



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 for D-Dimer in a human plasma matrix.

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** 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 -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.

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 = $0.75 * (\text{Level 1}) + 0.25 * (\text{Level 5})$

Level 3 Theoretical = $0.5 * (\text{Level 1}) + 0.5 * (\text{Level 5})$

Level 4 Theoretical = $0.25 * (\text{Level 1}) + 0.75 * (\text{Level 5})$

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

They are limited for use with: Stago STA® analyzer 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.

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(s) provided. Typical values for mid-levels are based on an equal distance (delta) between levels.

902st		Typical Recovered Values				
Lot#: 92AJ091190		on Stago STA®				
Analyte	Units	Level 1	Level 2	Level 3	Level 4	Level 5
D-Dimer	ng/mL FEU	341.44	1116.49	1891.54	2666.58	3441.63

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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	Lot	Days	N	Mean ug/mL	Within run SD	Within run %CV	Between - Run SD	Between - Run %CV	Between - Day SD	Between - Day %CV	Within - Laboratory SD	Within - Laboratory %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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Sample	N	mean	Repeatability		Within Laboratory		Reproducibility	
			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.

ORDERING INFORMATION

ORDER NO.: 902st for Stago

VALIDATE D-Dimer

Calibration Verification / Linearity Test Kit:

5 x 3 mL



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



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_req.php

Rx Only

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