



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 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:** albumin (ALB), blood urea nitrogen (BUN), calcium (CA), chloride (CL), cholesterol (CHOL), creatinine (CREAT), glucose (GLU), lactate (LAC), lithium (LITH), magnesium (MG), sodium (NA), phosphorus (PHOS), potassium (K), total protein (TP) and triglyceride (TRIG). **Set 2:** blood urea nitrogen (BUN), glucose (GLU) and phosphorus (PHOS).

Set 1 consists of one bottle each of Levels 1 through 5. Each bottle contains 4.0 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

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

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.

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.

$$\text{Level 3} - \text{Level 2} = \text{Delta}$$

$$\text{Level 1 Theoretical} = \text{Level 2 Recovered} - \text{Delta}$$

$$\text{Level 4 Theoretical} = \text{Level 3 Recovered} + \text{Delta}$$

$$\text{Level 5 Theoretical} = \text{Level 4 Theoretical} + \text{Delta}$$

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:

$$\text{Level 2 Theoretical} = 0.75 * (\text{Level 1}) + 0.25 * (\text{Level 5})$$

$$\text{Level 3 Theoretical} = 0.5 * (\text{Level 1}) + 0.5 * (\text{Level 5})$$

$$\text{Level 4 Theoretical} = 0.25 * (\text{Level 1}) + 0.75 * (\text{Level 5})$$

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 two (2) analytes are inverted in GC 1: Set 1: CREAT 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 Beckman Coulter UniCel® DxC / Synchron®
1100bc Lot: 10685426

Analyte	Units	Level 1	Level 2	Level 3	Level 4	Level 5
ALB	g/dL	1.1	2.5	3.9	5.3	6.7
BUN	mg/dL	6	30	55	79	104
CA	mg/dL	2.0	6.3	10.5	14.8	19.1
CL	mmol/L	50	87	124	160	197
CHOL	mg/dL	7	189	370	552	733
CREAT	mg/dL	23.6	17.8	12.0	6.2	0.4
GLU	mg/dL	5	175	345	516	686
LAC	mg/dL	3.3	26	49	72	95
LI	mmol/L	0.1	0.8	1.6	2.3	3.0
PHOS	mg/dL	12.5	9.7	7.0	4.2	1.4
K	mmol/L	1.6	4.8	8.0	11.3	14.5
MG	mg/dL	0.1	1.8	3.5	5.2	6.9
NA	mmol/L	102	125	149	172	195
TP	g/dL	3.0	5.2	7.3	9.5	11.6
TRIG	mg/dL	9	271	533	795	1057
BUN_m	mg/dL	2	37	71	106	140
GLU_m	mg/dL	14	162	309	456	603
PHOS_m	mg/dL	0.7	3.6	6.4	9.3	12.1

1100bc Lot: 10685426

Analyte	SI Units	Level 1	Level 2	Level 3	Level 4	Level 5
ALB	g/L	11	25	39	53	67
BUN	mmol/L	2.142	10.710	19.635	28.203	37.128
CA	mmol/L	0.500	1.575	2.625	3.700	4.775
CL	mmol/L	50	87	124	160	197
CHOL	mmol/L	0.181	4.895	9.583	14.297	18.985
CREAT	µmol/L	2079.2	1568.2	1057.2	546.2	35.2
GLU	mmol/L	0.278	9.713	19.148	28.638	38.073
LAC	mmol/L	0.366	2.886	5.439	7.992	10.545
LI	mmol/L	0.1	0.8	1.6	2.3	3.0
PHOS	mmol/L	4.038	3.133	2.261	1.357	0.452
K	mmol/L	1.6	4.8	8.0	11.3	14.5
MG	mmol/L	0.041	0.741	1.440	2.139	2.839
NA	mmol/L	102	125	149	172	195
TP	g/L	30	52	73	95	116
TRIG	mmol/L	0.102	3.062	6.023	8.984	11.944
BUN_m	mmol/L	0.714	13.209	25.347	37.842	49.980
GLU_m	mmol/L	0.777	8.991	17.150	25.308	33.467
PHOS_m	mmol/L	0.226	1.163	2.067	3.004	3.908

ORDERING INFORMATION

ORDER NO.: 1100bc

VALIDATE GC1

Calibration Verification / Linearity Test Kit:

Set 1: 5 x 4 mL

Set 2: 5 x 2 mL



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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 Clinical Diagnostics products:

- Lot Number
- Expiration Date
- Manufacturer
- Storage Temperature
- In Vitro Diagnostic Medical Device
- Catalog Number
- Insert
- Biological Risk
- Do Not Reuse

CE **EC REP** Weikang Ltd, Enterprise Hub, NW Business Complex, 1 Beraghmore Rd, Derry, BT45 8SE, Northern Ireland

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

Rx Only

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