## TRAINING UPDATE

Lab Location: **Department:** 

GEC, SGMC & WOMC Core & QA

**Date Distributed: Due Date:** 

8/17/2021 9/17/2021

### **DESCRIPTION OF REVISION**

Name of procedure:

# **Calibration and AMR Verification AHC.QA48 v4**

**Atellica / Chemistry Calibration Verification Summary SGMC AG.F618.1** 

Vista / Chemistry Calibration Verification Summary WOMC AG.F619.1

**EXL Calibration Verification Summary GEC AG.F620.1** 

**Description of change(s):** 

# SOP -

Header: removed specific labs, added All Labs Section 4: added recurring calendar Section 5: deleted calendar, added calibration summaries Section 9: deleted summaries (added to section 6) Footer: changed prefix to AHC

# Forms -

The charts were originally appendices attached at the end of the SOP and were outdated because of chemistry instrument changes at GEC & SG.

They have been re-formatted as 'forms' to provide easier access and updating, if necessary.

The revised SOP will be implemented Aug 25, 2021.

The charts were implemented on Aug 5, 2021

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 |  |  |  |  |
| <i>Refer to the electronic signature page for approval and approval dates.</i> |                       |      |  |  |  |  |
| 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;

- 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:

- 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.

### **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.
- 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. Atellica / Chemistry Calibration Verification Summary (AG.F618)
- 4. Vista / Chemistry Calibration Verification Summary (AG.F619)
- 5. EXL Calibration Verification Summary (AG.F620)

6. QA Recurring Calendar (AG.F347)

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

#### 9. ADDENDA AND APPENDICES

A. Dimension Vista / Chemistry Calibration Verification Summary
 B. Dimension Xpand Calibration Verification Summary
 None



| SGMC  |
|---|
| Atellica / Chemistry Calibration Verification Summary |

| Test<br>Code | Reagent                      | Calibrator             | Cal.<br>Levels | Lot<br>Calibration<br>Interval | Reagent<br>Pack<br>Calibration<br>Interval* | AMR        | Units   |
|--------------|------------------------------|------------------------|----------------|--------------------------------|---|------------|---------|
| ACTMP        | Acet                         | TOX CAL                | 1              | 62 days                        | 1 day                                       | 2.0-200.0  | μg/mL   |
| ALB          | Alb                          | CHEM CAL               | 1              | 97 days                        | 60 days                                     | 1.0-6.0    | g/dL    |
| ALCO         | ЕТОН                         | TOX CAL                | 1              | 60 days                        | 10 days                                     | 3-300      | mg/dL   |
| ALKPH        | ALP-2c                       | ALP-2 Cal              | 1              | 60 days                        | 17 days                                     | 10-1000    | U/L     |
| AMKR         | Amikacin<br>(EMIT)           | Amikacin<br>Calibrator | 5              | 19 days                        | 19 days                                     | 2.5-50.0   | μg/mL   |
| AMYL         | AMY-2                        | SPCL CHEM CAL          | 1              | 62 days                        | 31 days                                     | 20-1500    | U/L     |
| BUN          | UN-C                         | CHEM CAL               | 1              | 75 days                        | 6 days                                      | 1-150      | mg/dL   |
| CA           | CA-2                         | CHEM CAL               | 1              | 180 days                       | 63 days                                     | 1.0-16.0   | mg/dL   |
| CHOL         | Chol-2                       | CHEM CAL               | 1              | 50 days                        | 7days                                       | 25-618     | mg/dL   |
| CKMB         | СКМВ                         | CKMB Cal               | 2              | 66 days                        | 28 days                                     | 0.2-300.0  | ng/mL   |
| CL           | A-LYTE                       | A-Lyte Std A & B       | 2              | Every 4 hours                  | 1 pt cal with every sample.                 | 50-200     | mmol/L  |
| CO2          | CO2_c                        | CO2 CAL                | 1              | 30 days                        | 6 days                                      | 10 - 40    | mmol/L  |
| СРК          | CK-L                         | ENZ 3 Cal.             | 1              | 202 days                       | 21 days                                     | 7-1000     | U/L     |
| CRBM         | Carb                         | DRUG CAL 2             | 5              | 30 days                        | 7 days                                      | 0.5-20.0   | μg/mL   |
| CREAT        | Crea-2                       | CH CHEM CAL            | 1              | 180 days                       | 6 days                                      | 0.15-30.00 | mg/dL   |
| CRP          | CRP-2                        | CRP-2 Cal              | 6              | 60 days                        | 30 days                                     | 0.4-30.4   | mg/dL   |
| DBIL         | DBil-2                       | CH CHEM CAL            | 1              | 60 days                        | 30 days                                     | 0.1-15.0   | mg/dL   |
| DIG          | Dgn                          | TDM CAL                | 6              | 60 days                        | 7 days                                      | 0.06-5.00  | ng/mL   |
| FE           | Iron - 2                     | CH CHEM CAL            | 1              | 180 days                       | 30 days                                     | 2 - 1000   | μg/dL   |
| FERIT        | Fer                          | CAL - C                | 2              | 50 days                        | 28 days                                     | 1-1650     | ng/mL   |
| FOLAC        | Fol                          | Fol CAL                | 2              | 14 days                        | 7 days                                      | 0.6-24.0   | ng/mL   |
| FT4          | FT4                          | CAL-A                  | 2              | 21 days                        | 7 days                                      | 0.10-12.00 | ng/dL   |
| GENR         | GENT                         | DRUG CAL II            | 5              | 30 days                        | 7 days                                      | 0.5-12.0   | μg/mL   |
| GGT          | GGT                          | ENZ 1 CAL              | 1              | 60                             | 22  | 7 - 1200   | U/L     |
| GLUC         | GluH-3                       | CH CHEM CAL            | 1              | 182                            | 30  | 4-700      | mg/dL   |
| A1C          | A1c-E                        | A1c-E CAL              | 3              | 180                            | 63  | 3.8-14.0   | % HbA1c |
| HCGQ         | ThCG                         | CAL B                  | 2              | 34                             | 28  | 3-1000     | mIU/mL  |
| HDL          | D-HDL                        | HDL/LDL CAL            | 1              | 60                             | 30  | 20 - 29    | mg/dL   |
| К            | A-LYTE                       | A-Lyte Std A & B       | 2              | Every 4<br>hours               | 1 pt cal with every sample                  | 1.0-10.0   | mmol/L  |
| LACT         | LAC-2                        | SPCL CHEM CAL          | 1              | 62                             | 30  | 0.1-12.2   | mmol/L  |
| LDH<br>FLD   | LDLP                         | ENZ 1 CAL              | 1              | 60                             | 28  | 14 - 750   | U/L     |
| LI           | Li                           | CHEM CAL               | 1              | 63                             | 4   | 0.10-3.00  | mmol/L  |
| LIPA         | Lip                          | ENZ 1CAL               | 1              | 61                             | 9   | 11-75      | U/L     |
| MG           | Mg                           | CHEM CAL               | 1              | 180                            | 3   | 0.5 - 5.0  | mg/dL   |
| MYOGL        | MYO                          | CAL U                  | 2              | 33                             | 14  | 10 - 92    | ng/mL   |
| NH3          | AMM                          | Chem III               | 3              | 30                             | 3   | 10 - 750   | µmol/L  |
| PHOS         | Inorganic<br>Phosphorus (IP) | CHEM CAL               | 1              | 180                            | 7   | 0.3-40.0   | mg/dL   |
| PHENB        | Phnb                         | DRUG CAL               | 5              | 30                             | 7   | 15.0-40.0  | µg/mL   |
| PRALB        | PreAlb                       | LSP CAL                | 6              | 60                             | 7   | 5-70       | mg/dL   |
| РСТ          | РСТ                          | PCT Calibrator         | 2              | 82                             | 35  | 0.04-50.00 | ng/mL   |
| PSAT         | PSA                          | CAL Q                  | 2              | 29                             | 28  | 0.0-100.0  | ng/mL   |
| PTN          | Phny                         | DRUG CAL               | 5              | 28                             | 7   | 2.0-40.0   | μg/mL   |



| Test<br>Code | Reagent                  | Calibrator               | Cal.<br>Levels | Lot<br>Calibration<br>Interval | Reagent<br>Pack<br>Calibration<br>Interval* | AMR         | Units  |
|--------------|--------------------------|--------------------------|----------------|--------------------------------|---|-------------|--------|
| SALIC        | Sal                      | CH TOX CAL               | 1              | 180                            | 21  | 3.0-100.0   | mg/dL  |
| SGOT         | AST                      | ENZ 2 CAL                | 1              | 131                            | 30  | 8-1000      | U/L    |
| SGPT         | ALT                      | ENZ 2 CAL                | 1              | 131                            | 30  | 7-1100      | U/L    |
| SOD          | A-LYTE                   | A-Lyte<br>Standard A & B | 2              | Every 4<br>hours               | 1 pt cal with<br>every sample               | 50-200      | mmol/L |
| TBIL         | TBil - 2                 | CHEM CAL                 | 1              | 60                             | 30  | 0.1-25.0    | mg/dL  |
| THEO         | Theo                     | DRUG CAL                 | 5              | 30                             | 7   | 2.0-40.0    | µg/mL  |
| TIBCP        | TIBC                     | SPCL CHEM CAL            | 1              | 180                            | 7   | 40-670      | μg/dL  |
| TOBR         | Tob                      | DRUG CAL II              | 5              | 30                             | 7   | 0.3-12.0    | µg/mL  |
| TP<br>FTP    | Total Protein II<br>(TP) | CHEM CAL                 | 2              | 181                            | 30  | 2.0-12.0    | g/dL   |
| TRIG         | Trig                     | CHEM CAL                 | 1              | 60                             | 14  | 10-550      | mg/dL  |
| TROPI1       | TnIH                     | TnIH CAL                 | 2              | 47                             | 31  | 3-25000     | pg/mL  |
| TSH          | TSH3-UL                  | TSH3U                    | 2              | 49                             | 63  | 0.01-150.00 | µIU/mL |
| UCRR         | Crea-2                   | CH CHEM CAL              | 2              | 180 day                        | 6 days                                      | 3.00-245.00 | mg/dL  |
| UKR          | A-LYTE                   | A-Lyte<br>Standard A & B | 2              | Every 4<br>hours               | 1 pt cal with<br>every sample               | 1.0-300.0   | mmol/L |
| UNAR         | A-LYTE                   | A-Lyte<br>Standard A & B | 2              | Every 4<br>hours               | 1 pt cal with<br>every sample               | 5-300       | mmol/L |
| URIC         | UA                       | CHEM CAL                 | 2              | 183                            | 7   | 0.5-20.0    | mg/dL  |
| CTP<br>UTPR  | UCFP                     | UCFP CAL                 | 5              | 60                             | 7   | 6-250       | mg/dL  |
| UAMPT        | AMP                      | Syva® Emit® cal          | 5              | 60 days                        | 20 days                                     | N/A         | N/A    |
| UBART        | BARB                     | Syva® Emit® cal          | 5              | 60 days                        | 20 days                                     | N/A         | N/A    |
| UBENZT       | BENZ                     | Syva® Emit® cal          | 5              | 60 days                        | 20 days                                     | N/A         | N/A    |
| UCOCT        | COC                      | Syva® Emit® cal          | 5              | 60 days                        | 20 days                                     | N/A         | N/A    |
| UOPIT        | OPI                      | Syva® Emit® cal          | 5              | 60 days                        | 20 days                                     | N/A         | N/A    |
| UPCPT        | РСР                      | Syva® Emit® cal          | 5              | 60 days                        | 20 days                                     | N/A         | N/A    |
| UTHCT        | ТНС                      | Syva® Emit® cal          | 5              | 60 days.                       | 20 days                                     | N/A         | N/A    |
| VALP         | VPA                      | DRUG CAL II              | 5              | 30                             | 7   | 3.0-150.0   | μg/mL  |
| VANR         | Vanc                     | DRUG CAL II              | 5              | 30                             | 7   | 3.0-50.0    | μg/mL  |
| VTB12        | VB12                     | CAL C                    | 2              | 30                             | 18  | 42-2000     | pg/mL  |

SGMC Atellica / Chemistry Calibration Verification Summary

#### **OSMOMETER**

| OSMO,<br>UOSMO | N/A | OSMO Cal. Stds | 3 | 3 mo. |  | 50-2000 | mOsm/kg |
|----------------|-----|----------------|---|-------|--|---------|---------|
|----------------|-----|----------------|---|-------|--|---------|---------|

Linearity values are specific to the lot of calibrator and are added prior to testing.

\*At the end of the on-board reagent pack calibration interval (stability), replace the pack. Recalibration is not required unless the lot calibration interval is exceeded.



## **WOMC** Vista / Chemistry Calibration Verification Summary

| Test Code | Reagent /<br>Flex | Calibrator     | Cal.<br>Levels* | Cal.<br>Stability | AMR            | Units  |
|-----------|-------------------|----------------|-----------------|-------------------|----------------|--------|
| ACTMP     | ACTM              | Drug 2 Cal.    | 2               | 3 mo.             | 2.0 - 300.0    | μg/mL  |
| ALB       | ALB               | Chem 4 Cal.    | 2               | 3 mo.             | 0.0 8.0        | g/dL   |
| ALCO      | ЕТОН              | Chem 3 Cal.    | 2               | 1 mo.             | 3 - 300        | mg/dL  |
| ALKPH     | ALPI              | ALPI Cal.      | 2               | 3 mo.             | 10 - 1000      | U/L    |
| AMKR      | Amikacin          | Amikacin Cal   | 5               | 14 days           | 2.5 - 50.0     | μg/mL  |
| AMYL      | AMY               | ENZ 1 Cal.     | 2               | 3 mo.             | 2 - 650        | U/L    |
| BUN       | BUN               | Chem 1 Cal.    | 2               | 1 mo.             | 1 - 150        | mg/dL  |
| СА        | CA                | Chem 1 Cal.    | 2               | 3 mo.             | 5.0 - 15.0     | mg/dL  |
| CHOL      | CHOL              | Chem 1 Cal.    | 2               | 3 mo.             | 50 - 600       | mg/dL  |
| СКМВ      | MMB               | MMB Cal.       | 6               | 1 mo.             | 1.0 - 300.0    | ng/mL  |
| CL        | V-LYTE            | Standard A & B | 2               | 4 hrs             | 50 - 200       | mmol/L |
| CO2       | CO2               | Chem 3 Cal.    | 2               | 3 mo.             | 1 - 45         | mmol/L |
| СРК       | CKI               | ENZ 6 Cal.     | 2               | 3 mo.             | 7 - 1000       | U/L    |
| CRBM      | CRBM              | Drug 2 Cal.    | 5               | 1 mo.             | 0.5 - 20.0     | μg/mL  |
| CREAT     | CRE2              | Chem 1 Cal.    | 2               | 3 mo.             | 0.1 - 20.00    | mg/dL  |
| CRP       | CRP               | PROT 2 Cal.    | 7               | 45 days           | 0.3 - 19.0     | mg/dL  |
| DBIL      | DBIL              | BILI Cal.      | 2               | 3 mo.             | 0.1 - 16.0     | mg/dL  |
| DIG       | DIGXN             | Drug 4 Cal.    | 5               | 1 mo.             | 0.06 -5.00     | ng/mL  |
| FT4       | FT4               | LOCI I Cal.    | 5               | 30 days           | 0.10 - 8.00    | ng/mL  |
| GENR      | GENT              | Drug 2 Cal.    | 5               | 1 mo.             | 0.2 - 12.0     | μg/mL  |
| GGT       | GGT               | ENZ 1 Cal.     | 2               | 3 mo.             | 3 - 800        | U/L    |
| GLUC      | GLU               | Chem 1 Cal.    | 2               | 3 mo.             | 1 - 500        | mg/dL  |
| HCGQ      | BHCG              | BHCG Cal.      | 6               | 1 mo.             | 1 - 1000       | mIU/mL |
| HDL       | HDLC              | LIPID Cal.     | 2               | 3 mo.             | 3 - 150        | mg/dL  |
| К         | V-LYTE            | Standard A & B | 2               | 4 hrs             | 1.0 - 10.0     | mmol/L |
| LACT      | LA                | Chem 1 Cal.    | 2               | 3 mo.             | 0.1-15.0       | mmol/L |
| LDH       | LDI               | ENZ 5 Cal.     | 2               | 3 mo.             | 6 - 1000       | U/L    |
| LI        | LITH              | Drug 4 Cal.    | 5               | 2 mo.             | 0.20 - 3.00    | mmol/L |
| LIPA      | LIPL              | ENZ 1 Cal.     | 2               | 45 days           | 10 - 1500      | U/L    |
| MG        | MG                | Chem 1 Cal.    | 2               | 3 mo.             | 0.3 - 10.0     | mg/dL  |
| NH3       | AMM               | Chem 3 Cal.    | 2               | 2 mo.             | 10 - 750       | µmol/L |
| PHOS      | PHOS              | Chem 2 Cal.    | 2               | 3 mo.             | 0.1 - 9.0      | mg/dL  |
| PTN       | PTN               | Drug 1 Cal.    | 5               | 1 mo.             | 0.4 - 40.0     | μg/mL  |
| SALIC     | SAL               | Chem 2 Cal.    | 2               | 3 mo.             | 1.7 - 100.0    | mg/dL  |
| SGOT      | AST               | ENZ 2 Cal.     | 2               | 3 mo.             | 3 - 1000       | U/L    |
| SGPT      | ALTI              | ENZ 2 Cal.     | 2               | 3 mo.             | 6 - 1000       | U/L    |
| SOD       | V-LYTE            | Standard A & B | 2               | 4 hrs             | 50 - 200       | mmol/L |
| TBIL      | TBIL              | BILI Cal.      | 2               | 3 mo.             | 0.1 -25.0      | mg/dL  |
| THEO      | THEO              | Drug 1 Cal.    | 5               | 1 mo.             | 2.0 - 40.0     | μg/mL  |
| ТР        | ТР                | Chem 4 Cal.    | 2               | 3 mo.             | 0.0 -12.0      | g/dL   |
| TRIG      | TRIG              | Chem 2 Cal.    | 2               | 3 mo.             | 2 - 1000       | mg/dL  |
| TROPI     | TNIH              | THIH CAL       | 5               | 30 days           | 4 - 25000      | pg/mL  |
| TSH       | TSH               | LOCI 1 Cal.    | 6               | 30 days           | 0.01-100.00    | µIU/mL |
| UCRR      | CRE2              | Chem 1 Cal.    | 2               | 3 mo.             | 13.00 - 300.00 | mg/dL  |



| Test Code | Reagent /<br>Flex | Calibrator       | Cal.<br>Levels* | Cal.<br>Stability | AMR         | Units  |
|-----------|-------------------|------------------|-----------------|-------------------|-------------|--------|
| UKR       | V-LYTE            | Standard A & B   | 2               | 4 hours           | 1.0 - 300.0 | mmol/L |
| UNAR      | V-LYTE            | Standard A & B   | 2               | 4 hours           | 5 - 300     | mmol/L |
| URIC      | URCA              | Chem 1 Cal.      | 2               | 3 mo.             | 0.2 - 15.0  | mg/dL  |
| UTPR, CTP | UCFP              | UCFP Cal.        | 5               | 2 mo.             | 5 - 250     | mg/dL  |
| VALP      | VALP              | Drug 2 Cal.      | 5               | 1 mo.             | 3.0 - 150.0 | μg/mL  |
| VANR      | VANC              | Drug 2 Cal.      | 5               | 1 mo.             | 0.8 - 50.0  | μg/mL  |
| UAMPT     | AMPH              | UDAT Cal.        | 5               | 1 mo.             | N/A         | N/A    |
| UBART     | BARB              | UDAT Cal.        | 5               | 1 mo.             | N/A         | N/A    |
| UBENZT    | BENZ              | UDAT Cal.        | 5               | 1 mo.             | N/A         | N/A    |
| UCOCT     | COC               | UDAT Cal.        | 5               | 1 mo.             | N/A         | N/A    |
| UOPIT     | OPI               | UDAT Cal.        | 5               | 1 mo.             | N/A         | N/A    |
| UPCPT     | РСР               | UDAT Cal.        | 5               | 1 mo.             | N/A         | N/A    |
| UTHCT     | THC               | UDAT Cal.        | 5               | 1 mo.             | N/A         | N/A    |
| UBUP      | XBUP              | Syva® Emit Cals. | 5               | 14 days           | N/A         | N/A    |
| UMETHD    | METH              | UDAT Cal.        | 5               | 30 days           | N/A         | N/A    |
| ESTRD     | Estradiol         | LOC 8 Cal.       | 5               | 30 days           | 11-1500     | pg/mL  |
| FSH       | FSH               | LOC 8 Cal.       | 5               | 30 days           | 0.2 - 200.0 | mIU/mL |
| LH        | LH                | LOC 8 Cal.       | 5               | 30 days           | 0.2 - 150.0 | mIU/mL |
| PROGES    | PROG              | PROG Cal.        | 5               | 7 days            | 0.2 - 40.0  | ng/mL  |

# WOMC Vista / Chemistry Calibration Verification Summary

#### OSMOMETER

| OSMO,<br>UOSMO N/A OSMO Cal. Stds | 3 | 3 mo. | 50 - 2000 | mOsm/kg |
|-----------------------------------|---|-------|-----------|---------|
|-----------------------------------|---|-------|-----------|---------|

#### VIDAS

| ( IDINS |      |           |   |         |              |       |
|---------|------|-----------|---|---------|--------------|-------|
| BNPT    | BNP  | BNP Cal.  | 5 | 28 days | 2 - 5000     | pg/mL |
| IPTH    | iPTH | iPTH Cal. | 5 | 14 days | 6.3 - 2000.0 | pg/mL |

\*Linearity values are specific to the lot of calibrator and are added prior to testing.



# GEC EXL Calibration Verification Summary

| Test Code | Reagent /<br>Flex | Calibrator     | Cal.<br>Levels* | Cal.<br>Stability | AMR         | Units  |
|-----------|-------------------|----------------|-----------------|-------------------|-------------|--------|
| ALCO      | ETOH              | Chem III Cal.  | 3               | 3 mo.             | 3-300       | mg/dL  |
| ALB       | ALB               | TP/ALB Cal.    | 3               | 3 mo.             | 0.6-8.0     | g/dL   |
| ACTMP     | ACTM              | Drug II Cal.   | 3               | 3 mo.             | 0.0-300.0   | μg/mL  |
| ALKPH     | ALPI              | ALPI Cal.      | 3               | 3 mo.             | 10-1000     | U/L    |
| SGOT      | ALTI              | ENZ II Cal.    | 3               | 3 mo.             | 6-1000      | U/L    |
| AMYL      | AMY               | ENZ VER Cal.   | 3               | 3 mo.             | 0-650       | U/L    |
| SGPT      | AST               | ENZ VER Cal.   | 3               | 3 mo.             | 0-1000      | U/L    |
| BUN       | BUN               | Chem I Cal.    | 3               | 1 mo.             | 0-150       | mg/dL  |
| CA        | CA                | Chem I Cal.    | 3               | 3 mo.             | 5.0-15.0    | mg/dL  |
| CREAT     | CRE2              | Chem I Cal.    | 3               | 3 mo.             | 0.15-20.00  | mg/dL  |
| СРК       | CKI               | CKI/MBI Cal.   | 3               | 3 mo.             | 7-1000      | U/L    |
| TROPI1    | TNIH              | TNIH Cal.      | 5               | 21 days.          | 4 - 25000   | pg/mL  |
| CRP       | CRP               | CRP Cal.       | 5               | 2 mo.             | 0.2-12.0    | mg/dL  |
| CL        | QuikLYTE          | Standard A & B | 2               | 2 hrs             | 50-200      | mmol/L |
| DBIL      | DBI               | TBI/DBI Cal.   | 3               | 3 mo.             | 0.1-16.0    | mg/dL  |
| CO2       | ECO2              | Chem III Cal.  | 3               | 3 mo.             | 5 - 45      | mmol/L |
| GLUC      | GLUC              | Chem I Cal.    | 3               | 3 mo.             | 0-500       | mg/dL  |
| HCGQ      | LHCG              | HCG Cal.       | 5               | 2 mo.             | 1-1000      | mIU/mL |
| Κ         | QuikLYTE          | Standard A & B | 2               | 2 hrs             | 1.0 - 10.0  | mmol/L |
| LIPA      | LIPL              | LIPL Cal.      | 3               | 45 days           | 10-1500     | U/L    |
| LACT      | LA                | Chem I Cal.    | 3               | 3 mo.             | 0.3 - 15.0  | mmol/L |
| MG        | MG                | Chem II Cal.   | 3               | 3 mo.             | 0.0-20.0    | mg/dL  |
| СКМВ      | LMMB              | MMB Cal.       | 5               | 60 days           | 0.5-300.0   | ng/mL  |
| SOD       | QuikLYTE          | Standard A & B | 2               | 2 hrs             | 50-200      | mmol/L |
| SALIC     | SAL               | SAL Cal.       | 3               | 3 mo.             | 1.7-100     | mg/dL  |
| TBIL      | TBI               | TBI/DBI Cal.   | 3               | 3 mo.             | 0.1-25.0    | mg/dL  |
| ТР        | ТР                | TP/ALB Cal.    | 3               | 3 mo.             | 2.0-12.0    | g/dL   |
| TSH       | TSHL              | LOCI Thy Cal.  | 5               | 30 days           | 0.01-100.00 | µIU/mL |
| UTPR, CTP | UCFP              | UCFP Cal.      | 5               | 2 mo.             | 6 - 250     | mg/dL  |

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