D-Dimer FS
Emergency Test for Exclusion of Thrombosis

Diagnostic Sensitivity Meets Performance.

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- Over 25 years of experience in development and production of clinical chemistry tests
- Premium service in technics, applications and after sales
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- High performance, ready-to-use reagents with minimized interferences, long shelf life and on-board stability as well as traceability to international references
- Perfectly matched fluid-stable reagents, calibrators and controls
- High grade raw materials from traceable origin
- Processes and resources certified according to ISO 13485, fulfilling highest quality standards
- Sustainable processes and products preserve the environment
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 0.5 µg FEU/mL, whereby values above this cut-off have to undergo further investigations as sonography or phlebography.

The D-Dimer FS reagent has demonstrated diagnostic sensitivity of 98% and diagnostic specificity of 80.5% for DVT at a cut-off value of 0.5 µg FEU/mL. D-dimer levels below 0.5 µg FEU/mL have a NPV of 99.4% for exclusion of DVT. These results are according to CLSI requirements of a diagnostic sensitivity of ≥ 97% and a NPV of ≥ 98%.

Performance Characteristics

Diagnostic Sensitivity

- Sensitivity 98%
- Specificity 80.5%
- Cut-off 0.5 µg FEU/mL

Precision

<table>
<thead>
<tr>
<th></th>
<th>Intra-assay</th>
<th>Inter-assay</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>N=20</td>
<td>N=20</td>
</tr>
<tr>
<td>Mean (µg FEU/mL)</td>
<td>CV (%)</td>
<td>Mean (µg FEU/mL)</td>
</tr>
<tr>
<td>Low level sample</td>
<td>37.1</td>
<td>0.58</td>
</tr>
<tr>
<td>Medium level sample</td>
<td>59.5</td>
<td>0.79</td>
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<tr>
<td>High level sample</td>
<td>113</td>
<td>0.33</td>
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</tbody>
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Test Characteristics

- Ready-to-use 2-component reagent
- Wide measuring range up to 8.7 µg FEU/mL
- High prozone security up to 50 µg FEU/mL
- Excellent precision
- Superior onboard and calibration stability of 6 weeks
- Applicable to various clinical chemistry analyzers