

D-Dimer Reagent and Reference Range Change

On **March 8th** Nebraska LabLinc will begin using a new reagent for D-Dimer testing (test code 40450) which will require changing the Reference Range and VTE Exclusion Cutoff. The INNOVANCE™ D-Dimer assay from Siemens Healthcare Diagnostics will replace the current Advanced D-Dimer reagent.

INNOVANCE™ D-Dimer is an immunoturbidometric assay employing a highly sensitive and specific monoclonal antibody for the quantitation of D-dimer in human plasma. INNOVANCE D-Dimer has minimal susceptibility to interfering substances, particularly rheumatoid factor, lipemia and bilirubin. The high sensitivity of the assay assures better accuracy and precision of D-dimer results.

New Reference Range and decision threshold:

Reference Range: **≤ 0.59 mg/L FEU**

VTE Exclusion Cut-off*: **0.50 mg/L FEU**

*As an aid in the diagnosis of VTE (DVT or PE)

The INNOVANCE D-Dimer assay is intended for use as an aid in the diagnosis of venous thromboembolism (VTE) [deep vein thrombosis (DVT) or pulmonary embolism (PE)]. Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings. A very low percentage of patients with DVT may yield D-dimer results below the VTE Exclusion cut-off of 0.50 mg/L FEU. This is known to be more prevalent in patients with distal DVT.

Specimen requirements, CPT codes and charges will remain the same for the new method.