

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 300-8502. 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 14 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 350 Operator 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 (256 μmol/L), triglycerides up to 1280 mg/dL (14 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	4/10	360.4	3.0	814.5	2.1
Total	4/10	360.4	7.8	814.5	7.1

Method Comparison

Comparison Method (x)	Turbidimetric assay
Comparison Method Instrument (x)	ILab 600
Slope	1.059
y intercept	50.2
Mean X (ng/mL)	1283
Mean Y (ng/mL)	1299
r	0.97
n	137

Linearity

no rerun 53.5 – 1600 ng/mL ; with rerun 53.5 - 9600 ng/mL

Minimun Detection Limit

43.3 ng/mL

Quantification Limit

53.5 ng/mL

Instrument Settings

Chemistry Parameters		R1	
Method	<input type="text"/>	Reagent Name	<input type="text" value="DDimer"/> Volume <input type="text" value="150 μL"/>
Name	<input type="text" value="Ddimer"/>	R2	<input type="text" value="enable"/> <input type="text"/>
Unit	<input type="text" value="ng/dL"/>	Reagent Name	<input type="text" value="DDimer"/> Volume <input type="text" value="45 μL"/>
Assay Type	<input type="text" value="End"/>	Wash	<input type="text" value="disable"/> Reagent Name <input type="text"/>
			Reagent Type <input type="text"/>
		Diluent	<input type="text" value="enable"/> Reagent Name <input type="text" value="Saline"/>
Measuring Points	1 <input type="checkbox"/> enable start <input type="text" value="14"/> end <input type="text" value="14"/>	Decimal Points	<input type="text" value="1"/>
	2 <input type="checkbox"/> enable start <input type="text" value="20"/> end <input type="text" value="21"/>	Normal Range	<input type="text" value="0"/> <input type="text" value="200"/>
Wave Length	Prim <input type="text" value="600"/> Sec <input type="text"/>	Technical Range (Conc)	<input type="text" value="0.0"/> <input type="text" value="1600"/>
		mAbs/10	<input type="text" value="-30000"/> <input type="text" value="30000"/>
Sampling Volume	<input type="text" value="15 μL"/>	RPT Wash (R1)	<input type="text" value="Sys Water"/>
Dilution	<input type="text" value="disable"/> <input type="text" value="μL"/> <input type="text" value="μL"/>	(R2)	<input type="text" value="Sys Water"/>
Rerun (High)	<input type="text" value="15 μL"/>	Instrument Factor a	<input type="text" value="1"/> <input type="text" value="b"/> <input type="text" value="0"/>
Dilution	<input type="text" value="enable"/> <input type="text" value="25 μL"/> <input type="text" value="125 μL"/>	Stirring Speed	R1 <input type="text" value="mid"/> R2 <input type="text" value="mid"/>
Rerun (Low)	<input type="text" value="30 μL"/>		

Calibration Checks

** Duplicate Limit	<input type="text"/>	** mAbs/10	Sampling Method for Standards
** Sensitivity Limit	<input type="text"/>	** mAbs/10	<input checked="" type="checkbox"/> Duplicate
			<input type="checkbox"/> Triplicate
** Linearity Limit	<input type="text"/>	** %	Blank measurement
** Prozone Limit	<input type="text"/>	upper <input type="text"/>	<input checked="" type="checkbox"/> Enable Reagent blank
SL1-S	<input type="text"/>	SL1-F **	<input type="text" value="None"/>
SL2-S	<input type="text"/>	SL2-F **	Reagent blank measurement at calibration
Sens	<input type="text"/>	** mAbs/10	<input checked="" type="checkbox"/> Reagent blank (system water)
<input checked="" type="checkbox"/> Absorbance Limit	Reaction <input type="text" value="Increase"/>	** Multiplex measurement is the same as standards	Reagent Blank Limit Checks
Limit	<input type="text" value="25000"/> mAbs/10		<input type="text"/>
		** Duplicate limit	<input type="text" value="50"/> mAbs/10

Calibration

Method	<input type="text"/>	Name	<input type="text" value="Ddimer"/>	Interval	<input type="text" value="14"/> days
Calculation	<input type="text" value="Linear"/>				
	Conc	WORK	MASTER	Lot No	
S1	<input type="text" value="0"/>	<input type="text" value="-16"/>			K <input type="text" value="N/A"/>
S2	<input type="text" value="200"/>	<input type="text" value="509"/>			
S3	<input type="text" value="400"/>	<input type="text" value="925"/>			
S4	<input type="text" value="700"/>	<input type="text" value="1761"/>			
S5	<input type="text" value="1600"/>	<input type="text" value="3748"/>			
S6					

Calibration (2/2) Autodilution

Serial Dilution	<input checked="" type="checkbox"/> enable	<input type="checkbox"/> disable	Claculation	<input type="text" value="Point to Point"/>
	Conc	Post Sampling (μL)	Pre Sampling (μL)	Diluent(μL)
S1	<input type="text" value="0"/>	<input type="text" value="15"/>	<input type="text" value="0"/>	<input type="text" value="80"/>
S2	<input type="text" value="200"/>	<input type="text" value="15"/>	<input type="text" value="10"/>	<input type="text" value="70"/>
S3	<input type="text" value="400"/>	<input type="text" value="15"/>	<input type="text" value="20"/>	<input type="text" value="60"/>
S4	<input type="text" value="700"/>	<input type="text" value="15"/>	<input type="text" value="35"/>	<input type="text" value="45"/>
S5	<input type="text" value="1600"/>	<input type="text" value="15"/>	<input type="text" value="0"/>	<input type="text" value="0"/>
S6				

Reagent Registration

Reagent Code	<input type="text" value="0188"/>	Volume (L)	<input type="text"/>	Volume (S)	<input type="text"/>	Stability Check	<input type="text"/>	Term	<input type="text"/>
Reagent Name	<input type="text" value="Ddimer"/>		mL		mL	<input checked="" type="checkbox"/> enable		**	days
R1	<input checked="" type="checkbox"/> enable	**	mL	**	mL	<input checked="" type="checkbox"/> enable		**	days
R2	<input checked="" type="checkbox"/> enable	**	mL	**	mL	<input checked="" type="checkbox"/> enable		**	days

** Operator definable N/A not applicable to this test Calibration curve is only as example

