



## Chem 4 Calibration Verification / Linearity Test Kit

### INTENDED USE

**VALIDATE** Chem 4 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: alkaline phosphatase (ALP), alanine aminotransferase (ALT), amylase (AMY), aspartate aminotransferase (AST), creatine kinase (CK), gamma - glutamyl transferase (GGT), lactate dehydrogenase (LD) and lipase (LIP).

Each test kit consists of one bottle each of Levels 1 through 6. Each bottle contains 3.0 milliliters. There exists a linear relationship among Levels 1 through 6.

### SUMMARY

For each **VALIDATE** Calibration Verification / Linearity Test Kit, multiple levels are provided to establish the relationship between theoretical and actual performance of each of the included analytes. The **VALIDATE** 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 and constituents of human and/or animal source in a solution of bovine albumin.

Note: Some raw materials are purified from porcine.

#### 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 or CE approved methods and found to be non-reactive for HBV, HCV and HIV. 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

The **VALIDATE** Chem 4 Calibration Verification / Linearity Test Kit is 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.

### PREPARATION

Prior to use, remove the **VALIDATE** Chem 4 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 -10° to -25°C immediately after dispensing.

Discard any solutions that appear to have gross bacterial contamination.

**VALIDATE** Calibration Verification / Linearity Test Kits 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 Levels 1 through 5. This dilution scheme is consistent with the CLSI EP6 recommendation for preparing linearity sets.

Level 6 is manufactured to a specific target and the theoretical value is determined by multiplying the theoretical value of Level 3 by the factors provided:

Analyte	Factor	Analyte	Factor
ALP	4.13	CK	N/A
ALT	8.72	GGT	11.99
AMY	4.36	LD	4.50
AST	9.20	LIP	N/A

For CK and LIP, assay Levels 1 through 5 only.

Two examples for calculating the theoretical values of Levels 1 through 6 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 6.

Level 3 – Level 2 = Delta

Level 1 Theoretical = Level 2 Recovered – Delta  
Level 4 Theoretical = Level 3 Recovered + Delta  
Level 5 Theoretical = Level 4 Theoretical + Delta  
Level 6 Theoretical = Level 3 Recovered \* Level 6 factor

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)  
Level 6 Theoretical = Level 3 Theoretical \* Level 6 factor

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 LGC Maine Standards. 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** Calibration Verification / Linearity Test Kit solutions are not intended for use as routine quality control materials or as calibration materials.

## EXPECTED VALUES

VALIDATE Calibration Verification / Linearity Test Kits are manufactured such that an equal distance (delta) exists between levels as recommended by CLSI EP6 for assessing linearity. As the distance between Levels 1 through 5 is equal, any two levels between 1 and 5 can be held to be 'true' when assayed and the theoretical values for each of the other three levels can be calculated allowing this test kit to be used on multiple automated instrument systems. The theoretical value for Level 6 is calculated based on a known relationship to Levels 1 and 5 and can be calculated using the factor for each analyte listed in the factor table provided in the **ASSAY** section of this insert.

The reagent manufacturer's recommended diluent can be used to make dilutions of the low level to obtain a result lower than that level, 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 nonlinearity is an individual judgment based on methodology, clinical significance and medical decision levels of the test analyte.

Typical recovered values for Levels 1, 5 and 6 are presented in the table(s) provided. Typical values for mid-levels are based on an equal distance (delta) between levels 1 through 5.

Typical Recovered Values on Abbott ARCHITECT							
104ab Lot #: 4BI287200							
Analyte	Units	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
ALP	U/L	10	534	1059	1583	2107	4311
ALT	U/L	8	227	447	666	885	3769
AMY	U/L	7	696	1386	2075	2764	6130
AST	U/L	6	214	423	631	839	3835
CK	U/L	9	1003	1996	2990	3983	
GGT	U/L	8	353	699	1044	1389	7694
LD	U/L	24	471	919	1366	1813	3789
LIP	U/L	9	289	568	848	1127	



**CE Symbols** – This product fulfills the requirements of the European Directive 98/79/EC for *in vitro* medical devices. The following symbols may be used where applicable in labeling for Maine Standards Company products:



**Lot Number**



**Expiration Date**



**Manufacturer**



**Storage Temperature**



**In Vitro Diagnostic Medical Device**



**Catalog Number**



**Insert**



**Biological Risk**



**EC REP** Wellkang Ltd (www.CE-marking.eu)  
29 Harley St., London W1G 9QR, UK

For a list of countries in which VALIDATE® is registered see:  
[http://www.maineStandards.com/Products/ce\\_reg.php](http://www.maineStandards.com/Products/ce_reg.php)

**Rx Only**

## ORDERING INFORMATION

**ORDER NO.:** 104ab

**VALIDATE** Chem 4

Calibration Verification / Linearity Test Kit:  
6 x 3 mL

## CONTACT INFORMATION:



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