Reagent Kits
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</table>
PATHFAST cTnI-II
Reagent for PATHFAST

Summary
Cardiac troponin I (cTnI) is a cardiac muscle protein with a molecular weight of 22,500 daltons. In the cardiac muscle, troponin I (TnI) forms a troponin complex together with tropo-
nin T (TnT) and troponin C (TnC), which plays a very essential role for the transmission of the intracellular calcium signal of the actin-myosin interaction.\(^1\) Troponin I is quickly released in the blood 4-6 hours after the onset of an AMI (acute myocardial infarction) and its level remains increased for several days.\(^2,3\)

Sample Material
100 \(\mu\)L of whole blood or plasma using heparin-Na, heparin-Li, or EDTA-K\(_2\) blood collection tubes.

Expected Value
The reference interval for the PATHFAST cTnI-II assay was determined by testing 490 healthy individuals from Northeastern, Southeastern, and Southwestern US. The 99th percentile of the reference interval is 0.029 ng/mL.

Specific Performance Data
1. Reportable range: 0.019- 50 ng/mL
2. Method comparison (plasma samples):
   \[ y = 0.947x - 0.005; r=0.994, n=57 \]
   (y: this method; x: Siemens Stratus\textsuperscript{®} CS cTnI).

   Further method comparisons available upon request.
3. Standardization: The calibrators for PATHFAST cTnI-II can be traced back to the NIST Standard Reference Material for Human Cardiac Troponin Complex SRM 2921 by the National Institute of Standard and Technology in the USA, which has certified concentration for human cardiac troponin I.
### Whole Blood (ng/mL)

<table>
<thead>
<tr>
<th>Precision</th>
<th>LL</th>
<th>L</th>
<th>M</th>
<th>H</th>
</tr>
</thead>
<tbody>
<tr>
<td>Across instruments/within lot</td>
<td>0.096</td>
<td>0.930</td>
<td>12.6</td>
<td>38.5</td>
</tr>
<tr>
<td>S.D.</td>
<td>0.005</td>
<td>0.056</td>
<td>0.427</td>
<td>0.210</td>
</tr>
<tr>
<td>C.V.</td>
<td>4.7%</td>
<td>6.0%</td>
<td>3.4%</td>
<td>0.5%</td>
</tr>
<tr>
<td>Across lots/within instrument</td>
<td>0.096</td>
<td>1.01</td>
<td>12.4</td>
<td>41.3</td>
</tr>
<tr>
<td>S.D.</td>
<td>0.007</td>
<td>0.092</td>
<td>0.241</td>
<td>2.64</td>
</tr>
<tr>
<td>C.V.</td>
<td>7.0%</td>
<td>9.1%</td>
<td>1.9%</td>
<td>6.4%</td>
</tr>
</tbody>
</table>

*Further precision data is available upon request*

### Package Content

- Item No. PF1101-K
  - 60 test cartridges
  - 2 calibrators (2x 1.0 mL low, 2x 1.0 mL high)
  - Calibrator diluent

- Required but not supplied
  - 1 pipette tip per test
    (Item No. 300936)

### Reference

PATHFAST Myo-II
Reagent for PATHFAST

Summary
Myoglobin (Myo) is a low-molecular haemoprotein, which is present in the cardiac and skeletal muscle. As a consequence of the myocardium necrosis associated with an AMI (acute myocardial infarction), myoglobin is released and is one of the first markers to increase above its normal value. The myoglobin level is elevated within 1-3 hours after an infarct, reaches maximum values after 6-12 hours and returns to basic level after 24-36 hours.\(^1\) If a skeletal muscle trauma or other situations associated with a non-cardiac-related rise of the myoglobin level in the blood (e.g. kidney failure) can be excluded, the determination of myoglobin in the blood can serve as an early marker of an AMI. Different studies have proven that the detection of myoglobin in the early AMI phase, and possible subsequent testing thereafter, can be used as a fast and sensitive test together with the ECG for diagnosis and for patients with acute chest pain for exclusion of an AMI.\(^2,3\)

Sample Material
100 μL of whole blood or plasma using heparin-Na, heparin-Li, EDTA-Na, or EDTA-K blood collection tubes.

Expected Value
95% range (from the 2.5th to 97.5th percentile): 11.8 - 75.3 ng/mL in 98 healthy individuals.

Specific Performance Data
1. Reportable range: 5-1000 ng/mL
2. Method comparison (plasma samples):
   \[ y = 1.046x + 5.54; r = 0.996, n = 60 \]
   (y: this method; x: Siemens Stratus\textsuperscript{®} CS Myo).
   Further method comparisons available upon request.
3. Standardization: PATHFAST Myo-II calibrators are prepared from purified myoglobin from human heart tissue and assigned using internal working calibrators.

PATHFAST Test Principle

[Diagram of the test principle showing the steps: Sample Reaction, Separation, Enzyme Reaction, and Detection.]
### Measuring Range

<table>
<thead>
<tr>
<th>Sample</th>
<th>Mean (ng/mL)</th>
<th>S.D. (ng/mL)</th>
<th>C.V. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>QC-L</td>
<td>33.8</td>
<td>1.01</td>
<td>3.0</td>
</tr>
<tr>
<td>QC-M</td>
<td>102</td>
<td>2.85</td>
<td>2.8</td>
</tr>
<tr>
<td>QC-H</td>
<td>688</td>
<td>9.31</td>
<td>1.4</td>
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</table>

### Within Run Precision

<table>
<thead>
<tr>
<th>Sample</th>
<th>Mean (ng/mL)</th>
<th>S.D. (ng/mL)</th>
<th>C.V. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>QC-L</td>
<td>1.45</td>
<td>4.3</td>
<td></td>
</tr>
<tr>
<td>QC-M</td>
<td>3.86</td>
<td>3.8</td>
<td></td>
</tr>
<tr>
<td>QC-H</td>
<td>16.8</td>
<td>2.4</td>
<td></td>
</tr>
</tbody>
</table>

### Total Precision

<table>
<thead>
<tr>
<th>Sample</th>
<th>Mean (ng/mL)</th>
<th>S.D. (ng/mL)</th>
<th>C.V. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>QC-L</td>
<td>1.45</td>
<td>4.3</td>
<td></td>
</tr>
<tr>
<td>QC-M</td>
<td>3.86</td>
<td>3.8</td>
<td></td>
</tr>
<tr>
<td>QC-H</td>
<td>16.8</td>
<td>2.4</td>
<td></td>
</tr>
</tbody>
</table>

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### Package Content

**Item No. PF1111-K**

- 60 test cartridges
- 2 calibrators (2x 1.0 mL low, 2x 1.0 mL high)

**Required but not supplied**

1 pipette tip per test

(Item No. 300936)

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### Reference

PATHFAST CK-MB-II
Reagent for PATHFAST

Summary
Creatine kinase (CK) is a main enzyme of the muscular system’s energy metabolism, which catalyzes the reversible creatine phosphorylation. This dimeric enzyme has two subunits, M and B, which form the three isoenzymes CK-MM, CK-MB and CK-BB. CK-MM and CK-BB are mainly present in the skeletal muscles and the brain. CK-MB is mainly present in the coronary muscle and amounts to approximately 10-40% of the CK in the myocardium. Myocardium damage leads to the temporary and progressive release of CK-MB in the cardiovascular system. In this process, the CK-MB concentration increases within 2.5-5 hours after the onset of chest pain, reaches its maximum after 12-24 hours, and then returns to base line within 48-72 hours. This characteristic chronological progression is used as a diagnostic aid for verifying an AMI (acute myocardial infarction).1

The low concentration of CK-MB in serum of healthy subjects and non-cardiac tissues contributes to its widely accepted use as an aid for diagnosing and monitoring of myocardial injury.

Sample Material
100 μL of whole blood or plasma using heparin-Na, heparin-Li, EDTA-Na, or EDTA-K blood collection tubes.

Expected Value
95% range (from the 2.5th to 97.5th percentile): 0.189 – 3.01 ng/mL in 302 healthy individuals.

Specific Performance Data
1. Reportable range: 1-250 ng/mL
2. Method comparison (plasma samples):
y=1.007x - 0.274; r=0.988, n=60
(y: this method; x: Siemens Stratus® CS CKMB)
Further method comparisons available upon request.
3. Standardization: The calibrators for PATHFAST CK-MB-II are traceable to the certified reference material IRMM/IFCC -455 of the “Institute for Reference Materials and Measurements (IRMM)”, Geel/ Belgium, for which the concentration values for the CK-MB (mass) are stated.

PATHFAST Test Principle
<table>
<thead>
<tr>
<th>Sample</th>
<th>Measuring Range (ng/mL)</th>
<th>Within Run Precision</th>
<th>Total Precision</th>
</tr>
</thead>
<tbody>
<tr>
<td>QC-L</td>
<td>2.69</td>
<td>0.147</td>
<td>0.225</td>
</tr>
<tr>
<td>QC-M</td>
<td>36.0</td>
<td>1.42</td>
<td>2.29</td>
</tr>
<tr>
<td>QC-H</td>
<td>211</td>
<td>6.76</td>
<td>14.6</td>
</tr>
</tbody>
</table>

**Reference**

3. Galen RS and Gambino SR. Isoenzyme of CPK and LDH in myocardial infarction and certain other diseases. Pathobiol Annu 1975; 5: 283-315

**Package Content**

- Item No. PF1121-K
  - 60 test cartridges
  - 2 calibrators (2x 1.0 mL low, 2x 1.0 mL high)
  - Calibrator diluent

- Required but not supplied
  - 1 pipette tip per test (Item No. 300936)
PATHFAST D-Dimer
Reagent for PATHFAST

**Summary**
D-Dimer containing fibrin degradation product (XDP) fragments are released when cross-linked fibrin is degraded by plasmin. D-Dimer is a marker of the degradation of fibrin clots and an indirect marker of clot formation. The presence of elevated D-Dimer is reported in several clinical conditions including deep vein thrombosis (DVT), pulmonary embolism (PE), and disseminated intravascular coagulation (DIC). 1-6

**Sample Material**
100 μL of whole blood or plasma using heparin-Na, heparin-Li, or citrate-Na blood collection tubes.

**Expected Value**
Assay cutoff of 0.686 μg/mL FEU was established by calculating the 95th percentile of sodium citrated (3.2%) plasma from 113 apparently healthy individuals. Each laboratory should validate the cutoff based on their reference patient population.

**Specific Performance Data**
1. **Reportable range**: 0.005-5.00 μg/mL FEU
2. **Method comparison (plasma samples)**: 
   \[ y=1.01x + 0.069; \quad r=0.982, \quad n=235 \]
   (y: this method; x: Siemens Stratus® CS D-Dimer)
   Further method comparisons available upon request.
3. **Standardization**: The calibrators for PATHFAST D-Dimer consist of high molecular weight fraction of human cross-linked fibrin degradation products obtained by plasmin action.
### Measuring Range

<table>
<thead>
<tr>
<th>Sample</th>
<th>Mean (μg/mL FEU)</th>
<th>S.D. (μg/mL FEU)</th>
<th>C.V. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>QC-LL</td>
<td>0.024</td>
<td>0.001</td>
<td>3.8</td>
</tr>
<tr>
<td>QC-L</td>
<td>0.249</td>
<td>0.007</td>
<td>2.8</td>
</tr>
<tr>
<td>QC-M</td>
<td>0.654</td>
<td>0.020</td>
<td>3.0</td>
</tr>
<tr>
<td>QC-H</td>
<td>2.45</td>
<td>0.120</td>
<td>4.9</td>
</tr>
</tbody>
</table>

### Within Run Precision

<table>
<thead>
<tr>
<th>Sample</th>
<th>Mean (μg/mL FEU)</th>
<th>S.D. (μg/mL FEU)</th>
<th>C.V. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>QC-LL</td>
<td>0.002</td>
<td>0.002</td>
<td>6.1</td>
</tr>
<tr>
<td>QC-L</td>
<td>0.015</td>
<td>0.015</td>
<td>6.0</td>
</tr>
<tr>
<td>QC-M</td>
<td>0.029</td>
<td>0.029</td>
<td>4.5</td>
</tr>
<tr>
<td>QC-H</td>
<td>0.174</td>
<td>0.174</td>
<td>7.1</td>
</tr>
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</table>

### Total Precision

<table>
<thead>
<tr>
<th>Sample</th>
<th>Mean (μg/mL FEU)</th>
<th>S.D. (μg/mL FEU)</th>
<th>C.V. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>QC-LL</td>
<td>0.002</td>
<td>0.002</td>
<td>6.1</td>
</tr>
<tr>
<td>QC-L</td>
<td>0.015</td>
<td>0.015</td>
<td>6.0</td>
</tr>
<tr>
<td>QC-M</td>
<td>0.029</td>
<td>0.029</td>
<td>4.5</td>
</tr>
<tr>
<td>QC-H</td>
<td>0.174</td>
<td>0.174</td>
<td>7.1</td>
</tr>
</tbody>
</table>

### Package Content

**Item No. PF1051-KUS**
- 60 test cartridges
- 2 calibrators (2x 1.0 mL low, 2x 1.0 mL high)
- Calibrator diluent

**Required but not supplied**
1 pipette tip per test (Item No. 300936)

### Reference


PATHFAST NTproBNP
Reagent for PATHFAST

Summary
B-type natriuretic peptide (BNP) is a small peptide (32 amino acids) secreted by heart myocytes to augment regulation of blood pressure and fluid balance. Its pro form ProBNP is synthesized by the left cardiac ventricles as a single chain peptide of 108 amino acids. ProBNP is cleaved into two fragments which are secreted into the bloodstream as the 32 amino acids active BNP and the N-terminal fragment of 76 amino acids designated as NT-proBNP. Determination of NT-proBNP helps to identify individuals with left ventricular dysfunction. 1-5

Expected Value
The recommended medical cutoff value, by age group are:
- Patients < 75: 125 pg/mL
- Patients ≥ 75: 450 pg/mL

Reference group and disease group statistics available upon request.

Sample Material
100 μL of whole blood or plasma using heparin-Na, heparin-Li, EDTA-Na or EDTA-K blood collection tubes.

Specific Performance Data
1. Reportable range: 15.0-30,000 pg/mL
2. Method comparison (plasma samples):
y = 1.046x + 3.61; \( r = 0.985 \), n=346
(y: this method; x: Roche Elecsys® proBNP)
Further method comparisons available upon request.
3. Standardization: The calibrators for PATHFAST NTproBNP are synthetic NTproBNP (1-76) by Roche Diagnostics GmbH

PATHFAST Test Principle
<table>
<thead>
<tr>
<th>Measuring Range</th>
<th>Within Run Precision</th>
<th>Total Precision</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample</td>
<td>Mean (pg/mL)</td>
<td>S.D. (pg/mL)</td>
</tr>
<tr>
<td>QC-LL</td>
<td>101</td>
<td>4.14</td>
</tr>
<tr>
<td>QC-L</td>
<td>425</td>
<td>13.2</td>
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<tr>
<td>QC-M</td>
<td>2388</td>
<td>97.0</td>
</tr>
<tr>
<td>QC-H</td>
<td>12058</td>
<td>564</td>
</tr>
</tbody>
</table>

**Package Content**

- Item No. PF1061-KUS
  - 60 test cartridges
  - 2 calibrators (2x 1.0 mL low, 2x 1.0 mL high)
  - Calibrator diluent

- Required but not supplied
  - 1 pipette tip per test
    (Item No. 300936)

**Reference**

2. Struthers AD. How to use natriuretic peptide levels for diagnosis and prognosis. The European Society of Cardiology. Eur Heart J 1999; 20: 1374-1375
PATHFAST hsCRP
Reagent for PATHFAST

Summary
C-reactive protein (CRP) is an acute phase β-globulin with a molecular mass of approximately 118,000 daltons. CRP is highly conserved, composed of five identical cyclic globular subunits, and is classified as a member of the pentraxin superfamily of proteins.

As elevated CRP values are always associated with pathological changes, the CRP assay provides useful information for the diagnosis, therapy, and monitoring of inflammatory conditions and associated diseases.1-4

Additionally, measurement of CRP by high sensitivity CRP assay may add to the predictive value of other markers used to assess the risk of cardiovascular and peripheral vascular diseases.5-10

Expected Value
97.5th percentile for hsCRP in heparinized plasma samples of 275 (160 males and 115 females age range 16-77 years) apparently healthy individuals was 4.16 mg/L

Specific Performance Data
1. Reportable range: 0.05-30 mg/L
2. Method comparison (serum samples): y=1.01x - 0.056, r=0.990, n=60 (y: this method; x: Siemens Immulite® hsCRP)
   Further method comparisons available upon request.
3. Standardization: The calibrators for PATHFAST hsCRP are traceable to the reference material IRMM CRM 470.

Sample Material
100 μL of whole blood, plasma, or serum using heparin-Na, heparin-Li, EDTA-2Na or EDTA-2K blood collection tubes.

PATHFAST Test Principle
<table>
<thead>
<tr>
<th>Sample</th>
<th>Mean (mg/L)</th>
<th>S.D. (mg/L)</th>
<th>C.V. (%)</th>
<th>S.D. (mg/L)</th>
<th>C.V. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>QC-LL</td>
<td>0.916</td>
<td>0.069</td>
<td>7.5</td>
<td>0.068</td>
<td>7.4</td>
</tr>
<tr>
<td>QC-L</td>
<td>4.63</td>
<td>0.279</td>
<td>6.0</td>
<td>0.374</td>
<td>8.1</td>
</tr>
<tr>
<td>QC-M</td>
<td>15.1</td>
<td>1.19</td>
<td>7.8</td>
<td>1.29</td>
<td>8.5</td>
</tr>
<tr>
<td>QC-H</td>
<td>25.6</td>
<td>1.24</td>
<td>4.8</td>
<td>1.37</td>
<td>5.3</td>
</tr>
</tbody>
</table>

**Reference**

4. Pulliam PN, Attia MW, Cronan KM. Undetectable serious bacterial infection C-reactive protein in febrile children 1 to 36 months of age with clinically undetectable serious bacterial infection. Pediatrics 2001; 108:1275-9
## Product List

**PATHFAST for critical care diagnostics**

<table>
<thead>
<tr>
<th>Item number</th>
<th>Pack size</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SYSTEM</strong></td>
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</tr>
<tr>
<td>PATHFAST Immunoassay Analyzer</td>
<td>300929</td>
</tr>
<tr>
<td>Analyzer for the measurement of cardiac and other emergency parameters</td>
<td></td>
</tr>
<tr>
<td><strong>REAGENT KITS</strong></td>
<td></td>
</tr>
<tr>
<td>PATHFAST cTnl-II</td>
<td>PF1101-K</td>
</tr>
<tr>
<td>PATHFAST Myo-II</td>
<td>PF1111-K</td>
</tr>
<tr>
<td>PATHFAST CK-MB-II</td>
<td>PF1121-K</td>
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<tr>
<td>PATHFAST D-Dimer</td>
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<td>PATHFAST hsCRP</td>
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<td><strong>CONSUMABLES AND ACCESSORIES</strong></td>
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<td>PATHFAST Tips</td>
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<td>PATHFAST Waste Box</td>
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<td>PATHFAST Roll Paper</td>
<td>300943</td>
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</table>
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Tel: 800-345-2822 • Fax: 401-642-9001
www.vitaldiagnostics.com

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