



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 chemistry systems for the following analytes: immunoglobulin A (IgA), immunoglobulin G (IgG), immunoglobulin M (IgM), complement C3 (C3), complement C4 (C4) and transferrin (TRF).

Each test set consists of one bottle each of Levels 1 through 5 and a High IgM. Levels 1 through 5 contain 1.0 milliliters. The bottle labeled "High IgM" is a sixth level for IgM testing only. The High IgM contains 0.7 milliliters. There exists a linear relationship among Levels 1 through 5. For IgM only, there exists a linear relationship among Levels 1 through 5 and High IgM.

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 chemistry systems, reagent problems and calibration anomalies.

REAGENTS

Reactive Ingredients:

Purified chemicals for immunoglobulin A (IgA), immunoglobulin G (IgG), immunoglobulin M (IgM), complement C3 (C3), complement C4 (C4) and transferrin (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 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.

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 stable until the expiration date printed on the storage container when stored at -10° to -20°C and handled according to instructions. **Do NOT store in a frost-free freezer.**

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 air be minimized. Tightly cap opened bottles and return to -10° to -20° 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 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. The bottle labeled "High IgM" is a sixth level that is manufactured to a specific target for IgM only and the theoretical value is determined by multiplying the value of Level 3 by 11.1.

Two examples for calculating the theoretical values of Levels 1 through 5, and High IgM, 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	26
Level 2	120
Level 3	215
Level 4	309
Level 5	401
Level 6	2388

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

Level 3 – Level 2 = Delta, or (215 – 120 = 95)

Level 1 Theoretical = Level 2 Recovered – Delta, or (120– 95 = 25)

Level 4 Theoretical = Level 3 Recovered + Delta, or (215 + 95 = 310)

Level 5 Theoretical = Level 4 Theoretical + Delta, or (309 + 95 = 404)

Level 6 Theoretical = Level 3 Recovered * 11.1 (IgM factor) or (215 * 11.1 = 2386)

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	25	26
2	120	120
3	215	215
4	310	309
5	404	401
6	2386	2388

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)

Level 6 = Level 3 Theoretical * 11.1 (IgM factor)

Using the recovered values for Level 1 (26) and Level 5 (401), the following applies:

Level 2 = 0.75 (26) + 0.25 (401) = 120

Level 3 = 0.5 (26) + 0.5 (401) = 213

Level 4 = 0.25 (26) + 0.75 (401) = 307

Level 6 = Level 3 Theoretical * 11.1 (IgM factor) = 2364

Level	Theoretical (x-axis)	Recovered (y-axis)
1	26	26
2	120	120
3	213	215
4	307	309
5	401	401
6	2364	2388

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 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 the Levels 1 through 5. The sixth bottle is an additional level for IgM testing only.

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

Typical Values by Level 60Ibcs							
Analyte	Units	1	2	3	4	5	High IgM
IgA	mg/dL	40	205	370	535	700	NA
IgG	mg/dL	200	1,050	1,900	2,750	3,600	NA
IgM	mg/dL	25	119	213	306	400	2,400
C3	mg/dL	35	114	193	271	350	NA
C4	mg/dL	10	40	70	100	130	NA
TRF	mg/dL	75	244	413	581	750	NA

ORDERING INFORMATION

ORDER NO.: 601bcs

VALIDATE SP1 Calibration Verification / Linearity Test Kit
5 x 1 mL
1 x 0.7 mL High IgM

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