GC1 Calibration Verification / Linearity Test Kit

INTENDED USE

VALIDATE GC1 Calibration Verification / Linearity Test Kit solutions are intended for *in vitro* diagnostic use in the determination of linearity, calibration verification and verification of reportable range in automated instrument systems for the following analytes: **Set 1:** albumin (ALB), blood urea nitrogen (BUN), calcium (CA), chloride (CL), cholesterol (CHOL), creatinine (CREA), glucose (GLU), lactate (LAC), lithium (LI), magnesium (MG), phosphorus (PHOS), potassium (K), sodium (NA), total protein (TP) and triglyceride (TRIG). **Set 2:** albumin (ALB) and creatinine (CREA).

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

Set 1 consists of one bottle each of Levels 1 through 5. Each bottle contains 2.0 milliliters. **Set 2** consists of one bottle each of Levels 1 through 5. Each bottle contains 2.0 milliliters. There exists a linear relationship among Levels 1 through 5 for each set.

Note for testing Creatinine and Albumin: If using the Creatinine Plus Method or Albumin BCG Method, use Set 1 for testing. If using the Creatinine Jaffe Method or Albumin BCP Method, use Set 2 for testing.

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.
Full SDS is available at www.mainestandards.com\doc-search.
Consult this SDS for detailed safety information including handling spills.

WARNING: Potentially Biohazardous
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 storage container when handled according to instructions. Do not use the Kit past its expiration date. ***Minimal exposure to room temperature 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 use.

After use of the product, discard appropriately.

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 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 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 analytes are inverted in GC 1: Set 1: LITH and PHOS. 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 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.

Typical Recovered Values on Roche COBAS®

C-1100LC Lot: 10741868

Analyte	Units	Level 1	Level 2	Level 3	Level 4	Level 5
ALB	g/dL	0.5	2.0	3.5	4.9	6.4
BUN	mg/dL	4	32	60	88	116
CA	mg/dL	1.4	6.0	10.6	15.2	19.8
CL	mmol/L	70	87	105	122	139
CHOL	mg/dL	5	217	429	641	853
CREAT	mg/dL	0.2	8.2	16.1	24.0	32.0
GLU	mg/dL	4	187	369	552	734
LAC	mg/dL	2.3	39	76	112	149
Li	mmol/L	3.1	2.4	1.6	0.9	0.1
PHOS	mg/dL	20.5	15.5	10.4	5.4	0.4
K	mmol/L	2.0	3.9	5.9	7.8	9.8
MG	mg/dL	0.4	1.5	2.5	3.6	4.6
NA	mmol/L	90	112	134	155	177
TP	g/dL	0.3	3.4	6.5	9.6	12.7
TRIG	mg/dL	12	239	465	691	918
ALBP	g/dL	0.3	2.9	5.5	8.1	10.7
Creat Jaffe	mg/dL	0.2	6.9	13.6	20.3	26.9

C-1100LC Lot: 10741868

Analyte	SI Units	Level 1	Level 2	Level 3	Level 4	Level 5
ALB	g/L	5	20	35	49	64
BUN	mmol/L	1.428	11.424	21.420	31.416	41.412
CA	mmol/L	0.350	1.500	2.650	3.800	4.950
CL	mmol/L	70	87	105	122	139
CHOL	mmol/L	0.130	5.620	11.111	16.602	22.093
CREAT	µmol/L	17.6	722.4	1418.4	2114.4	2819.2
GLU	mmol/L	0.222	10.379	20.480	30.636	40.737
LAC	mmol/L	0.255	4.329	8.436	12.432	16.539
Li	mmol/L	3.1	2.4	1.6	0.9	0.1
PHOS	mmol/L	6.622	5.007	3.359	1.744	0.129
K	mmol/L	2.0	3.9	5.9	7.8	9.8
MG	mmol/L	0.165	0.617	1.029	1.481	1.892
NA	mmol/L	90	112	134	155	177
TP	g/L	3	34	65	96	127
TRIG	mmol/L	0.136	2.701	5.255	7.808	10.373
ALBP	g/L	3	29	55	81	107
Creat Jaffe	µmol/L	17.6	607.9	1198.2	1788.4	2369.9

Note: When using the Creatinine Plus Method or Albumin-BCG Method, use Set 1 for testing. When using the Creatinine Jaffe Method or Albumin-BCP Method, use Set 2 for testing.

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

Lot Number

Expiration Date

Manufacturer

Temperature Limit

***In Vitro* Diagnostic Medical Device**

Catalog Number

Instructions for Use

Biological Risk

Do Not Reuse

Caution

ORDERING INFORMATION

ORDER NO.: C-1100LC

VALIDATE GC1
Calibration Verification / Linearity Test Kit:
Set 1: 5 x 2.0 mL
Set 2: 5 x 2.0 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:

LGC Clinical Diagnostics, Inc.
221 US Route 1
Cumberland Foreside, ME 04110 USA

1-800-377-9684
+1-207-892-1300
+1-207-892-2266 Fax
msc.sales@LGCGroup.com
msc.techsupport@LGCGroup.com
www.mainestandards.com

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