

quantex D-Dimer

Kit Configuration

P/N 3000-8501	2 x 13 mL D-Dimer R1
	2 x 3 mL D-Dimer R2

Reagent Preparation

P/N 3000-8501 D-Dimer R1: Ready to use
 D-Dimer R2: Reconstitute the vial with 3 mL of NCCLS Type II water or equivalent.⁹ Replace the stopper and swirl gently. Make sure of the complete reconstitution of product. Keep the reagent at 15-25°C for 30 minutes and invert to mix before use. Do not shake.
 Place the bottles into reagent tray.

In Use Stability

D-Dimer R1 Opened vial: 1 month at 2-8°C in the original vial, 2 weeks at 15°C on board.
 D-Dimer R2: Reconstituted vial: 1 month at 2-8°C in the original vial, 2 weeks at 15°C on board. Do not freeze.
 For optimal stability remove reagents from the system and store them at 2-8°C in the original vial securely closed.

Specimen

Serum.

Calibration

Use quantex D-DIMER standard Cat. No 3000-8502. The calibrator contains 3200 ng/mL of D-Dimer. Prepare the following serial dilution of the standard with saline: (0) saline, 200, 400, 800 1600 and 3200 ng/mL (undiluted)
 A reagent blank should be run daily before sample analysis. Recalibrate every 30 days or when a new lot of reagent is used.

Quality Control

Use quantex D-DIMER control I/II Cat. No. 3000-8503.

Calculation of Analytical Results

The results concentration is automatically calculated by the instrument against the Calibration curve. For detailed description, refer to the Instrument settings and to the ILab 600/650 Operator's Manual.

Reference Interval

Upper Normal range: 198 ng/mL
 The Upper Normal range was performed on 56 men, 61 women with age range 18-66. The upper limit of the normal range was calculated as recommended by the IFCC. These results were obtained using a specific lot of reagents. The upper normal range limit was estimated testing plasma samples from healthy adult blood bank donors.
 Due too many variables which may affect results, each laboratory should establish its own normal range.

References / Literatur / Bibliografía / Bibliographie / Bibliografia /

See package insert enclosed in the kit

Performance Characteristics

Limitation/Interfering Substances

D-Dimer results are not affected by hemoglobin up to 500 mg/dL (0.3 mmol/L), bilirubin up to 18 mg/dL (308 μmol/L), triglycerides up to 1280 mg/dL (14.5 mmol/L) and heparin (LMW and UF) up to 1.5 IU/L. Rheumatoid factor interferes with the assay. Hemolysed samples should not be assayed.

The monoclonal antibody (MA-8D3) used in the reagent has major specificity for the D-Dimer domain of cross-linked Fibrin Degradation Products and has demonstrated low cross-reactivity to Fibrinogen Degradation Products with plasma samples spiked with purified Fragments D and E.

Precision

	Samples/Runs	Mean (ng/mL)	CV(%)	Mean (ng/mL)	CV(%)
Within run	6/10	302	4.0	637	2.2
Total	6/10	302	5.7	637	2.8

Method Comparison

Comparison Method (x)	Turbidimetric assay
Slope	1.059
y intercept	50.2
Range (ng/mL)	17 - 24149
Mean X (ng/mL)	1283
Mean Y (ng/mL)	1299
r	0.987
n	137

Linearity

no rerun 150 – 3200 ng/mL ; with rerun 150 - 32000 ng/mL

Instrument Settings

Photometric Test Parameters		Serum
Test No.		**
Test Name, Test Code		D-Dimer,D-Dimer
Sample Type		Others (Plasma)
Reporting Unit, Decimal Points		ng/mL, 0
Reaction Cycle		Standard
Twin Analysis		OFF
Methodology Type, Measuring Point		Rate, 19/28
Photometric Methodology		1 Wavelength
Primary/Secondary Wavelength		660
Sampling Conditions		
<i>Sampling 1</i>	Sample Vol.	20
	Sample/Diluent Vol.	0/0
<i>Sampling 2</i>	Sample Vol.	20
	Sample/Diluent Vol.	15/135
<i>Sampling 3</i>	Sample Vol.	***
	Sample/Diluent Vol.	0/0
<i>Sampling 4</i>		***
Diluent Code		Saline
Diluent Warning Limit		***
First Run		Sampling 1
Below/Above Normal Range		***
Panic L		***
Panic H		Sampling 2
Noise		***
Prozone		N/A
High!, ABS!		Sampling 2
Sample Volume Reduction		**
Reagent Volumes		
R1	Code	01941
	Rgt/Dil. Vol. Stirring	200/0, ON
	Low Vol. Warning Limit	***
	Stability (days)	14
R2	Code	01942
	Rgt/Dil. Vol. Stirring	60/5, ON
	Low Vol. Warning Limit	***
	Stability (days)	14

Ranges and Evaluation Criteria	Serum
Normal Range-Male	**
Normal Range-Female	**
Normal Range-Other	**
Valid Range	0 - 3200
Hemolysis/Icterus/Lipemia Limit	***
Reaction Slope	Positive
Absorbance Limit	Above, 1350
Prozone Limit	N/A
Non Linear Limit	N/A
Slope/Intercept Correction	1/0
Qualitative Report	OFF
Calibration Conditions	
Calibration	6 Points, point to point, 2 Reps
Stability (days)	30
Calibrator, Concentration	D-Dimer Std* (0 Saline)
R-Blank Limit (mAbs)	1500
Cal. Reps Range (%)	***
Min Cal. Response (mAbs)	***
Cal. Factor Change (%)	***
M-Point Curve Fit (%)	N/A
Reagent Blank	ON
Auto R-Blank by Bottle	ON

- * Lot dependent
- ** operator definable
- *** optional
- N/A not applicable to this test