Exclude Pulmonary Embolism at the Point of Care

Stratus CS Acute Care D-Dimer Assay—Lab-Quality Testing at the Point of Patient Care

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Stratus CS Acute Care D-Dimer Assay—Clinical Utility

The Stratus® CS Acute Care™ D-Dimer assay is a useful diagnostic aid for physicians treating patients with suspected thromboembolic disease. The D-dimer assay is intended for use in conjunction with a non-high clinical pretest probability (PTP) assessment model to exclude pulmonary embolism (PE) disease, and as an aid in the diagnosis of venous thromboembolism (VTE) [deep vein thrombosis (DVT) or pulmonary embolism (PE)] at the point of care.

Siemens D-dimer assay is offered in a convenient TestPak format, and runs on the Stratus CS Acute Care Diagnostic System to measure cross-linked fibrin degradation products (D-dimer) in whole blood or plasma.

Elevated D-dimer values are indicative of reactive fibrinolysis,¹ which may in turn be indicative of VTE, DVT,² or PE.³

Negative Predictive Value Utility

Samples collected from outpatients enrolled in a multi-center study were measured. Patients presenting to the emergency department with clinically suspected PE were evaluated using Wells pretest probability models to assess the probability of PE.⁴,⁵

 Patients were diagnosed as PE positive by standard objective tests, and patients initially diagnosed as negative were followed for three months.

A negative predictive value of 99.1% indicates the utility of the Stratus CS Acute Care D-dimer test to exclude pulmonary embolism where the probability is non-high.

<table>
<thead>
<tr>
<th>PE Patients (n)</th>
<th>Cutoff ng/mL FEU</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>NPV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Citrated Plasma: In patients with low and moderate pretest probability</td>
<td>625</td>
<td>98.7</td>
<td>43.0</td>
<td>99.6</td>
</tr>
<tr>
<td>Heparinized Plasma: In patients with low and moderate pretest probability</td>
<td>401</td>
<td>97.9</td>
<td>29.9</td>
<td>99.1</td>
</tr>
</tbody>
</table>

Increases in D-dimer concentration observed with thromboembolic events can be variable due to localization, extent, and age of the thrombus. Therefore, a thromboembolic event cannot be excluded with certainty solely on the basis of a D-dimer concentration being within the expected values of ostensibly healthy persons.⁶
### Stratus CS Acute Care D-Dimer Assay

#### Specifications

<table>
<thead>
<tr>
<th>Sample Type</th>
<th>Test Volume</th>
<th>Analytical Measurement Range</th>
<th>Analytical Sensitivity</th>
<th>Assay Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole blood* in lithium heparin or sodium citrate, or heparinized plasma**</td>
<td>75 µL</td>
<td>6–5000 ng/mL (FEU)</td>
<td>6 ng/mL (FEU)</td>
<td>14 minutes</td>
</tr>
</tbody>
</table>

*Whole blood sample must be collected in a tube qualified for use on the Stratus CS Acute Care Diagnostic System.

**Minimum volume requirements will vary depending on the qualified collection tube used.

### Precision

<table>
<thead>
<tr>
<th>Material</th>
<th>Mean (ng/mL) (FEU)</th>
<th>Standard Deviation (% CV)</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Within Run</td>
<td>Total</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Citrated Human Plasma Pool 400 ng/mL (FEU)*</td>
<td>412</td>
<td>11.4 (2.8)</td>
<td>17.1 (4.1)</td>
<td></td>
</tr>
<tr>
<td>Citrated Human Plasma Pool 1300 ng/mL (FEU)*</td>
<td>1311</td>
<td>51.2 (3.9)</td>
<td>74.5 (5.7)</td>
<td></td>
</tr>
<tr>
<td>Citrated Human Plasma Pool 3700 ng/mL (FEU)*</td>
<td>3679</td>
<td>99.1 (2.7)</td>
<td>99.1 (2.7)</td>
<td></td>
</tr>
</tbody>
</table>

*Controls were analyzed in duplicate for 20 days. The within-run and total coefficients of variation (% CV) were calculated by the analysis of variance method according to the Clinical and Laboratory Standards Institute (NCCLS) Guideline EP5-A (February 1999).

### Ordering Information

<table>
<thead>
<tr>
<th>Catalog No.</th>
<th>Contents</th>
<th>No. of Tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>CDDMRE</td>
<td>Stratus CS Acute Care DDMR TestPak</td>
<td>60</td>
</tr>
</tbody>
</table>

**Materials required but not provided**

<table>
<thead>
<tr>
<th>Catalog No.</th>
<th>Description</th>
<th>Calibration Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>CDDMR-C</td>
<td>Stratus CS Acute Care DDMR CalPak – 6 levels</td>
<td>Every new TestPak lot</td>
</tr>
<tr>
<td>CDDMR-D</td>
<td>Stratus CS Acute Care DDMR DilPak†</td>
<td>Every 60 days per lot</td>
</tr>
</tbody>
</table>

†Samples between 5000 and 17500 ng/mL (FEU) may be run using a DDMR DilPak along with a DDMR TestPak. The instrument will automatically perform a dilution of the sample. The result obtained will already be corrected for the dilution factor.

### References:


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