ACTM	Drug 2 Cal.	2	Linear	3 mo.		2.0-300.0	µg/mL
ALB	ALB	Chem 4 Cal.	2	Linear	3 mo.		0.0-8.0	g/dL
ALCO	ETOH	Chem 3 Cal.	2	Linear	1 mo.		3-300	mg/dL
ALKPH	ALPI	ALPI Cal.	2	Verifier	3 mo.		10-1000	U/L
AMYL	AMY	ENZ 1 Cal.	2	Verifier	3 mo.		2-650	U/L
BUN	BUN	Chem 1 Cal.	2	Linear	1 mo.		1-150	mg/dL
CA	CA	Chem 1 Cal.	2	Linear	3 mo.		5.0-15.0	mg/dL
CHOL	CHOL	Chem 1 Cal.	2	Linear	3 mo.		50-600	mg/dL
CKMB	MMB	MMB Cal.	6	Logit	1 mo.		0.5-300.0	ng/mL
CL	V-LYTE	Standard A & B	2	Linear	4 hrs		50-200	mmol/L
CO2	CO2	Chem 3 Cal.	2	Linear	3 mo.		1 - 45	mmol/L
CPK	CKI	ENZ 6 Cal.	2	Verifier	3 mo.		7-1000	U/L
CRBM	CRBM	Drug 2 Cal.	5	Logit	1 mo.		0.5-20.0	µg/mL
CREAT	CREA	Chem 1 Cal.	2	Linear	3 mo.		0.1-20.0	mg/dL
CRP	CRP	PROT 2 Cal.	7	Logit	45 days		0.3-19.0	mg/dL
DBIL	DBIL	BILI Cal.	2	Linear	3 mo.		0.1-16.0	mg/dL
DIG	DIGXN	Drug 4 Cal.	5	Logit	1 mo.		0.06-5.00	ng/mL
FE	IRON	IRON Cal.	2	Linear	3 mo.		5-1000	µg/dL
FERIT	FERR	LOCI 4 Cal.	5	Logit	1 mo.		0.5-2000	ng/mL
FOLAC	Folate	LOCI 4 Cal.	5	Logit	1 mo.		0.5-20.0	ng/mL
FT4	FT4	LOCI 1 Cal.	5	Logit	30 days		0.10-8.00	ng/dL
GENR	GENT	Drug 2 Cal.	5	Logit	1 mo.		0.2-12.0	µg/mL
GGT	GGT	ENZ 1 Cal.	2	Verifier	3 mo.		3-800	U/L
GLUC	GLU	Chem 1 Cal.	2	Linear	3 mo.		1-500	mg/dL
HCGQ	BHCG	BHCG Cal.	6	Logit	1 mo.		1-1000	mIU/mL
HDL	HDLC	LIPID Cal.	2	Linear	3 mo.		3-150	mg/dL
K	V-LYTE	Standard A & B	2	Linear	4 hrs		1.0-10.0	mmol/L
LACT	LA	Chem 1 Cal.	2	Linear	3 mo.		0.1-15.0	mmol/L
LDH	LDI	ENZ 5 Cal.	2	Verifier	3 mo.		6-1000	U/L
LI	LITH	Drug 4 Cal.	5	Logit	2 mo.		0.20-3.00	mmol/L
LIPA	LIPL	ENZ 1 Cal.	2	Linear	45 days		10-1500	U/L
MG	MG	Chem 1 Cal.	2	Linear	3 mo.		0.2-20.0	mg/dL
MYOGL	MYO	MYO Cal.	6	Logit	1 mo.		1-1000	ng/mL
NH3	AMM	Chem 3 Cal.	2	Linear	2 mo.		10-750	µmol/L
PHENB	PHNO	Drug 1 Cal.	5	Logit	1 mo.		2.1-80.8	µg/mL
PHOS	PHOS	Chem 2 Cal.	2	Linear	3 mo.		0.1-9.0	mg/dL
PRALB	Prealbumin	PROT1 Cal.	6	Logit	1 mo.		3 - 60	mg/dL
PSAT	TPSA	PSA Cal.	6	Logit	1 mo.		0.1-100.0	ng/mL
PTN	PTN	Drug 1 Cal.	5	Logit	1 mo.		0.4-40.0	ug/mL

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

APPENDIX A

Dimension Vista Calibration Verification Summary (Continued)

Test Code	Reagent / Flex	Calibrator	Cal. Levels	Cal. Type	Cal. Stability	Linearity Values *	AMR	Units
SALIC	SAL	Chem 2 Cal.	2	Linear	3 mo.		1.7-100.0	mg/dL
SGOT	AST	ENZ 2 Cal.	2	Verifier	3 mo.		3-1000	U/L
SGPT	ALTI	ENZ 2 Cal.	2	Verifier	3 mo.		6-1000	U/L
SOD	V-LYTE	Standard A & B	2	Linear	4 hrs		50-200	mmol/L
TBIL	TBIL	BILI Cal.	2	Linear	3 mo.		0.1-25.0	mg/dL
THEO	THEO	Drug 1 Cal.	5	Logit	1 mo.		2.0-40.0	ug/mL
TIBCP	TIBC	TIBC Cal.	2	Linear	3 mo.		8-1000	µg/dL
TOBR	TOBR	Drug 2 Cal.	5	Logit	1 mo.		0.3-12.0	µg/mL
TP	TP	Chem 4 Cal.	2	Linear	3 mo.		0.0-12.0	g/dL
TRIG	TRIG	Chem 2 Cal.	2	Linear	3 mo.		2-1000	mg/dL
TROPI	CTNI	CTNI Cal.	6	Logit	1 mo.		0.02-40.00	ng/mL
TSH	TSH	LOCI 1 Cal.	6	Logit	30 days		0.01-100.00	µIU/mL
UCRR	CREA	Chem 1 Cal.	2	Linear	3 mo.		0.1-200.0	mg/dL
UKR	V-LYTE	Standard A & B	2	Linear	4 hours		1.0-300.0	mmol/L
UNAR	V-LYTE	Standard A & B	2	Linear	4 hours		5-300	mmol/L
URIC	URCA	Chem 1 Cal.	2	Linear	3 mo.		0.2-15.0	mg/dL
UTPR, CTP	UCFP	UCFP Cal.	5	Logit	2 mo.		5-250	mg/dL
VALP	VALP	Drug 2 Cal.	5	Logit	1 mo.		3.0-150.0	µg/mL
VANR	VANC	Drug 2 Cal.	5	Logit	1 mo.		0.8-50.0	µg/mL
VTB12	VB12	LOCI 4 Cal.	5	Logit	21 days		60-2000	pg/mL
UAMPT	AMPH	UDAT Cal.	5	Logit	1 mo.		N/A	N/A
UBART	BARB	UDAT Cal.	5	Logit	1 mo.		N/A	N/A
UBENZT	BENZ	UDAT Cal.	5	Logit	1 mo.		N/A	N/A
UCOCT	COC	UDAT Cal.	5	Logit	1 mo.		N/A	N/A
UOPIT	OPI	UDAT Cal.	5	Logit	1 mo.		N/A	N/A
UPCPT	PCP	UDAT Cal.	5	Logit	1 mo.		N/A	N/A
UTHCT	THC	UDAT Cal.	5	Logit	1 mo.		N/A	N/A
OSMO, UOSMO	N/A	OSMO Cal. Stds	3	Logit	3 mo.		50-2000	mOsm/Kg
BNPT	BNP	BNP Cal.	5	Logit	28 days		2 - 5000	pg/mL
IPTH	iPTH	iPTH Cal.	5	Logit	14 days		6.3-1900.0	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 Code	Reagent / Flex	Calibrator	Cal. Levels	Cal. Type	Cal. Stability	Linearity Values *	AMR	Units
ALCO	ETOH	Chem III Cal.	3	Linear	3 mo.		3-300	mg/dL
ALB	ALB	TP/ALB Cal.	3	Linear	3 mo.		0.6-8.0	g/dL
ACTMP	ACTM	Drug II Cal.	3	Linear	3 mo.		0.0-300.0	µg/mL
ALKPH	ALPI	ALPI Cal.	3	Verifier	3 mo.		10-1000	U/L
SGOT	ALTI	ENZ II Cal.	3	Verifier	3 mo.		6-1000	U/L
AMYL	AMY	ENZ VER Cal.	3	Verifier	3 mo.		0-650	U/L
SGPT	AST	ENZ VER Cal.	3	Verifier	3 mo.		0-1000	U/L
BUN	BUN	Chem I Cal.	3	Linear	1 mo.		0-150	mg/dL
CA	CA	Chem I Cal.	3	Linear	3 mo.		5.0-15.0	mg/dL
CREAT	CREA	Chem I Cal.	3	Linear	3 mo.		0.0-20.0	mg/dL
CPK	CKI	CKI/MMI Cal.	3	Verifier	3 mo.		7-1000	U/L
TROPI	CTNI	CTNI Cal.	5	Logit	2 mo.		0.04-40.00	ng/mL
CRP	CRP	CRP Cal.	5	Logit	2 mo.		0.2-12.0	mg/dL
CL	QuikLYTE	Standard A & B	2	Linear	2 hrs		50-200	mmol/L
DBIL	DBI	TBI/DBI Cal.	3	Linear	3 mo.		0.1-16.0	mg/dL
CO2	ECO2	Chem III Cal.	3	Linear	3 mo.		5 - 45	mmol/L
GLUC	GLUC	Chem I Cal.	3	Linear	3 mo.		0-500	mg/dL
HCGQ	HCG	HCG Cal.	5	Logit	2 mo.		1-1000	mIU/mL
K	QuikLYTE	Standard A & B	2	Linear	2 hrs		1 - 10	mmol/L
LIPA	LIPL	LIPL Cal.	3	Linear	45 days		10-1500	U/L
LACT	LA	Chem I Cal.	3	Linear	3 mo.		0.3 - 15.0	mmol/L
MG	MG	Chem II Cal.	3	Linear	3 mo.		0.0-20.0	mg/dL
CKMB	MMB	MMB Cal.	5	Logit	2 mo.		0.5-300.0	ng/mL
SOD	QuikLYTE	Standard A & B	2	Linear	2 hrs		50-200	mmol/L
SALIC	SAL	SAL Cal.	3	Linear	3 mo.		0.2-100	mg/dL
TBIL	TBI	TBI/DBI Cal.	3	Linear	3 mo.		0.1-25.0	mg/dL
TP	TP	TP/ALB Cal.	3	Linear	3 mo.		2.0-12.0	g/dL
TSH	TSH	THY Cal.	5	Logit	2 mo.		0.01-50.0	µIU/mL
UTPR, CTP	UCFP	UCFP Cal.	5	Logit	2 mo.		6 - 250	mg/dL

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

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