



TECHNICAL NOTICE

SOUTH BEND MEDICAL FOUNDATION

D-Dimer, quantitative – New Cutoff for DVT/ PE Assessment

Effective Date: June 22, 2011

Clinical Significance: The Innovance D-Dimer assay may be used in conjunction with a non-high clinical pre-test probability (PTP) assessment model to exclude deep-vein thrombosis (DVT) and pulmonary embolism (PE).

The Innovance D-Dimer assay was evaluated on the Sysmex CA-1500 to produce the following results. Out of consecutive 455 patients presenting to emergency department with suspected DVT, 269 patients were with unlikely pre-test probability. At the cutoff of 0.50 mg/L FEU, sensitivity was 100%, specificity was 38.6% and negative predictive value (NPV) was 100% for DVT.

Out of consecutive 701 patients presenting to emergency department with suspected PE, 614 patients were with low and moderate pre-test probability. At the cutoff of 0.50 mg/L FEU, sensitivity was 98.6%, specificity was 40% and NPV was 99.5%.

PLEASE NOTE THAT THE CUTOFF FOR DVT/PE RISK HAS DECREASED FROM THE NUMERIC VALUE OF 1.00 TO THE NEW VALUE 0.50

Method: Siemens Innovance D-Dimer is a quantitative turbidimetric method for D-Dimer. The assay is standardized to use mg/L FEU (fibrinogen equivalent units).

Reference Range: Reference range based on normal population study: 0.00-0.53 mg/L FEU. Cutoff at 0.50 mg/L FEU yields NPV of 100% for DVT and 99.5% for PE.

Specimen Requirements and Collection: (Sample requirements have not changed)

Specimen: Light blue top (3.2% buffered sodium citrate) tube

Preferred Volume: 0.5mL

Minimum Volume: 0.3 mL

Transport: Frozen

Causes for Rejection: Citrate tube underfilled; Sample clotted or hemolyzed; Plasma not frozen within 4 hours of collection

Stability: Four hours room temperature (20-30 C); Two weeks frozen (-20 C) – Do not use frost-free units that undergo repeated freeze/thaw cycles.

Testing Schedule: Daily, STAT testing available.

Order: D-Dimer, Quantitative, Plasma Test #: 23017 CPT: • 85379

For additional information contact Deborah H. Sun, Ph.D. (dsun@sbfm.org) or Brett Colter, Director of General Laboratory Operations (bcolter@sbfm.org) or South Bend Medical Foundation, (574) 234-4176 or (800) 544-0925.

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