SP1 Calibration Verification / Linearity Test Kit

INTENDED USE

VALIDATE SP1 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:
α1-Antitrypsin (AAT), complement C3 (C3), complement C4 (C4), immunoglobulin A (IgA), immunoglobulin G (IgG), immunoglobulin M (IgM) and transferrin (TRF).

Each test kit consists of one bottle each of Levels 1 through 5. Each bottle contains 2.0 milliliters. There exists a linear relationship among Levels 1 through 5.

SUMMARY

Each **VALIDATE** SP1 Calibration Verification / Linearity Test Kit contains purified chemicals 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** SP1 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 for AAT, C3, C4, IgA, IgG, IgM and TRF in a solution of human serum.

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.

WARNING: Sodium Azide
Sodium Azide may react with lead and copper plumbing to form potentially explosive metal azides. On disposal, flush with a large volume of water to prevent azide build-up.

STORAGE AND STABILITY

VALIDATE SP1 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.

PREPARATION

Prior to use, remove the **VALIDATE** SP1 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.

The **VALIDATE** SP1 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.

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.

Two examples for calculating the theoretical values of Levels 1 through 5 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 and 5:

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

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

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)

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 SP1 Calibration Verification / Linearity Test Kit solutions are not intended for use as routine quality control materials or as calibration materials.

EXPECTED VALUES

VALIDATE SP1 Calibration Verification / Linearity Test Kits are manufactured such that a linear relationship exists among Levels 1 through 5.

TRACEABILITY

VALIDATE SP 1 Calibration Verification / Linearity Test Kit solutions are tested during manufacturing with standards traceable to the IFCC reference preparation to plasma proteins, BCR-470, where available. For analytes where BCR-470 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 recovered values for Level 1 and Level 5 are presented in the table below. Typical values for Mid-Levels are based on an equal distance (delta) between levels.

Typical Recovered Values on Beckman Coulter UniCel® DxC / Synchron®

601bc Lot #: 61AJ343190

Analyte	Units	Level 1	Level 2	Level 3	Level 4	Level 5
AAT	mg/dL	27	165	302	440	577
C3	mg/dL	18	96	175	253	331
C4	mg/dL	12	37	62	87	112
IGA	mg/dL	64	211	358	504	651
IGG	mg/dL	263	900	1537	2173	2810
IGM	mg/dL	35	122	209	296	383
TRFN	mg/dL	89	272	456	639	822

601bc Lot #: 61AJ343190

Analyte	SI Units	Level 1	Level 2	Level 3	Level 4	Level 5
AAT	g/L	0.270	1.645	3.020	4.395	5.770
C3	g/L	0.18	0.96	1.75	2.53	3.31
C4	g/L	0.12	0.37	0.62	0.87	1.12
IGA	g/L	0.6	2.1	3.6	5.0	6.5
IGG	g/L	2.6	9.0	15.4	21.7	28.1
IGM	g/L	0.4	1.3	2.1	3.0	3.8
TRFN	g/L	0.9	2.7	4.6	6.4	8.2

AAT Typical recovered values are obtained from the Roche cobas®.

ORDERING INFORMATION

ORDER NO.: 601bc

VALIDATE SP1
Calibration Verification / Linearity Test Kit 5 x 2 mL

Contact Information:
1-800-377-9684
+1-207-892-1300
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Please allow 5 to 7 days for delivery.

1-800-377-9684 • United States and Canada
+1-207-892-1300 • Outside the United States and Canada
+1-207-892-2266 • Fax
www.mainestandards.com

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 LGC Maine Standards products:

Lot Number

Expiration Date

Manufacturer

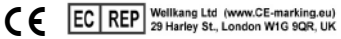
Storage Temperature

***In Vitro* Diagnostic Medical Device**

Catalog Number

Insert

Biological Risk



For a list of countries in which VALIDATE® is registered see:
http://www.mainestandards.com/Products/ce_reg.php

A worksheet to assist with manually calculating theoretical values can be found at www.mainestandards.com/Products or by calling Customer Support at 1-800-377-9684

Rx Only

Maine Standards Company, LLC., 221 US Route 1, Cumberland Foreside, ME 04110 USA

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