GC 1 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: albumin (ALB), blood urea nitrogen (BUN), calcium (CA), chloride (CL), cholesterol (CHOL), creatinine (CREAT), glucose (GLU), lactate (LAC), lithium (LITH), magnesium (MG), phosphorus (PHOS), potassium (K), sodium (NA), total protein (TP) and triglyceride (TRIG).

Each test kit consists of one bottle each of Levels 1 through 5 and an additional bottle for High TP. Each bottle contains 4.0 milliliters. There exists a linear relationship among Levels 1 through 5. For TP, a linear relationship exists among Levels 1 through 5 and High TP.

SUMMARY

Each **VALIDATE** GC 1 Calibration Verification / Linearity Test Kit contains purified chemicals in a human serum protein base. Multiple levels are provided to establish the relationship between theoretical and actual performance of each of the included analytes. The **VALIDATE** GC 1 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, CREAT, GLU, K, LAC, LITH, MG, NA, PHOS, TP, TRIG 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

VALIDATE GC 1 Calibration Verification / Linearity Test Kits are 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** GC 1 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.

The **VALIDATE** GC 1 Calibration Verification / Linearity Test Kit 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.

The bottle labeled 'High TP' is a sixth level that is manufactured to a specific target for TP only and the theoretical value is determined by multiplying the value of Level 3 by 2.94.

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

Example 1:

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

Mean Recovered Values

Level 1	0.6
Level 2	3.4
Level 3	6.2
Level 4	9.1
Level 5	11.7
High TP	18.0

Using Level 2 and Level 3 recovered values to calculate the Delta, the above data produces the following:

Level 3 – Level 2 = Delta, or (6.2 – 3.4 = 2.8)

Level 1 Theoretical = Level 2 Recovered - Delta, or (3.4 – 2.8 = 0.6)
Level 4 Theoretical = Level 3 Recovered + Delta, or (6.2 + 2.8 = 9.0)
Level 5 Theoretical = Level 4 Theoretical + Delta, or (9.0 + 2.8 = 11.8)
High TP Theoretical = Level 3 Recovered * TP factor, or (6.2 * 2.94 = 18.2)

Using the delta between Level 2 and Level 3, the theoretical value for each level would be:

Level	Theoretical (x-axis)	Recovered (y-axis)
1	0.6	0.6
2	3.4	3.4
3	6.2	6.2
4	9.0	9.1
5	11.8	11.7
High TP	18.2	18.0

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)
Level 6 Theoretical = Level 3 Theoretical * TP factor

Using the recovered values for Level 1 (0.6) and Level 5 (11.7), the following applies:

Level 2 Theoretical = 0.75 * (0.6) + 0.25 * (11.7) = 3.4
Level 3 Theoretical = 0.5 * (0.6) + 0.5 * (11.7) = 6.2
Level 4 Theoretical = 0.25 * (0.6) + 0.75 * (11.7) = 9.0
High TP Theoretical = 6.2 (Level 3 Theoretical) * 2.94 (TP factor) = 18.2

Level	Theoretical (x-axis)	Recovered (y-axis)
1	0.6	0.6
2	3.4	3.4
3	6.2	6.2
4	9.0	9.1
5	11.7	11.7
High TP	18.2	18.0

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.

Customers that are using commercially available linearity software to analyze a six level analyte and have questions, please contact LGC Maine Standards Technical Support at 800-377-9684 for assistance.

LIMITATIONS

VALIDATE GC 1 Calibration Verification / Linearity Test Kit solutions are not intended for use as routine quality control materials or as calibration materials.

EXPECTED VALUES

VALIDATE GC 1 Calibration Verification / Linearity Test Kits are manufactured such that a linear relationship exists among Levels 1 through 5. For TP, there is a linear relationship exists among Levels 1 through 5 and High TP.

The following analytes are inverted in GC 1: LITH and PHOS. Level 1 contains the highest concentration for these analytes and concentration decreases from Level 1 down to Level 5.

TRACEABILITY

VALIDATE Calibration Verification / Linearity Test Kit solutions are tested during manufacturing with standards traceable to National Institute of Standards and Technology (NIST) Standard Reference Material (SRM), where available. For analytes where NIST materials are not available, primary analytical standards are used.

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 Values by Level 1100ab

Analyte	Units	1	2	3	4	5	High TP
ALB	g/dL	0.4	2.9	5.5	8.0	10.5	
BUN	mg/dL	2	33	64	94	125	
CA	mg/dL	2.0	7.5	13.0	18.5	24.0	
CHOL	mg/dL	7	182	356	531	705	
CL	mmol/L	50	75	100	125	150	
CREAT	mg/dL	0.2	9.4	18.6	27.8	37.0	
GLU	mg/dL	5	204	403	601	800	
K	mmol/L	1.0	3.3	5.5	7.8	10.0	
LAC	mg/dL	1.5	31.1	60.8	90.4	120.0	
LITH	mmol/L	3.5	2.7	1.8	1.0	0.1	
MG	mg/dL	0.7	2.9	5.1	7.3	9.5	
NA	mmol/L	100	125	150	175	200	
PHOS	mg/dL	25.3	19.2	13.0	6.9	0.7	
TP	g/dL	0.8	3.6	6.4	9.2	12.0	18.4
TRIG	mg/dL	7	360	714	1,067	1,420	

ORDERING INFORMATION

ORDER NO.: 1100ab

VALIDATE GC 1
Calibration Verification / Linearity Test Kit 6 x 4 mL

For technical assistance or to place an order, please call:
800-377-9684 or
207-892-1300
Fax 207-892-2266

Please allow 5 to 7 days for delivery.

800-377-9684 • 207-892-1300 • FAX 207-892-2266
www.mainestandards.com

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 LGC Maine Standards products:

Lot Number

Expiration Date

Manufacturer

Storage Temperature

***In Vitro* Diagnostic Medical Device**

Catalog Number

Insert

Biological Risk

For a list of countries in which VALIDATE® is registered see:
www.mainestandards.com/ce

A worksheet to assist with manually calculating theoretical values can be found at www.mainestandards.com/Products or by calling Customer Support at 1-800-377-9684

Rx Only

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