



Chem 4 Calibration Verification/Linearity Test Set

INTENDED USE

VALIDATE Chem 4 Calibration Verification/Linearity Test Set solutions are intended for *in vitro* diagnostic use in quantitative determination of linearity, calibration verification and verification of reportable range in automated, semi-automated and manual chemistry 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), lipase (LIP).

Each test set consists of one bottle each of Levels 1 through 5 plus a zero. Each bottle contains 5.0 milliliters. There exists a linear relationship among Levels 1 through 5.

SUMMARY

Each **VALIDATE** Chem 4 Calibration Verification/Linearity Test Set contains purified chemicals in a solution of bovine albumin stabilized with ethylene glycol. Multiple levels are provided to establish the relationship between theoretical and actual performance of each of the included analytes. The **VALIDATE** Chem 4 Calibration Verification/Linearity Test Set 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:

Purified enzymes: alkaline phosphatase (ALP) from human placenta, alanine aminotransferase (ALT) from porcine heart, amylase (AMY) from porcine pancreas, aspartate aminotransferase (AST) from porcine heart, creatine kinase (CK) from rabbit muscle, gamma-glutamyl transferase (GGT) from bovine kidney, lactate dehydrogenase (LD) from chicken heart, and lipase (LIP) from porcine pancreas. The purified materials are in a solution of bovine albumin stabilized with ethylene glycol.

Nonreactive Ingredients:

Preservatives and stabilizers.

Precautions and Warnings:

For In Vitro Diagnostic Use

WARNING: Potentially Biohazardous

Human source material is considered potentially biohazardous. This material was tested for communicable diseases (HIV, Hepatitis B and Hepatitis C) with kits approved by the FDA (where available) and found to be negative (non-reactive). 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 Chem 4 Calibration Verification/Linearity Test Sets are stored at -10 to -20°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** Chem 4 Calibration Verification/Linearity Test Set 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 -20°C immediately after dispensing.

Discard any solutions that appear to have gross bacterial contamination.

The **VALIDATE** Chem 4 Calibration Verification/Linearity Test Set 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.

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, 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 formula applies:

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 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 Chem 4 Calibration Verification/Linearity Test Set 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

Each lot of the **VALIDATE** Chem 4 Calibration Verification/Linearity Test Set is manufactured such that a linear relationship exists among the Levels 1 through 5. The expected value of the Level 0 is zero, however, in some instances a non-zero result may be obtained. The Level 0 can be used to make dilutions of Level 1 to obtain a result lower than Level 1, 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 non-linearity is an individual judgment based on methodology, clinical significance and medical decision levels of the test analyte

Typical Values by Level 104bc						
Analyte	Units	1	2	3	4	5
ALP	U/L	5	254	503	751	1,000
ALT	U/L	5	104	203	301	400
AMY	U/L	5	204	403	601	800
AST	U/L	5	104	203	301	400
CK	U/L	5	304	603	901	1,200
GGT	U/L	5	191	378	564	750
LD	U/L	5	191	378	564	750
LIP	U/L	10	58	105	153	200

Typical Values by Level 104db						
Analyte	Units	1	2	3	4	5
ALP	U/L	0	250	500	750	1,000
ALT	U/L	0	250	500	750	1,000
AMY	U/L	0	163	325	488	650
AST	U/L	0	250	500	750	1,000
CK	U/L	0	200	400	600	800
GGT	U/L	0	200	400	600	800
LD	U/L	0	150	300	450	600
LIP	U/L	50	413	775	1,138	1,500

Typical Values by Level 104ro						
Analyte	Units	1	2	3	4	5
ALP	U/L	3	302	602	901	1,200
ALT	U/L	4	103	202	301	400
AMY	U/L	3	377	752	1,126	1,500
AST	U/L	4	203	402	601	800
CK	U/L	4	578	1,152	1,726	2,300
GGT	U/L	3	302	602	901	1,200
LD	U/L	5	254	503	751	1,000
LIP	U/L	3	77	152	226	300

Typical Values by Level 104ri						
Analyte	Units	1	2	3	4	5
ALP	U/L	3	302	602	901	1,200
ALT	U/L	2	177	351	526	700
AMY	U/L	3	502	1,002	1,501	2,000
AST	U/L	2	177	351	526	700
CK	U/L	7	505	1,004	1,502	2,000
GGT	U/L	3	302	602	901	1,200
LD	U/L	10	258	505	753	1,000
LIP	U/L	3	77	152	226	300

ORDERING INFORMATION

ORDER NO. 104

VALIDATE Chem 4 Calibration Verification/Linearity Test Set 6 x 5 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