



TDM1

Calibration Verification / Linearity Test Kit

INTENDED USE

VALIDATE TDM1 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: acetaminophen, carbamazepine, digoxin, gentamicin, phenobarbital, phenytoin, salicylate, theophylline, tobramycin, valproic acid and vancomycin.

Each test set consists of one bottle each of Levels 1 through 5. Each bottle contains 3.0 milliliters. There exists a linear relationship among Levels 1 through 5.

SUMMARY

Each VALIDATE TDM1 Calibration Verification / Linearity Test Kit contains the therapeutic drugs in a human serum base. Multiple levels are provided to establish the relationship between theoretical and actual performance of each of the included analytes. The VALIDATE TDM1 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:

Acetaminophen, carbamazepine, digoxin, gentamicin, phenobarbital, phenytoin, salicylate, theophylline, tobramycin, valproic acid and vancomycin in a human serum 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.

WARNING: Potentially Biohazardous

Human source material is considered potentially biohazardous. Material of human origin used in the manufacture of this test kit was tested at the donor level using FDA approved methods and found to be non-reactive for HBsAg and to 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 TDM1 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.

PREPARATION

Prior to use, remove the VALIDATE TDM1 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 to -10° to -25°C immediately after dispensing.

Discard any solutions that appear to have gross bacterial contamination.

The VALIDATE TDM1 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 in duplicate.

To reduce evaporation effects and enhance product performance for TDM1, it is recommended that TDM1 be run in reverse order (level 5 to level 1).

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:

Table with 2 columns: Level, Mean Recovered Values. Rows: 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:

Table with 3 columns: Level, Theoretical (x-axis), Recovered (y-axis). Rows: Level 1 (53, 51), Level 2 (164, 164), Level 3 (275, 275), Level 4 (386, 388), Level 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

Table with 3 columns: Level, Theoretical (x-axis), Recovered (y-axis). Rows: Level 1 (51, 51), Level 2 (163.5, 164), Level 3 (276, 275), Level 4 (388.5, 388), Level 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 TDM1 Calibration Verification / Linearity Test Kit solutions are not intended for use as routine quality control materials or as calibration materials.

EXPECTED VALUES

VALIDATE TDM1 Calibration Verification / Linearity Test Kits are manufactured such that a linear relationship exists among the Levels 1 through 5.

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.

ORDERING INFORMATION

ORDER NO.: 301

VALIDATE TDM1 Calibration Verification / Linearity Test Kit 5 x 3 mL

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.

Table with 6 columns: Analyte, Units, 1, 2, 3, 4, 5. Rows: ACTM, CARB, DIGN, GENT, PHNO, PHYT, SALY, THEO, TOB, VALP, VANC

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