D-Dimer Calibration Verification / Linearity Test Kit

INTENDED USE

VALIDATE D-Dimer 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 the following analyte: D-Dimer in a clinical laboratory setting by laboratory personnel. The product is intended for use with quantitative assays on the indicated analyzers specified in the labeling.

Each test kit contains one bottle each of Levels 1 through 5. Each bottle contains 3 milliliters. There exists a linear relationship among Levels 1 through 5.

SUMMARY

Each **VALIDATE** D-Dimer 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 D-Dimer analyte. The **VALIDATE** D-Dimer 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 human plasma.

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. Use the Centers for Disease Control (CDC) recommended universal precautions for handling VALIDATE products.

STORAGE AND STABILITY

The **VALIDATE** D-Dimer 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***. A maximum of four (4) freeze-thaw cycles is recommended.***

PREPARATION

Prior to use, remove the **VALIDATE** D-Dimer 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 -25ºC 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.

MATERIALS REQUIRED BUT NOT PROVIDED

Stago STA® analyzer and LiaTest reagent.

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.

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.

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 Clinical Diagnostics. 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 calibration materials. They are limited for use with: Stago STA® analyzers and LiaTest reagent.

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 is equal, any two levels 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 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 are calculated based on CLSI EP6 equal distance (delta) manufacturing protocols where two recovered values can be held as "True", and other levels calculated based on equal distance. VALIDATE typically uses Level 1 and Level 3 to calculate additional target values.

Typical Recovered Values on Stago STA®

902st Lot: 10825453

Analyte	Units	Level 1	Level 2	Level 3	Level 4	Level 5
D-Dimer	ng/mL FEU	204.44	980.78	1757.11	2533.44	3309.78

902st Lot: 10825453

Analyte	SI Units	Level 1	Level 2	Level 3	Level 4	Level 5
D-Dimer	µg/mL FEU	0.20	0.98	1.76	2.53	3.31

PRECISION AND REPRODUCIBILITY

Product precision and reproducibility were established following the CLSI EP05-A3 standard requirements. Three lots of VALIDATE® D-Dimer product were tested with one lot of Stago Lia Test D-Dimer reagent and quality controls on the Stago STA-R® 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.

VALIDATE® D-Dimer Precision Study Summary Three Individual Lots - STAGO

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				Mean	Within run		Between - Run		Between - Day		Within - Laboratory	
	Lot	Days	N	ug/mL	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Level 1	AA35315RD	20	80	0.44	0.08	18.5%	0.000	0.00%	0.027	6.2%	0.086	19.5%
	AF35315RD	20	80	0.46	0.055	11.8%	0.015	3.20%	0.03	6.5%	0.064	13.8%
	AK35315RD	20	80	0.46	0.057	12.6%	0.043	9.40%	0.045	9.8%	0.085	18.6%
Level 2	AA35315RD	20	80	1.15	0.055	4.7%	0.000	0.00%	0.016	1.4%	0.057	4.9%
	AF35315RD	20	80	1.15	0.054	4.7%	0.013	1.20%	0.025	2.2%	0.061	5.3%
	AK35315RD	20	80	1.14	0.051	4.4%	0.019	1.70%	0.016	1.4%	0.057	4.9%
Level 3	AA35315RD	20	80	1.88	0.059	3.1%	0.024	1.30%	0.000	0.0%	0.064	3.4%
	AF35315RD	20	80	1.92	0.042	2.2%	0.000	0.00%	0.036	1.9%	0.055	2.9%
	AK35315RD	20	80	1.88	0.06	3.2%	0.000	0.00%	0.041	2.2%	0.072	3.9%
Level 4	AA35315RD	20	80	2.68	0.117	4.4%	0.000	0.00%	0.068	2.5%	0.135	5.0%
	AF35315RD	20	80	2.67	0.067	2.5%	0.38	1.40%	0.000	0.0%	0.077	2.9%
	AK35315RD	20	80	2.67	0.136	5.1%	0.000	0.00%	0.054	2.0%	0.146	5.5%
Level 5	AA35315RD	20	80	3.53	0.171	4.8%	0.000	0.00%	0.000	0.0%	0.171	4.8%
	AF35315RD	20	80	3.56	0.168	4.7%	0.000	0.00%	0.077	2.2%	0.185	5.2%
	AK35315RD	20	80	3.56	0.08	2.2%	0.058	1.60%	0.051	1.4%	0.111	3.1%

Reproducibility was evaluated with the VALIDATE® D-Dimer kit containing 5 levels following the product package insert instructions. One lot of VALIDATE® D-Dimer Calibration Verification / Linearity Test Kit was tested with one lot of Stago LiaTest D-Dimer 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® D-Dimer Reproducibility Study - STAGO Lot AA35315RD

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			Repeatability		Within Laboratory		Reproducibility	
Sample	N	mean	SD	%CV	SD	%CV	SD	%CV
Level 1	75	0.44	0.061	13.8%	0.066	15.0%	0.069	15.5%
Level 2	75	1.15	0.054	4.7%	0.054	4.7%	0.063	5.5%
Level 3	75	1.87	0.065	3.5%	0.065	3.5%	0.089	4.7%
Level 4	75	2.65	0.052	2.0%	0.059	2.2%	0.081	3.1%
Level 5	75	3.5	0.275	7.9%	0.282	8.1%	0.3	1.2%

Precision and reproducibility met all acceptance criteria.

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 Clinical Diagnostics products:

Lot Number

Expiration Date

Manufacturer

Storage Temperature

In Vitro Diagnostic Medical Device

Catalog Number

Insert

Biological Risk

Do Not Reuse

EC REP Wellkang Ltd, Enterprise Hub, NW Business Complex, 1 Beraghmore Rd, Derry, BT48 8SE, Northern Ireland

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

Rx Only

ORDERING INFORMATION

ORDER NO.: 902st for Stago

VALIDATE D-Dimer
Calibration Verification / Linearity Test Kit:
5 x 3 mL

CONTACT INFORMATION:

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