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 instrument systems. Each **VALIDATE** CM2 Calibration Verification / Linearity Test Kit contains NT-proBNP, hs-CRP and Troponin-T (TnT).

Each test kit consists of one bottle each of Levels 1 through 5, plus a Base Matrix and a High NT-proBNP. Each bottle contains 2.5 milliliters. There exists a linear relationship among Levels 1 through 5. For NT-proBNP only, there exists a linear relationship among Levels 1 through 5 and High NT-proBNP.

SUMMARY

Each **VALIDATE** CM2 Calibration Verification / Linearity Test Kit contains purified materials in a solution of human serum. Multiple levels are provided to establish the relationship between theoretical and actual performance of each of the included analytes. 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 instrument systems, reagent problems and calibration anomalies.

REAGENTS

Reactive Ingredients:

TnT from human heart tissue, recombinant NT-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 kit 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 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** 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 temperature be minimized. Tightly cap opened bottles and return them to -10° to -25°C 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.

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 NT-proBNP" is a sixth level that is manufactured to a specific target for NT-proBNP only. The theoretical value is determined by multiplying the value of Level 3 by 3.61.

Two examples for calculating the theoretical values of Levels 1 through 5 and High NT-proBNP, 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 High NT-proBNP:

Mean Recovered Values	
Level 1	46
Level 2	3,822
Level 3	7,624
Level 4	11,341
Level 5	14,867
High NT-proBNP	32,123

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

Level 3 – Level 2 = Delta, or (7,624 – 3,822 = 3,802)

Level 1 Theoretical = Level 2 Recovered – Delta, or (3,822– 3,802 = 20)
Level 4 Theoretical = Level 3 Recovered + Delta, or (7,624+ 3,802 = 11,426)
Level 5 Theoretical = Level 4 Theoretical + Delta, or (11,426 + 3,802 = 15,228)
Level 6 Theoretical = Level 3 Recovered * 3.61 (NT-proBNP factor) or,
(7,624 * 3.61 = 27,523)

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	20	46
2	3,822	3,822
3	7,624	7,624
4	11,426	11,341
5	15,228	14,867
High NT-proBNP	27,523	32,123

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 NT-proBNP Theoretical = Level 3 Theoretical * 3.61 (NT-proBNP factor)

Using the recovered values for Level 1 (46) and Level 5 (14,867), the following applies:

Level 2 Theoretical = 0.75 * (46) + 0.25 * (14,867) = 3,751
Level 3 Theoretical = 0.5 * (46) + 0.5 * (14,867) = 7,457
Level 4 Theoretical = 0.25 * (46) + 0.75 * (14,867) = 11,162
High NT-proBNP Theoretical = Level 3 Theoretical (7,457) * 3.61 (NT-proBNP factor) = 26,920

Level	Theoretical (x-axis)	Recovered (y-axis)
1	46	46
2	3,751	3,822
3	7,457	7,624
4	11,162	11,341
5	14,867	14,867
High NT-proBNP	26,920	32,123

After the 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 nonlinearity 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 Levels 1 through 5. The sixth bottle is an additional level for NT-proBNP testing only. 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.

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 nonlinearity is an individual judgment based on methodology, clinical significance and medical decision levels of the test analyte.

Typical Values by Level 402re							
Analyte	Units	1	2	3	4	5	High NT-proBNP
NT-proBNP	pg/mL	5	3,754	7,503	11,251	15,000	35,000
hs-CRP	mg/L	0.20	5.2	10.1	15.1	20.0	n/a
TnT	ng/mL	0.01	6.3	12.5	18.8	25.0	n/a

ORDERING INFORMATION

ORDER NO.: 402

VALIDATE CM2
Calibration Verification / Linearity Test Kit 7 x 2.5 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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