PATHFAST® D-Dimer
REAGENT FOR PATHFAST®
60 Determinations

D-Dimer containing fibrin degradation product (XDP) fragments is released when cross-linked fibrin is degraded by plasmin. D-Dimer is a specific marker of degradation of fibrin clot and an indirect marker of clot formation. D-Dimer is elevated in several clinical conditions including DVT*, PE* and disseminated intravascular coagulation (DIC). The exclusion of the presence of DVT or PE is possible when the D-Dimer concentration is below the cut off established by rigorous clinical studies. D-Dimer measurement can also be used as an aid in detection of DIC*.

Package Content
60 determinations
2 calibrators (2x low, 2x high)
2 diluents
additionally required:
1 pipette tip per canal (42 pipettes/box)

Sample Material
For testing 100 μl of whole blood or plasma samples are taken with qualified collection tubes containing heparin-Na, heparin-Li or citrate-Na.

Reference Range
95 % range (from the 2.5th to 97.5th percentile): 0.063 – 0.701 μg/ml FEU (corresponds to 32 – 350 ng/ml).
The measured D-Dimer values ranged from 0.036 μg/ml FEU (18 ng/ml) – 0.708 μg/ml FEU (354 ng/ml) with a mean value of 0.239 μg/ml FEU (120 ng/ml) in 73 healthy individuals.

Specific Performance Data
1. Test measuring range:
   0.005 – 5 μg/ml FEU
2. Method comparison (plasma samples):
   \[ y = 0.99x + 0.198; \quad r = 0.913; \quad n = 113 \]
   (y: this method; x: Dade Behring Stratus® CS D-Dimer).
   Further method comparisons on request.
3. Correlation between whole blood and plasma:
\[ y = 1.01x + 0.003; r = 0.994; n = 68 \]
(y: Heparin whole blood, x: Heparin plasma)
\[ y = 1.10x - 0.012; r = 0.996; n = 68 \]
(y: Citrate whole blood; x: citrate plasma)
\[ y = 0.90x + 0.0002; r = 0.989; n = 68 \]
(y: Citrate whole blood; x: Heparin whole blood)

4. Standardization:
The calibrator for PATHFAST® D-Dimer consists of the macromolecular weight fraction of degradation products of human cross-linked fibrin, obtained by plasmin action.

5. Detection Limit:
0.005 μg/ml FEU

<table>
<thead>
<tr>
<th>Measuring range</th>
<th>Precision</th>
<th>Overall precision</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample</td>
<td>Mean value (ng/ml FEU)</td>
<td>S.D. (ng/ml FEU)</td>
</tr>
<tr>
<td>QC-L</td>
<td>0.024</td>
<td>0.001</td>
</tr>
<tr>
<td>QC-MD</td>
<td>0.249</td>
<td>0.007</td>
</tr>
<tr>
<td>QC-H</td>
<td>2.448</td>
<td>0.120</td>
</tr>
</tbody>
</table>

*DVT: Deep venous thrombosis  PE: Pulmonary embolism  DIC: Disseminated intravascular coagulation

Literature