For the Exclusion of Deep Vein Thrombosis and Pulmonary Embolism
In the Diagnosis of DVT and PE

Diagnosis of Venous Thromboembolism (VTE), which includes Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE), often begins with a clinical evaluation, followed by D-Dimer testing. Confirmatory tests generally involve imaging techniques. For DVT, these are lower-limb venous Compression Ultrasonography (CUS) and venography, which is invasive and considered the gold standard. For PE, imaging tests are Computerized Tomography (CT) scanning or ventilation/perfusion (V/Q) lung scanning and angiography, which are also invasive.

A substantial number of recent publications report the use of D-Dimer, together with a pre-test probability (PTP) assessment, as a safe, cost-effective management strategy for the evaluation of patients presenting with clinically-suspected VTE. This approach allows DVT and/or PE to be ruled out in outpatients with suspected VTE who have a low or low-moderate PTP and a negative D-Dimer, reducing the number of imaging tests required, particularly invasive ones.

Other Clinical Applications

D-Dimer testing has been evaluated in a number of clinical applications, such as predictive factors, for recurrences of VTE after discontinuation of oral anticoagulant therapy and as an indicator of pregnancy complications. Other studies suggest that elevated D-Dimer levels in the normal population may indicate the risk for thrombosis.

D-Dimer testing is also included in recent definitions of clinical laboratory criteria for the diagnosis and staging of Disseminated Intravascular Coagulation (DIC).

D-Dimer Levels in VTE and DIC Patient Groups vs. Normal Subjects

In patients with PE, DVT and DIC, D-Dimer levels are > 500 ng/mL FEU.
HemosIL D-Dimer HS 500

Liquid, and ready to use, D-Dimer HS 500 is used for the exclusion of VTE in outpatients suspected of DVT and PE, in conjunction with a clinical PTP assessment model.

The latex reagent is a suspension of polystyrene latex particles of uniform size, coated with the F(ab')2 fragment of a monoclonal antibody, highly specific for the D-Dimer domain included in fibrin degradation products or derivatives.

The use of the F(ab')2 fragment allows for more specific D-Dimer detection, minimizing interference from certain endogenous factors, such as Rheumatoid Factor.

The assay is optimized for a wavelength of 671 nm, providing a very high analytical sensitivity, enhanced working range, and minimized interference from Hemoglobin.

SAVE S TIME AND RESOURCES

- Liquid, ready-to-use
- Fully automated

PROVIDES RAPID PATIENT RESPONSE

- Results in: < 5 minutes

REDUCES NUMBER OF UNNECESSARY IMAGING TECHNIQUES

- High Specificity and Sensitivity for VTE

ENHANCES PATIENT CARE

- FDA-cleared for the exclusion of VTE with superior accuracy and precision
  - 100% Negative Predictive Value (NPV)
  - In conjunction with a PTP score, excludes DVT and PE using a cut-off value of 500 ng/mL Fibrinogen Equivalent Units (FEU)
  - Minimized interference from Rheumatoid Factor and Hemoglobin

D-Dimer HS 500, with a PTP Score, Safely Excludes DVT and PE

Using a cut-off of 500 ng/mL FEU, D-Dimer HS 500 successfully excluded DVT and PE in over 1,000 patients (two clinical studies) with an NPV of 100% and Sensitivity of 100%.

SINGLE-CENTER MANAGEMENT STUDY

- 295 outpatients
- NPV = 100%
- Specificity for VTE = 42.3%

MULTI-CENTER MANAGEMENT STUDY

- 747 outpatients
- NPV = 100%
- Specificity for DVT = 42.1%
- Specificity for PE = 48.3%

For more detail, see management studies section, under this page.
Excellent Correlation

A comparison study of HemosIL D-Dimer HS 500 vs. VIDAS D-Dimer Exclusion, on samples from outpatients suspected of VTE, demonstrated excellent correlation and slope.

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Enhancing Diagnosis of DVT and PE

An outcome study was performed on 295 frozen samples from patients suspected of PE or DVT (25.4% frequency of VTE). Positive samples were confirmed through standard imaging techniques. Results, below, are based on a cut-off value of 500 ng/mL FEU for D-Dimer HS 500 and VIDAS D-Dimer Exclusion; and 230 ng/mL D-DU for D-Dimer HS.

### Single-Center Management Study

<table>
<thead>
<tr>
<th>VTE PERFORMANCE</th>
<th>D-DIMER HS 500 (%)</th>
<th>D-DIMER HS (%)</th>
<th>VIDAS D-DIMER EXCLUSION (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Samples (n)</td>
<td>295</td>
<td>295</td>
<td>295</td>
</tr>
<tr>
<td>Sensitivity (%)</td>
<td><strong>100 (95.2 - 100)</strong></td>
<td><strong>100 (95.2 - 100)</strong></td>
<td><strong>100 (95.2 - 100)</strong></td>
</tr>
<tr>
<td>Specificity (%)</td>
<td><strong>42.3 (35.7 - 49.1)</strong></td>
<td><strong>45.5 (38.7 - 52.3)</strong></td>
<td><strong>35 (28.7 - 41.7)</strong></td>
</tr>
<tr>
<td>NPV (%)</td>
<td><strong>100 (96.1 - 100)</strong></td>
<td><strong>100 (96.4 - 100)</strong></td>
<td><strong>100 (95.3 - 100)</strong></td>
</tr>
</tbody>
</table>

### Multi-Center Management Study

Excluding DVT and PE

A multi-center management study was performed at four hospitals on 747 samples from patients suspected of PE (n=346) or DVT (n=401). Patient management was based on a study-specific diagnostic algorithm, involving PTP scoring. DVT and PE patients were confirmed through standard imaging techniques. Negative patients were confirmed at a three-month follow-up. Results, below, are based on a cut-off value of 500 ng/mL FEU on the ACL TOP.

<table>
<thead>
<tr>
<th>DVT PERFORMANCE</th>
<th>ALL SAMPLES (%)</th>
<th>HIGH PTP (%)</th>
<th>LOW + MODERATE PTP (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Samples (n)</td>
<td>401</td>
<td>79</td>
<td>322</td>
</tr>
<tr>
<td>Sensitivity (%)</td>
<td><strong>100 (90/90)</strong> (96 - 100)</td>
<td><strong>100 (45/45)</strong> (92.1 - 100)</td>
<td><strong>100 (45/45)</strong> (92.1 - 100)</td>
</tr>
<tr>
<td>Specificity (%)</td>
<td><strong>42.1 (131/311)</strong> (36.6 - 47.8)</td>
<td><strong>32.4 (11/34)</strong> (17.4 - 50.5)</td>
<td><strong>43.3 (120/277)</strong> (37.4 - 49.4)</td>
</tr>
<tr>
<td>NPV (%)</td>
<td><strong>100 (131/131)</strong> (97.2 - 100)</td>
<td><strong>100 (11/11)</strong> (71.5 - 100)</td>
<td><strong>100 (120/120)</strong> (97 - 100)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PE PERFORMANCE</th>
<th>ALL SAMPLES (%)</th>
<th>HIGH PTP (%)</th>
<th>LOW + MODERATE PTP (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Samples (n)</td>
<td>346</td>
<td>24</td>
<td>322</td>
</tr>
<tr>
<td>Sensitivity (%)</td>
<td><strong>100 (52/52)</strong> (93.2 - 100)</td>
<td><strong>100 (9/9)</strong> (66.4 - 100)</td>
<td><strong>100 (43/43)</strong> (91.8 - 100)</td>
</tr>
<tr>
<td>Specificity (%)</td>
<td><strong>48.3 (142/294)</strong> (42.5 - 54.2)</td>
<td><strong>33.3 (5/15)</strong> (11.8 - 61.6)</td>
<td><strong>49.1 (137/279)</strong> (43.1 - 55.1)</td>
</tr>
<tr>
<td>NPV (%)</td>
<td><strong>100 (142/142)</strong> (97.4 - 100)</td>
<td><strong>100 (5/5)</strong> (47.8 - 100)</td>
<td><strong>100 (137/137)</strong> (97.3 - 100)</td>
</tr>
</tbody>
</table>
D-Dimer HS 500 Kit Composition

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>PART NUMBER</th>
<th>KIT CONFIGURATION</th>
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</thead>
<tbody>
<tr>
<td>D-Dimer HS 500</td>
<td>0020500100</td>
<td>3 x 4 mL Latex Reagent (liq)</td>
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<tr>
<td></td>
<td></td>
<td>3 x 6 mL Reaction Buffer (liq)</td>
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<tr>
<td></td>
<td></td>
<td>2 x 1 mL Calibrator (lyo)</td>
</tr>
<tr>
<td>D-Dimer HS 500 Controls</td>
<td>0020500200</td>
<td>5 x 1 mL Low D-Dimer HS 500 control (lyo)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5 x 1 mL High D-Dimer HS 500 control (lyo)</td>
</tr>
</tbody>
</table>

References


Additional Literature


For more information, contact your local IL sales representative or distributor.

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