



CM2 Calibration Verification / Linearity Test Kit

INTENDED USE

VALIDATE CM2 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 chemistry systems for the following analytes: brain natriuretic peptide (BNP), high sensitivity C-reactive protein (hs CRP) and Troponin-I (TnI).

Each test set consists of one bottle each of Levels 1 through 5, plus a Base Matrix. There exists a linear relationship among Levels 1 through 5.

SUMMARY

Each **VALIDATE** CM2 Calibration Verification / Linearity Test Kit contains purified materials in a solution of human serum. The **VALIDATE** CM2 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 chemistry systems, reagent problems and calibration anomalies.

REAGENTS

Reactive Ingredients:

Recombinant Troponin I, recombinant proBNP and human C-reactive protein in a human serum matrix.

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 a potentially biohazardous material. Material of human origin used in the manufacture of this test set has been tested at the donor level using FDA approved methods or methods cleared in compliance with the European Directive 98/79/EC, Annex I, III or IV and found to be non-reactive for HBsAg and antibodies to HCV and HIV-1/2. Because no test method can offer complete assurance that infectious agents are absent, these specimens should be handled and treated as potentially infectious.

STORAGE AND STABILITY

VALIDATE CM2 Calibration Verification / Linearity Test Kits are stored at -10° to -25°C. **Do NOT store in a frost-free freezer.** Test sets 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** CM2 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 air be minimized. Tightly cap opened bottles and return them to -10° to -25°C storage immediately after dispensing.

Discard any solutions that appear to have gross bacterial contamination.

The **VALIDATE** CM2 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 guideline for linearity, use a random analytical sequence to assay each level in duplicate.

CALCULATION OF RESULTS

Each set of **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.

Two examples for calculating the theoretical values of Levels 1 through 5 are provided below.

Example 1:

At least two consecutive levels must be of known value. Calculate the delta between the recovered values for any two consecutive Levels. 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	51
Level 2	164
Level 3	275
Level 4	388
Level 5	501

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

Level 3 – Level 2 = Delta, or (275 – 164 = 111)

Level 1 Theoretical = Level 2 Recovered - Delta, or (164 - 111 = 53)

Level 4 Theoretical = Level 3 Recovered + Delta, or (275 + 111 = 386)

Level 5 Theoretical = Level 4 Theoretical + Delta, or (386 + 111 = 497)

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	53	51
2	164	164
3	275	275
4	386	388
5	497	501

NOTE: The user can select the calculated delta between any two consecutive points to calculate the theoretical values. Typically, the user should choose an area of recovery known to be linear within the chemistry 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 = 0.75 (Level 1) + 0.25 (Level 5)

Level 3 = 0.5 (Level 1) + 0.5 (Level 5)

Level 4 = 0.25 (Level 1) + 0.75 (Level 5)

Using the recovered values for Level 1 (51) and Level 5 (501), the following applies:

Level 2 = 0.75 (51) + 0.25 (501) = 163.5

Level 3 = 0.5 (51) + 0.5 (501) = 276

Level 4 = 0.25 (51) + 0.75 (501) = 388.5

Level	Theoretical (x-axis)	Recovered (y-axis)
1	51	51
2	163.5	164
3	276	275
4	388.5	388
5	501	501

For each analyte, plot the expected (Theoretical) value on the x-axis versus the recovered (Experimental) 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 upper limit of 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 CM2 Calibration Verification / Linearity Test Kit solutions are not intended for use as routine quality control materials or as calibration materials.

These solutions are not intended for use on systems employing reflectance spectroscopy.

EXPECTED VALUES

VALIDATE CM2 Calibration Verification / Linearity Test Kits are manufactured such that a linear relationship exists among the Levels 1 through 5. The expected value of the Base Matrix is zero, however, in some instances a non-zero result may be obtained.

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 402bc						
Analyte	Units	1	2	3	4	5
BNP	pg/mL	1	1,251	2,501	3,750	5,000
hs-CRP	mg/dL	0.02	1.5	3.0	4.5	6.0
Trop-I	ng/mL	0.01	25	50	75	100

ORDERING INFORMATION

ORDER NO.: 402

VALIDATE CM2

Calibration Verification / Linearity Test Kit 6 x 2 mL

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

Please allow 5 to 7 days for delivery.

Maine Standards Company
765 Roosevelt Trail
Windham, ME 04062