GC1 Calibration Verification / Linearity Test Kit

INTENDED USE

VALIDATE GC 1 Calibration Verification / Linearity Test Kit solutions are intended for *in vitro* diagnostic use in the quantitative determination of linearity, calibration verification and verification of reportable range in automated, semi-automated and manual instrument systems for the following analytes: **Set 1:** calcium (CA), cholesterol (CHOL), creatinine (CREAT), glucose (GLU), lactate (LAC), lithium (LITH), phosphorus (PHOS), triglyceride (TRIG) and uric acid (UA). **Set 2:** albumin (ALB), blood urea nitrogen (BUN), chloride (CL), magnesium (MG), potassium (K), sodium (NA) and total protein (TP).

Set 1 consists of one bottle each of Levels 1 through 5. Each bottle contains 3.0 milliliters. Set 2 consists of one bottle each of Levels 1 through 5. Each bottle contains 3.0 milliliters. There exists a linear relationship among Levels 1 through 5 for each set.

SUMMARY

For each VALIDATE Calibration Verification / Linearity Test Kit, multiple levels are provided to establish the relationship between theoretical and actual performance of each of the included analytes. The VALIDATE Calibration Verification / Linearity Test Kit will assist in the documentation of linearity, calibration verification and verification of linear range required by many inspection agencies. The solutions will also provide assistance when troubleshooting instrument systems, reagent problems and calibration anomalies.

REAGENTS

Reactive Ingredients:
Purified chemicals for ALB, CA, CHOL, CL, CREA, GLU, K, LAC, LITH, MG, NA, PHOS, TP, TRIG, UA and urea nitrogen in a human serum protein base.

Nonreactive Ingredients:
Preservatives and stabilizers.

Precautions and Warnings:
For In Vitro Diagnostic Use
Disposal of all waste material should be in accordance with local guidelines.

WARNING: Potentially Biohazardous
Human source material is considered potentially biohazardous. Material of human origin used in the manufacture of this test kit was tested at the donor level using FDA or CE approved methods and found to be non-reactive for HBV, HCV and HIV. Because no test method can offer complete assurance that infectious agents are absent, these specimens should be handled and treated as potentially infectious.

STORAGE AND STABILITY

The **VALIDATE** GC1 Calibration Verification / Linearity Test Kit is stored at -10° to -25°C. ***Do NOT store in a frost-free freezer.*** Test kits are stable until the expiration date printed on the bottle and storage container when handled according to instructions***. A maximum of four (4) freeze-thaw cycles is recommended.***

PREPARATION

Prior to use, remove the **VALIDATE** GC1 Calibration Verification / Linearity Test Kit from storage and allow to come to room temperature (18° to 25°C). Invert gently several times before dispensing.

To maximize stability, it is recommended that exposure to room temperature be minimized. Tightly cap opened bottles and return to -10° to -25°C immediately after dispensing.

Discard any solutions that appear to have gross bacterial contamination.

VALIDATE Calibration Verification / Linearity Test Kits should be treated in the same manner as patient samples. If dilutions or pre-treatment are required as part of the testing procedure, follow the manufacturer's instructions.

ASSAY

Analyze each level in replicates. If following the CLSI EP6 guidelines for linearity, use a random analytical sequence to assay each level.

CALCULATION OF RESULTS

VALIDATE Calibration Verification / Linearity material is prepared in a manner such that an equal distance (delta) exists between Levels 1 through 5. This dilution scheme is consistent with the CLSI EP6 recommendation for preparing linearity sets.

Two examples for calculating the theoretical values of Levels 1 through 5 are provided below.

Example 1:
Choose two consecutive levels and calculate the delta between the recovered values. The following example demonstrates the use of the delta between Levels 2 and 3 to calculate the theoretical value for Levels 1, 4, and 5.

Level 3 – Level 2 = Delta

Level 1 Theoretical = Level 2 Recovered – Delta
Level 4 Theoretical = Level 3 Recovered + Delta
Level 5 Theoretical = Level 4 Theoretical + Delta

NOTE: The user can select the calculated delta between any two consecutive levels to calculate the theoretical values. Typically, the user should choose an area of recovery known to be linear for the method being studied.

Example 2:
Theoretical values can be determined using the recovered values for Levels 1 and 5. Using this method, the following formulas apply:

Level 2 Theoretical = 0.75 * (Level 1) + 0.25 * (Level 5)
Level 3 Theoretical = 0.5 * (Level 1) + 0.5 * (Level 5)
Level 4 Theoretical = 0.25 * (Level 1) + 0.75 * (Level 5)

After theoretical values are calculated, for each analyte plot the expected (Theoretical) value on the x-axis versus the Recovered value on the y-axis using standard linear graph paper. If the system is linear, the plot should approximate a straight line. The point at which the line is no longer straight can be used to determine the limit of linearity or the reportable range.

Data reduction is available from LGC Maine Standards. Commercially available linear regression software may also be used. The software should provide data point display and x-y graphical presentation. Linear regression should be interpreted using standard statistical analysis and the results should be compared with the instrument manufacturer's claims for linearity or with individual laboratory performance requirements. The degree of acceptable nonlinearity is an individual judgment based on methodology, clinical significance and medical decision levels of the test analyte.

LIMITATIONS

VALIDATE Calibration Verification / Linearity Test Kit solutions are not intended for use as routine quality control materials or as calibration materials.

EXPECTED VALUES

VALIDATE Calibration Verification / Linearity Test Kits are manufactured such that an equal distance (delta) exists between levels as recommended by CLSI EP6 for assessing linearity. As the distance between levels is equal, any two levels can be held to be 'true' when assayed and the theoretical values for each of the other three levels can be calculated allowing this test kit to be used on multiple automated instrument systems.

The reagent manufacturer's recommended diluent can be used to make dilutions of the low level to obtain a result lower than that level, if needed.

The following five (5) analytes are inverted in GC 1: Set 1: CHOL, LAC, LITH, PHOS and UA. The following analyte is inverted in GC 1: Set 2: BUN. Level 1 contains the highest concentration for these analytes and concentration decreases from Level 1 down to level 5.

TYPICAL VALUES
Actual results obtained may vary depending on instrumentation, methodology and assay temperature. Results may also be dependent on the accuracy of the instrument / reagent system calibration. The degree of acceptable nonlinearity is an individual judgment based on methodology, clinical significance and medical decision levels of the test analyte.

Typical recovered values for Level 1 and Level 5 are presented in the table(s) provided. Typical values for mid-levels are based on an equal distance (delta) between levels.

Typical Recovered Values on Ortho Vitros®

1100vt Lot #: 11AY192200

Analyte	Units	Level 1	Level 2	Level 3	Level 4	Level 5
CA	mg/dL	1.4	4.5	7.5	10.6	13.6
CREAT	mg/dL	0.0	3.2	6.5	9.7	12.9
CHOL	mg/dL	315	255	194	134	73
GLU	mg/dL	27	167	308	448	588
LAC	mmol/L	11.3	8.6	6.0	3.3	0.6
Li	mmol/L	4.0	3.1	2.2	1.3	0.4
PHOS	mg/dL	11.8	9.0	6.2	3.4	0.6
TRIG	mg/dL	26	142	259	375	491
UA	mg/dL	17	13	9	5	1
ALB	g/dL	1.4	2.5	3.5	4.6	5.6
BUN	mg/dL	113	86	58	31	3
CL	mmol/L	51	80	109	137	166
K	mmol/L	1.2	4.3	7.4	10.4	13.5
MG	mg/dL	0.4	2.5	4.6	6.7	8.8
NA	mmol/L	86	122	158	194	230
TP	g/dL	2.4	4.4	6.3	8.3	10.2

1100vt Lot #: 11AY192200

Analyte	SI Units	Level 1	Level 2	Level 3	Level 4	Level 5
CA	mmol/L	0.350	1.113	1.875	2.638	3.400
CREAT	µmol/L	0.0	284.1	568.3	852.4	1136.5
CHOL	mmol/L	8.159	6.592	5.025	3.458	1.891
GLU	mmol/L	1.499	9.283	17.067	24.850	32.634
LAC	mmol/L	11.3	8.6	6.0	3.3	0.6
Li	mmol/L	4.0	3.1	2.2	1.3	0.4
PHOS	mmol/L	3.811	2.907	2.003	1.098	0.194
TRIG	mmol/L	0.294	1.608	2.921	4.235	5.548
UA	µmol/L	1011	773	535	297	59
ALB	g/L	14	25	35	46	56
BUN	mmol/L	40.341	30.524	20.706	10.889	1.071
CL	mmol/L	51	80	109	137	166
K	mmol/L	1.2	4.3	7.4	10.4	13.5
MG	mmol/L	0.165	1.029	1.893	2.756	3.620
NA	mmol/L	86	122	158	194	230
TP	g/L	24	44	63	83	102

CE Symbols – This product fulfills the requirements of the European Directive 98/79/EC for *in vitro* medical devices. The following symbols may be used where applicable in labeling for Maine Standards Company products:

Lot Number

Expiration Date

Manufacturer

Storage Temperature

In Vitro Diagnostic Medical Device

Catalog Number

Insert

Biological Risk

EC REP Wellkang Ltd (www.CE-marking.eu) 29 Harley St., London W1G 9QR, UK

For a list of countries in which VALIDATE® is registered see:
http://www.mainestandards.com/Products/ce_reg.php

Rx Only

ORDERING INFORMATION

ORDER NO.: 1100vt

VALIDATE GC1
Calibration Verification / Linearity Test Kit:
Set 1: 5 x 3 mL
Set 2: 5 x 3 mL

CONTACT INFORMATION:

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