



GC 3 Calibration Verification / Linearity Test Kit

INTENDED USE

VALIDATE GC 3 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: alkaline phosphatase (ALP), alanine aminotransferase (ALT), amylase (AMY), aspartate aminotransferase (AST), creatine kinase (CK), gamma-glutamyl transferase (GGT), lactate dehydrogenase (LD) and lipase (LIP).

Each test kit consists of one bottle each of Levels 1 through 6. Each bottle contains 3.0 milliliters. There exists a linear relationship among Levels 1 through 6.

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.

Note: Some raw materials are purified from porcine.

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** GC 3 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** GC 3 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.

Level 6 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:

Analyte	Factor	Analyte	Factor
ALP	8.69	CK	N/A
ALT	18.60	GGT	25.10
AMY	9.72	LD	10.06
AST	19.54	LIP	N/A

For CK and LIP, assay Levels 1 through 5 only.

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 6.

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

Level 6 Theoretical = Delta * Level 6 factor

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 = Delta * Level 6 factor

(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 factor table provided in the **ASSAY** section of this insert.

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.

Typical Recovered Values on Abbott ALINITY

1300ab Lot: 10719146

Analyte	Units	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
ALP	U/L	8	511	1013	1515	2017	3883
ALT	U/L	7	206	405	605	804	3198
AMY	U/L	6	716	1427	2137	2847	6230
AST	U/L	6	217	429	640	852	3853
CK	U/L	11	1047	2084	3120	4157	
GGT	U/L	9	376	742	1109	1475	8135
LD	U/L	21	502	982	1462	1943	4150
LIP	U/L	7	296	584	872	1161	

1300ab Lot: 10719146

Analyte	SI Units	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
ALP	µkat/L	0.13	8.53	16.92	25.30	33.68	64.85
ALT	µkat/L	0.12	3.44	6.76	10.10	13.43	53.41
AMY	µkat/L	0.10	11.96	23.83	35.69	47.54	104.04
AST	µkat/L	0.10	3.62	7.16	10.69	14.23	64.35
CK	µkat/L	0.18	17.48	34.80	52.10	69.42	
GGT	µkat/L	0.15	6.28	12.39	18.52	24.63	135.85
LD	µkat/L	0.35	8.38	16.40	24.42	32.45	69.31
LIP	µkat/L	0.12	4.94	9.75	14.56	19.39	

LIP typical recovered values are obtained from the Beckman Coulter AU analyzer.



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** Wallkang Ltd, Enterprise Hub,
NW Business Complex, 1 Beraghmore Rd,
Derry, BT48 8SE, Northern Ireland

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.: 1300ab

VALIDATE GC 3

Calibration Verification / Linearity Test Kit:
6 x 3 mL

CONTACT INFORMATION:

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