

# FLETCHER ALLEN HEALTH CARE

## PATHOLOGY & LABORATORY MEDICINE

### ***TEST UPDATE: D-DIMER ASSAY***

#### **ASSAY INFORMATION:**

Beginning Monday April 7, 2010, the Hematology Laboratory will begin using a new methodology for quantitative D-dimer testing. The HemosIL brand D-dimer assay is specifically approved by the Food and Drug Administration (FDA) for the use in excluding Venous Thromboembolism in low and moderate risk patients.

#### **CLINICAL APPLICATION:**

Elevated levels of D-Dimer are found in clinical conditions such as deep vein thrombosis (DVT), pulmonary embolism (PE), and disseminated intravascular coagulation (DIC). D-Dimer levels also rise during the normal pregnancy; nonetheless, very high levels are associated with complications.

A D-Dimer result less than 230 ng/mL, when combined with a clinical assessment of low pretest probability, has been shown to have a high negative predictive value for DVT or PE.

#### **METHOD:**

The Quantitative D-dimer assay uses latex microparticles to photo-optically detect binding of specific monoclonal antibody to D-dimer in a patient's plasma. These latex microparticles aggregate in the presence of fibrin derivatives containing the D-dimer domain. The rate of latex microparticle aggregation is proportional to the concentration of D-dimer in the patient's plasma. The patient's D-dimer concentration is then interpolated from a reference curve. The results of the new D-dimer assay are expressed in nanograms of D-dimer units per microliter (ng/mL). Currently we are reporting µg fibrinogen equivalent units (FEU) /mL.

Below are examples of unit comparisons for informational purposes only. Since methods vary in antibody specificity and calibrator composition, they are equivalent mathematically but represent only an approximate comparison between methods.

<b>Current Units: µg FEU/mL</b>	<b>New Units: ng/mL D-dimer</b>
0.50	250
1.00	500
5.00	2,500
20.00	10,000

The following D-dimer interpretative data will also be appended to all D-dimer assay results along with an assay-specific normal range:

Normal Range:                      Less than 230 ng/mL

Cutoff Value for the Exclusion of DVT and PE: 230 ng/mL

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### ***TEST UPDATE: D-DIMER ASSAY***

#### **ORDERING AND SAMPLE INFORMATION:**

<b>Test Name:</b>	D-Dimer
<b>Test Code:</b>	DDT
<b>Bracket Code:</b>	171
<b>CPT Code:</b>	85379
<b>Sample Requirements:</b>	Submit 3.5 mL blue top tube at room temperature within 3-hours of collection. Tube must be full to black marker on tube. For delayed delivery spin and freeze plasma.
<b>Days performed:</b>	Daily
<b>Analytical Time:</b>	Same day
<b>Expected Value:</b>	Less than 230 ng/mL
<b>Price:</b>	Please contact laboratory Customer Service for pricing information, 847-5121 or (800) 991-2799.
<b>Effective Date:</b>	April 7, 2010



*In alliance with  
the University of Vermont*

A Publication of  
Pathology & Laboratory Medicine  
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Phone: (802)847-5121 or  
(800)991-2799  
<http://www.fahc.org/pathology>

INTERIM LABORATORY REPORT  
PRINTED @ 03/29/2010

DDT, EXAMPLE  
MRN: LABH9-61  
DOB: 05/05/1955

Loc: LABH9  
Sex: M

Clinician: LUNDE MD, JOHN H

M4496 COLL: 03/29/2010 10:50 REC: 03/29/2010 10:52 PHYS: LUNDE MD, JOHN H

D-Dimer <200 [<230] ng/ml  
CUTOFF VALUE FOR THE EXCLUSION OF DVT and PE:  
230 ng/ml  
\*\*\*Please note new reporting units  
and normal range effective  
04/07/2010\*\*\*

**D-Dimer Report of a Normal Value**

END OF REPORT

H = High L = Low \* = Critical

DDT, EXAMPLE  
Edwin Bovill, M.D. Director  
Printed @ 11:27

111 Colchester Ave. Burlington, Vermont 05401

MRN: LABH9-61

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INTERIM LABORATORY REPORT  
PRINTED @ 03/29/2010

DDT, EXAMPLE2  
MRN: LABH9-62  
DOB: 07/07/1947

Loc: LABH9  
Sex: F

Clinician: LUNDE MD, JOHN H

M4497 COLL: 03/29/2010 10:50 REC: 03/29/2010 10:52 PHYS: LUNDE MD, JOHN H

D-Dimer H 2609 [<230] ng/ml  
CUTOFF VALUE FOR THE EXCLUSION OF DVT and  
PE: 230 ng/ml  
\*\*\*Please note new reporting units  
and normal range effective  
04/07/2010\*\*\*

**D-Dimer Report of an Abnormal Value**

END OF REPORT

H = High L = Low \* = Critical

DDT, EXAMPLE2  
Edwin Bovill, M.D. Director  
Printed @ 11:19

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