Fibrinogen Calibration Verification / Linearity Test Kit

INTENDED USE
VALIDATE Fibrinogen Calibration Verification / Linearity Test Kit solutions are assayed quality control materials intended for *in vitro* diagnostic use in the quantitative determination of linearity, calibration verification and verification of reportable range for Fibrinogen activity on automated instruments in a clinical laboratory setting by laboratory personnel. The product is intended for use on IL TOP® analyzers.

SUMMARY
Each **VALIDATE** Fibrinogen Calibration Verification / Linearity Test Kit contains purified chemicals in a human plasma matrix. Multiple levels are provided to establish the relationship between theoretical and actual performance of the Fibrinogen analyte. The **VALIDATE** Fibrinogen 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.

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

REAGENTS
Reactive Ingredients:
Purified chemicals for Fibrinogen in a human plasma matrix.

Nonreactive Ingredients:
Preservatives and stabilizers.

Precautions and Warnings:
For In Vitro Diagnostic Use
Disposal of all waste materials 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
VALIDATE Fibrinogen Calibration Verification / Linearity Test Kits are stored at -10° to -25°C. ***Do NOT store in a frost-free freezer.***

Test kits are stable for up to six hours after thawing.

PREPARATION
Prior to use, remove the **VALIDATE** Calibration Verification / Linearity Test Kit from storage. Do NOT thaw at room temperature, thaw for 5 minutes in 37°C water bath. Invert gently several times before dispensing.

Discard any solutions that appear to have gross bacterial contamination.

The **VALIDATE** 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.

MATERIALS REQUIRED BUT NOT PROVIDED
IL TOP® analyzer

ASSAY
Analyze each level in replicates of 2 or 3. 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:

Mean Recovered Values	
Level 1	1
Level 2	496
Level 3	990
Level 4	1483
Level 5	1990

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

Level 3 - Level 2 = Delta, or (990 - 496 = 494)

Level 1 Theoretical = Level 2 Recovered - Delta, or (496 - 494 = 2)
Level 4 Theoretical = Level 3 Recovered + Delta, or (990 + 494 = 1484)
Level 5 Theoretical = Level 4 Theoretical + Delta, or (1484 + 494 = 1978)
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	2	1
2	496	496
3	990	990
4	1484	1483
5	1978	1990

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)

Using the recovered values for Level 1 (1) and Level 5 (1990), the following applies:

Level 2 Theoretical = 0.75 * (1) + 0.25 * (1990) = 498
Level 3 Theoretical = 0.5 * (1) + 0.5 * (1990) = 996
Level 4 Theoretical = 0.25 * (1) + 0.75 * (1990) = 1493

Level	Theoretical (x-axis)	Recovered (y-axis)
1	1	1
2	498	496
3	996	990
4	1493	1483
5	1990	1990

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 Fibrinogen Calibration Verification / Linearity Test Kit solutions are not intended for use as calibration materials. They are limited for use with: IL TOP® analyzers.

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

TYPICAL VALUES
Actual results obtained may vary depending on instrumentation and methodology. 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.

VALIDATE Fibrinogen Calibration Verification / Linearity Test Kit solutions are manufactured such that an equal distance (delta) exists between levels as recommended by CLSI EP6 for assessing linearity.

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 IL ACL TOP®						
904il Lot #: 94AQ052200						
Analyte	**Units**	**Level 1**	**Level 2**	**Level 3**	**Level 4**	**Level 5**
Fibrinogen	mg/dL	55	258	461	664	867

904il Lot #: 94AQ052200						
Analyte	**SI Units**	**Level 1**	**Level 2**	**Level 3**	**Level 4**	**Level 5**
Fibrinogen	g/L	0.055	0.258	0.461	0.664	0.867

PRECISION AND REPRODUCIBILITY

Product precision and reproducibility were established following the CLSI EP05-A3 standard requirements. Three lots of **VALIDATE** Fibrinogen were tested with one lot of IL TOP® reagent and quality controls on the IL TOP® instrument system over 20 days, 2 runs per day, 2 replicates per run for Level 1 through Level 5 to obtain a total of eighty (80) replicates per kit Level per individual lot (total of 240 replicates per kit Level over 3 lots).

VALIDATE Fibrinogen Precision Study Summary Three Individual Lots – IL TOP®

VALIDATE® Fibrinogen Precision Study Summary Three Individual Lots - IL Top												
			Within-Run		Between-Run		Between-Day		Between-Lot		Total	
Sample	N	mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Level 1	240	54	5.4	10%	1.1	2%	0.0	0%	0.5	1%	5.5	10%
Level 2	240	225	12.6	6%	6.6	3%	0.0	0%	1.9	1%	14.4	6%
Level 3	240	405	22.3	6%	13.2	3%	3.1	1%	0.0	0%	26.1	6%
Level 4	240	598	31.8	5%	12.4	2%	1.9	0%	1.2	0%	34.2	6%
Level 5	240	793	40.3	5%	19.0	2%	10.5	1%	45.8	6%	45.8	6%

Reproducibility was evaluated with the **VALIDATE** Fibrinogen kit containing 5 levels following the product package insert instructions. One lot of **VALIDATE** Fibrinogen Calibration Verification / Linearity Test Kit was tested with one lot of IL TOP® reagent and quality controls on three instruments, multi-site, over 5 days, with 1 run per day of Level 1 through Level 5, with 5 replicates per run to obtain seventy-five (75) replicates per kit level.

VALIDATE® Fibrinogen Reproducibility Study - IL Top Lot AD15817RD mg/dL								
			Repeatability		Within Laboratory		Reproducibility	
Sample	N	mean	SD	%CV	SD	%CV	SD	%CV
Level 1	75	54	3.7	7%	4.1	8%	4.3	8%
Level 2	75	237	11.2	5%	13.8	6%	13.8	6%
Level 3	75	434	20.8	5%	20.8	5%	28.3	7%
Level 4	75	641	24.7	4%	26.1	4%	41.9	7%
Level 5	75	843	34.0	4%	34.0	4%	53.1	6%

ORDERING INFORMATION

ORDER NO.: 904il

VALIDATE Fibrinogen
Calibration Verification / Linearity Test Kit: 5 x 2 mL

For technical assistance or to place an order, call:
1-800-377-9684
+1-207-892-1300
+1-207-892-2266 Fax
msc.sales@LGCGroup.com
msc.techsupport@LGCGroup.com
www.mainestandards.com

Please allow 5 to 7 days for delivery.

Maine Standards Company
221 US Route 1
Cumberland Foreside, ME 04110 USA
1-800-377-9684
+1-207-892-1300
+1-207-892-2266 Fax
www.mainestandards.com

Symbols – 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:
www.mainestandards.com/ce

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