



GC 2 Calibration Verification / Linearity Test Kit

INTENDED USE

VALIDATE GC 2 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: carbon dioxide (CO₂), ethyl alcohol (ETOH), ammonia (NH₃) and iron (FE).

Each test kit consists of one bottle each of Levels 1 through 5, a High ETOH, plus a Base Matrix. Each bottle contains 3.0 milliliters. There exists a linear relationship among Levels 1 through 5. For ETOH only, there exists a linear relationship among Levels 1 through 5 and High ETOH.

SUMMARY

Each **VALIDATE** GC 2 Calibration Verification / Linearity Test Kit contains purified chemicals in an aqueous base. Multiple levels are provided to establish the relationship between theoretical and actual performance of each of the included analytes. The **VALIDATE** GC 2 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 CO₂, ETOH, NH₃ and FE in an aqueous 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.

STORAGE AND STABILITY

VALIDATE GC 2 Calibration Verification / Linearity Test Kits are stored at 2° to 8°C. **DO NOT FREEZE**. Test kits are stable until the expiration date printed on the bottle and storage container when handled according to instructions.

PREPARATION

Prior to use, remove the **VALIDATE** GC 2 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 2° to 8°C immediately after dispensing.

Discard any solutions that appear to have gross bacterial contamination.

The **VALIDATE** GC 2 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 each consecutive level. This dilution scheme is consistent with the CLSI EP6 recommendation for preparing linearity sets.

The bottle labeled "High ETOH" is a sixth level that is manufactured to a specific high target for ETOH only and the theoretical value is determined by multiplying the calculated theoretical value of Level 3 by 2.35.

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:

Mean Recovered Values	
Level 1	500
Level 2	378
Level 3	255
Level 4	132
Level 5	10
High ETOH	598

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

Level 2 – Level 3 = Delta, or (378 - 255 = 123)

Level 1 Theoretical = Level 2 Recovered + Delta, or (378 + 123 = 501)

Level 4 Theoretical = Level 3 Recovered - Delta, or (255 - 123 = 132)

Level 5 Theoretical = Level 4 Theoretical - Delta, or (132 - 123 = 9)

High ETOH = Level 3 Recovered * 2.35 (High ETOH factor) or (255 * 2.35 = 599)

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	501	500
2	378	378
3	255	255
4	132	132
5	9	10
High ETOH	599	598

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 ETOH Theoretical = Level 3 theoretical * 2.35 (High ETOH factor)

Using the recovered values for Level 1 (500) and Level 5 (10) the following applies:

Level 2 Theoretical = 0.75 * (500) + 0.25 * (10) = 377.5
 Level 3 Theoretical = 0.5 * (500) + 0.5 * (10) = 255
 Level 4 Theoretical = 0.25 * (500) + 0.75 * (10) = 132.5
 High ETOH Theoretical = Level 3 theoretical * 2.35 (High ETOH Factor) = 255 * 2.35 = 599

Level	Theoretical (x-axis)	Recovered (y-axis)
1	500	500
2	377.5	378
3	255	255
4	132.5	132
5	10	10
High ETOH	599	598

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 Maine Standards Company (see worksheet for instructions). 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 non-linearity is an individual judgment based

on methodology, clinical significance and medical decision levels of the test analyte.

LIMITATIONS

VALIDATE GC 2 Calibration Verification / Linearity Test Kit solutions are not intended for use as routine quality control materials or as calibration materials.

EXPECTED VALUES

VALIDATE GC 2 Calibration Verification / Linearity Test Kits are manufactured such that a linear relationship exists among Levels 1 through 5. The expected value of the Base Matrix is zero, however, in some instances a non-zero result may be obtained. The Base Matrix can be used to make dilutions of Level 1 to obtain a result lower than Level 1, if needed.

The following analytes are inverted in GC2: CO₂, ETOH and NH₃. Concentration decreases from Level 1 down to Level 5. Only ETOH has an additional high level.

TRACEABILITY

VALIDATE Calibration Verification / Linearity Test Kit solutions are tested during manufacturing with standards traceable to National Institute for 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 non-linearity is an individual judgment based on methodology, clinical significance and medical decision levels of the test analyte.

Typical Values by Level 1200au							
Analyte	Units	1	2	3	4	5	High ETOH
CO ₂	mmol/L	45	34	24	13	2	
ETOH	mg/dL	500	378	255	133	10	600
NH ₃	µmol/L	600	453	305	158	10	
FE	µg/dL	10	258	505	753	1,000	

ORDERING INFORMATION

ORDER NO.: 1200

VALIDATE GC 2 Calibration Verification / Linearity Test Kit 7 x 3 mL

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

Please allow 5 to 7 days for delivery.

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