

KIVO D-DIMER

(Latex Enhanced Turbidimetric Immuno Assay)
(LETIA)



Emergency Test for
exclusion of
DVT or PE

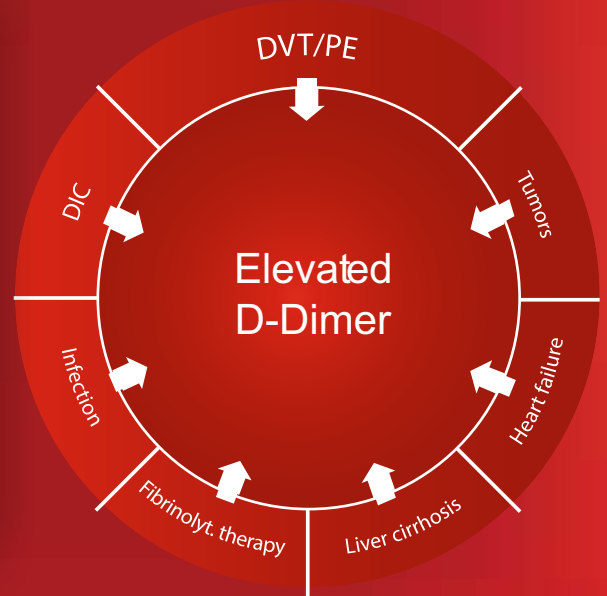
Coagulation
Marker

Clinical Implications:

- Deep Vein Thrombosis (DVT)
- Pulmonary Embolism(PE)
- Disseminated Intravascular Coagulation (DIC)
- Fibrinolytic Therapy
- Tumors
- Infection
- Heart Failure
- Liver Cirrhosis

Clinical Relevance

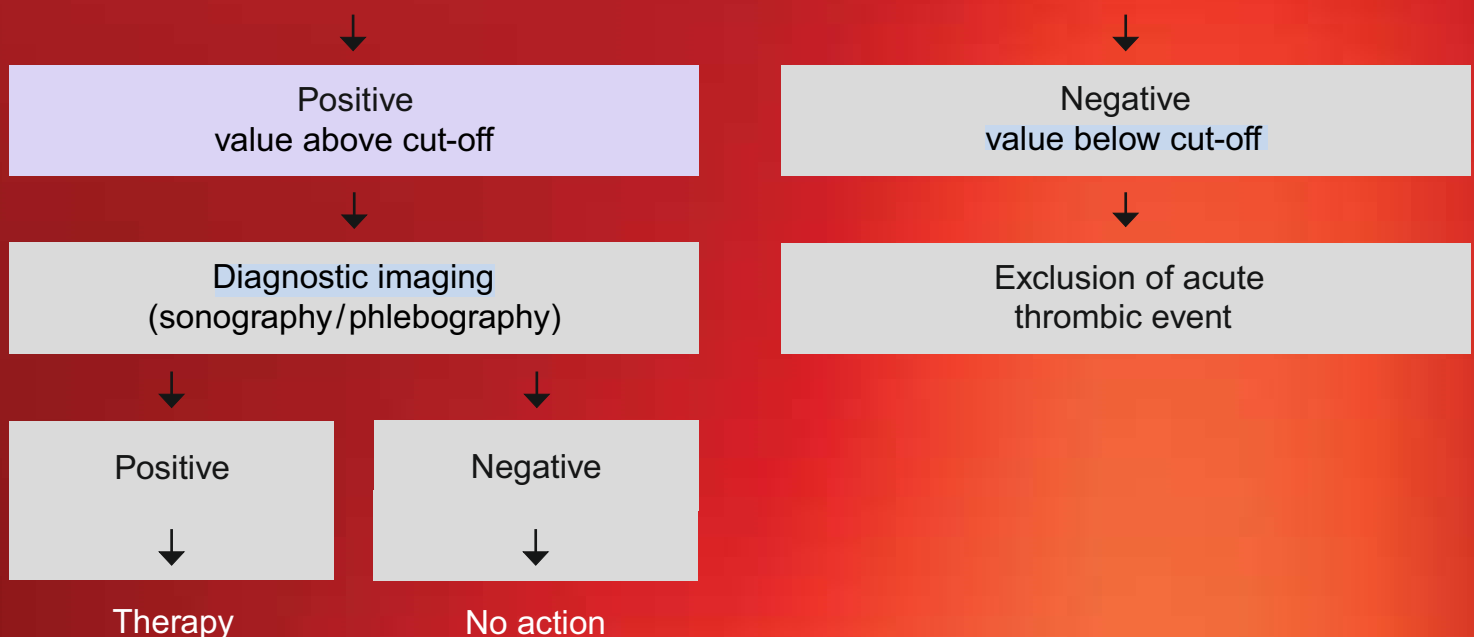
The fibrin degradation product, D-Dimer is detectable after plasmin degradation of cross-linked fibrin. Elevated D-Dimer values indicate increased thrombin activity and fibrin formation and are therefore an indirect marker of Venous Thrombotic Events (VTE). D-Dimer values are increased in various conditions, such as cancer, liver cirrhosis or infections, which make a reliable diagnosis of a thrombotic event difficult. However, D-Dimer results have a high negative predictive value (NPV) in order to exclude Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE).



Diagnostic Value of D-Dimer

Individuals with signs or symptoms suggestive of a thromboembolic phenomenon are initially screened with a D-Dimer test to exclude DVT or PE. DVT is ruled out in patients with D-Dimer levels below the cut-off value of $0.8 \mu\text{g FEU/mL}$, whereby values above this cut-off have to undergo further investigations as sonography or phlebography. The Kivo D-Dimer reagent has demonstrated diagnostic sensitivity of 98% and diagnostic specificity of 95.0% for DVT at a cut-off value of $0.8 \mu\text{g FEU/mL}$. D-Dimer levels below $0.8 \mu\text{g FEU/mL}$ have a NPV of 99.4% for exclusion of DVT. These results are according to CLSI requirements of a diagnostic sensitivity of $\geq 97\%$ and a NPV of $\geq 98\%$

D-Dimer testing in suspected VTE

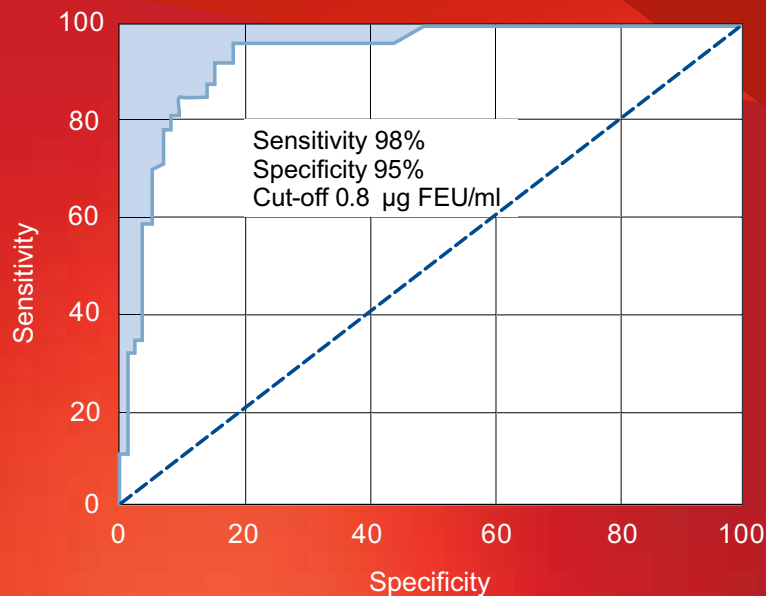


Product Attributes and Advantages

- Latex Enhanced Turbidimetric Immuno Assay (LETIA)
- Ready-to-use liquid stable two reagents
- 6 Level Calibrator set provided
- 2 Level Controls provided (Optional)
- Measuring wavelength 570 nms (570-600 nms)
- 10 Minutes Test Procedure
- Linearity 8.7 µg FEU/ml
- High prozone security up to 50 µg FEU/mL
- Superior onboard and calibration stability of 6 weeks
- Excellent precision
- Excellent correlations compared to existing commercial D-Dimer assays
- Excellent low limit of quantitation : 0.15 µg/mL FEU

Performance Characteristics

Diagnostic Sensitivity



	Positive for DVT	Negative for DVT
Kivo D-Dimer Positive > Cut-off 0.8 µg FEU/mL	True positive 49	False positive 10
Negative < Cut-off 0.8 µg	False negative 1	True negative 190

n = 250, 50 confirmed DVT; 100 suspected of DVT, but not confirmed; 100 outpatients were tested for D Dimer

Precision

Intra-assay N = 20	Mean (µg FEU/mL)	CV (%)	Inter-assay N = 20	Mean (µg FEU/mL)	CV (%)
Low level sample	37.3	0.58	Low level sample	0.66	4.59
Medium level sample	59.5	0.79	Medium level sample	0.95	2.18
High level sample	113	0.33	High level sample	3.59	1.10

ASSAY SPECIFICATIONS

Method	Latex Enhanced Turbidimetric Immuno Assay (LETIA)
Sample Type & Volume	Human Na Citrate Plasma Sample Volume 3 μ L
Method Correlation	N = 128 y-intercept = 0.106 Slope = 0.979 R ² = 0.939 Samples ranged from 0.17 - 7.95 μ g/mL FEU in comparison with an existing commercial D-Dimer assay method
Linearity	0.15 to 8.7 μ g/mL FEU
LOD LOB LOQ	0.06 μ g/mL FEU 0.09 μ g/mL FEU 0.15 μ g/mL FEU
Calibration Levels	6-Point Calibration
Reagent On-Board Stability	6 weeks when stored at 2-8°C

D-Dimer Assay Procedure*



*Analyzer Dependent

Bibliography:

1. Sandkamp, M et al. Clin Chem 1990;36:20-23
2. Medicon CE folder data
3. Bick R.L. et al. Thromb Res 1992;65:785-90.
4. Wo, J.H. et al. Clin Chem 1993;39:209-212
5. Gaffney PJ. Fibrinolysis Supplement 2.1993;7:2-8



ASSAY PRECISION

Precision Evaluation of Kivo's D-Dimer Assay

The precision of Kivo's D-Dimer Assay was evaluated according to Clinical Laboratory Standards Institute EP5-A guidelines. The study tested three levels of pooled citrated plasma specimens with D-Dimer concentrations of 0.60 μ g/mL, 2.41 μ g/mL, and 5.88 μ g/mL FEU. The low plasma sample was unaltered, while the other two samples were spiked with D-Dimer stock solution to achieve targeted concentrations. Three levels of D-Dimer controls with concentrations of 0.97, 2.99, and 7.47 μ g/mL FEU were also tested.

	Level 1	Level 2	Level 3
Mean (μ g/mL FEU)	0.60	2.41	5.88
SD (μ g/mL FEU)	0.03	0.05	0.08
CV (%)	5.0%	2.0%	1.4%

Plasma Samples Total Precision

	Level 1	Level 2	Level 3
Mean (μ g/mL FEU)	0.60	2.41	5.88
SD (μ g/mL FEU)	0.04	0.07	0.19
CV (%)	6.2%	2.7%	3.2%

Control Samples Within-Run Precision

	Level 1	Level 2	Level 3
Mean (μ g/mL FEU)	0.97	2.99	7.47
SD (μ g/mL FEU)	0.03	0.05	0.11
CV (%)	2.9%	1.6%	1.4%

Control Samples Total Precision

	Level 1	Level 2	Level 3
Mean (μ g/mL FEU)	0.97	2.99	7.47
SD (μ g/mL FEU)	0.04	0.08	0.27
CV (%)	4.4%	2.8%	3.6%

INTERFERENCE STUDIES

The following substances do not interfere with this assay at the levels tested (less than 10% bias):

Hemoglobin:	up to 500 mg/dL	Bilirubin Conjugated:	up to 40 mg/dL
Bilirubin:	up to 40 mg/dL	Ascorbic acid:	up to 176 mg/dL
Triglycerides:	up to 1000 mg/dL	Rheumatoid Factor :	up to 100 IU/mL
Heparin:	up to 1.5 IU/mL	HAMA:	up to 490 ng/mL

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