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: **GC1 Set:** albumin (ALB), blood urea nitrogen (BUN), 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). **CA Set:** calcium (CA)

VALIDATE Test Kits are non-automated and intended for laboratory professional use only.

Each GC1 Set 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.
Each CA Set 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.

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 and constituents of human and/or animal source in human serum

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
Full SDS is available at www.mainestandards.com\doc-search.
Consult this SDS for detailed safety information including handling spills.
Human source material is considered potentially biohazardous. Use the Centers for Disease Control (CDC) recommended universal precautions for handling VALIDATE products.

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.

High TP is manufactured based on a known relationship to Levels 1 and 5. The theoretical value is determined by multiplying the Delta value by the factor provided: 6.98

Two examples for calculating the theoretical values of Levels 1 through 6 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, 5 and High TP.

Level 3 Recovered – Level 2 Recovered = Delta

Level 1 Theoretical = Level 2 Recovered – Delta
Level 4 Theoretical = Level 3 Recovered + Delta
Level 5 Theoretical = Level 4 Theoretical + Delta
High TP Theoretical = Delta * 6.98

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)
High TP Theoretical = Delta * 6.98

(Level 3 Theoretical – Level 2 Theoretical = Delta)

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 Clinical Diagnostics. 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 1 through 5 is equal, any two levels between 1 and 5 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 theoretical value for Level 6 is calculated based on a known relationship to Levels 1 and 5 and can be calculated using the factor for each analyte listed in the **CALCULATION OF RESULTS** section of this insert.

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.

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.

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 are calculated based on CLSI EP6 equal distance (delta) manufacturing protocols where two recovered values can be held as "True", and other levels calculated based on equal distance. VALIDATE typically uses Level 1 and Level 3 to calculate additional target values.

NOTE: Do not use Typical Recovered Values as inputs for data reduction/linearity analysis – see ***Calculation of Results*** for detailed instructions.

Typical Recovered Values on Abbott ALINITY

1100ab Lot: 10691473

Analyte	Units	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
ALB	g/dL	0.6	3.0	5.4	7.8	10.1	
BUN	mg/dL	6	34	61	89	117	
CL	mmol/L	56	77	99	120	141	
CHOL	mg/dL	12	175	338	502	665	
CREAT	mg/dL	0.4	9.0	17.6	26.2	34.8	
GLU	mg/dL	9	191	372	554	735	
LAC	mg/dL	3.2	31	59	87	115	
Li	mmol/L	3.4	2.6	1.8	1.0	0.2	
PHOS	mg/dL	25.9	19.8	13.6	7.4	1.2	
K	mmol/L	1.2	3.2	5.2	7.2	9.2	
MG	mg/dL	1.0	2.9	4.8	6.7	8.7	
NA	mmol/L	109	129	149	169	190	
TP	g/dL	1.0	3.8	6.5	9.3	12.0	16.3
TRIG	mg/dL	12	352	692	1033	1373	
CA	mg/dL	2.4	7.9	13.3	18.8	24.2	

1100ab Lot: 10691473

Analyte	SI Units	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
ALB	g/L	6	30	54	78	101	
BUN	mmol/L	2.142	12.138	21.777	31.773	41.769	
CL	mmol/L	56	77	99	120	141	
CHOL	mmol/L	0.311	4.533	8.754	13.002	17.224	
CREAT	µmol/L	35.2	792.9	1550.6	2308.2	3065.9	
GLU	mmol/L	0.500	10.601	20.646	30.747	40.793	
LAC	mmol/L	0.355	3.441	6.549	9.657	12.765	
Li	mmol/L	3.4	2.6	1.8	1.0	0.2	
PHOS	mmol/L	8.366	6.395	4.393	2.390	0.388	
K	mmol/L	1.2	3.2	5.2	7.2	9.2	
MG	mmol/L	0.411	1.193	1.975	2.756	3.579	
NA	mmol/L	109	129	149	169	190	
TP	g/L	10	38	65	93	120	163
TRIG	mmol/L	0.136	3.978	7.820	11.673	15.515	
CA	mmol/L	0.600	1.975	3.325	4.700	6.050	

Issue Date	Modification
May 16, 2023	Internal clerical change only, not visible in IFU.

The following symbols may be used where applicable in labeling for LGC Clinical Diagnostics products:

Lot Number


Expiration Date


Manufacturer


Storage Temperature

In Vitro Diagnostic Medical Device

Catalog Number


Insert


Biological Risk


Do Not Reuse

Rx Only

ORDERING INFORMATION

ORDER NO.: 1100ab

VALIDATE GC1
Calibration Verification / Linearity Test Kit:
GC1 Set: 6 x 4 mL
CA Set: 5 x 3 mL

Any serious incident occurring in relation to the use of this device shall be reported to the Manufacturer as well as the Competent Authority of the member state in which the user/patient is established.

CONTACT INFORMATION:


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