PATHFAST™ EMERGENCY & CRITICAL CARE

» 6 samples in parallel
» in less than 17 minutes
» from whole blood
» in central lab quality

hs Trop I, NTproBNP, D-Dimer, hsCRP, Myoglobin, CK-MB mass

Quantitative measurement of 6 analytes in parallel

High Sensitivity
NEW MARKER
Troponin I

LSI Medience Corporation
The PATHFAST™ analysis system combines the accuracy of a full-scale lab with the flexibility of a mobile solution. Best prerequisites for fast differential diagnosis at the point of care. Easy to operate, install and network. Highest precision makes this device an adequate "outpost" of a full-scale lab on a cardiology, intensive care or emergency ward. Parallel processing enables the examination of six samples in <17 minutes.

Parallel Processing for fast action
Six parallel channels. Six quantitative analysis simultaneously. Six results in <17 minutes. This gives PATHFAST™ its unique speed. It doesn't make a difference whether you want to examine all parameters of relevance for a safe differential diagnosis in one process or samples obtained from different patients. Perfect efficiency.

Principle and Precision
PATHFAST™ is a fully automatic immunoassay analyzer, which combines the progressive chemiluminescence technology with the patented Magtration™ technology. Small sample volumes can be detected with high accuracy and precision. The device and the reagent strips provide optimum sensitivity. The results are perfectly reproducible and correlate outstandingly with lab analyses.

Concept and Application
Its compact design and low weight make PATHFAST™ the ideal analysis system in emergency labs, hospitals and medical offices. Applied wherever fast quantitative results with full-scale lab quality provide decisive diagnostic advantages. Directly at the point of care. With its space-saving design and large degree of flexibility, PATHFAST™ is also an ideal supplement for major analysis systems in central labs. It can be applied at any time without interfering with the processes of routine analysis.

Operation and Safety
Insert the reagent cartridge, apply the samples and press the "Start" button. PATHFAST™ takes care of everything else fully automatic. A simple 3-step method provides results in lab quality. No additional reagents, buffer solution or sample pipettes (e.g. capillaries) required. A water connection or drain is not necessary. The lab personnel does not require any special skills or certifications. Additional advantages are the highest level of operational safety and minimum maintenance efforts. The device is designed for permanent use and available for 24 hours, even if the central lab is not ready for operation.

Equipment and Networking
The PATHFAST™ analysis system offers a complete range of equipment. Computer and printer are integrated, operation via touchscreen monitor. The barcode of the samples is read with a scanner. With its interface (RS-232C), it can be easily connected to the LIMS (Laboratory Information Management System). Networking enables direct data transfer to the central lab and access to the results from any PC.

Biomarker and Diagnosis
PATHFAST™ determines the quantity of hs Troponin I, NTproBNP, D-Dimer, hsCRP, Myoglobin and CK-MB mass from one single whole blood sample. The quantitative data of the parallel analyses provide results within minutes, which facilitate the therapeutic decision. Basis for a safe diagnosis on-site for patients with acute coronary syndrome, venous thromboembolism and suspected coronary insufficiency.
High sensitivity Tropinin I

High sensitivity cTnI results are used to assist in the diagnosis of acute myocardial infarction and to aid in the risk stratification of patients with acute coronary syndromes with respect to their relative risk of mortality.1-6

Precision at low concentrations

The imprecision profile at low concentrations was determined by using plasma samples. The within-run and total standard deviations were calculated by CLSI EP5-A2 guidelines. The following results were obtained:

<table>
<thead>
<tr>
<th>Precision</th>
<th>Plasma (ng/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>#1</td>
</tr>
<tr>
<td>Within-run</td>
<td>mean</td>
</tr>
<tr>
<td>SD</td>
<td>1.25</td>
</tr>
<tr>
<td>CV</td>
<td>5.9%</td>
</tr>
<tr>
<td>Total SD</td>
<td>1.45</td>
</tr>
<tr>
<td>CV</td>
<td>6.8%</td>
</tr>
</tbody>
</table>

Sensitivity and measurable normal value

The limit of blank (LoB) and the limit of detection (LoD) of the PATHFAST™ hs-cTnI assay were determined, where LoB was 1.23 ng/L and LoD was 2.33 ng/L. The limit of quantitation (LoQ) at 20% coefficient of variation (CV) was determined to be 4 ng/L. The limit of quantitation (LoQ) at 10% coefficient of variation (CV) was determined to be 15 ng/L. These results were obtained from plasma samples.

The measurable number of healthy subjects between LoD and 99th percentile was 487 from 734 healthy subjects, in whom cardiovascular diseases were excluded by the following criteria: age < 18; HbA1c ≥ 6.5%; NTpro-BNP ≥ 125 ng/L < 75; NTpro-BNP ≥ 450 ng/L ≥ 75 years; eGFR < 60 mL/min/1.73m².

PATHFAST™ hs-cTnI was classified as a high sensitive assay according to IFCC guidelines. With PATHFAST™ hs-cTnI assay classified as a high sensitivity assay, the gender specific 99th percentile and the measurable number of healthy subjects between LoD and 99th percentile were identified.7

Reference ranges

The reference interval for the PATHFAST™ hs-cTnI assay was determined by testing 490 healthy individuals. The 99th percentile of the reference interval is 29 ng/L. The CV value at the 99th percentile concentration is 6.1%.7

Diagnostic performance criteria

cTnI concentrations were measured by using the PATHFAST™ hs-cTnI assay in EDTA plasma samples obtained at 0 hour, 1 hour and 3 hours after admission to the chest pain unit (CPU) from 993 patients with suspicion of acute coronary syndrome. The final diagnosis identified 219 AMI patients (23.5%). The ROC analysis revealed AUC values for the discrimination between AMI and non-AMI patients including the clinical sensitivity and specificity, as well as the positive (PPV) and negative (NPV) predictive values based on the 99th percentile upper reference limit (URL) of 27.0 ng/L.8

NTproBNP

NTproBNP results are used as an aid to assist in the diagnosis and assessment of severity of congestive heart failure (CHF) and risk stratification in patients with acute coronary syndromes (ACS).9-11

Reference ranges

Outpatients with symptoms suggestive of heart failure show a cut-off value for NTproBNP of 125 pg/ml. NTproBNP values < 125 pg/ml rule out ventricular dysfunction in patients with symptoms suggestive of heart failure. The International Collaborative of NTproBNP Study revealed in 1256 patients presenting with acute shortness of breath to emergency departments of four hospitals cutpoint of 300 pg/ml for ruling out acute heart failure in the emergency room setting. To identify acute heart failure age-related cutpoints of 450, 900 and 1800 pg/ml for ages < 50, 50-75, and > 75 years were defined.10,11
Risk stratification with NYHA classification
Blood samples were obtained from 72 patients diagnosed with congested heart failure (CHF). The descriptive studies and New York Heart Association (NYHA) functional classes are provided.

<table>
<thead>
<tr>
<th>All CHF</th>
<th>NYHA I</th>
<th>NYHA II</th>
<th>NYHA III</th>
<th>NYHA IV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>3350</td>
<td>1314</td>
<td>2872</td>
<td>8721</td>
</tr>
<tr>
<td>SD</td>
<td>4737</td>
<td>1350</td>
<td>2700</td>
<td>7055</td>
</tr>
<tr>
<td>Median</td>
<td>1531</td>
<td>715</td>
<td>2254</td>
<td>6431</td>
</tr>
<tr>
<td>95th</td>
<td>11538</td>
<td>4988</td>
<td>9123</td>
<td>25797</td>
</tr>
<tr>
<td>% &gt; cut-off</td>
<td>94.4</td>
<td>100</td>
<td>95.8</td>
<td>100</td>
</tr>
<tr>
<td>n</td>
<td>72</td>
<td>16</td>
<td>16</td>
<td>24</td>
</tr>
</tbody>
</table>

D-Dimer
The D-Dimer concentration is an indicator for the fibrinolytic activity of plasmin in the vascular system. Acute deep vein thrombosis (DVT) and pulmonary embolism (PE) can be ruled out with very high accuracy by D-Dimer testing.

**Reference ranges**
For the PATHFAST® D-Dimer assay, the preliminary reference interval measured in 73 healthy individuals was calculated to be: 95% interval (ranging from 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) to 0.708 μg/ml FEU (354 ng/ml) with a mean of 0.239 μg/ml FEU (120 ng/ml). A preliminary cut-off of 0.5 μg/ml FEU for exclusion of venous thromboembolism has been established using 60 plasma samples obtained from patients with pulmonary embolism independently diagnosed by echocardiography, spiral-CT and pulmonary angiography.

hsCRP
Elevated CRP levels are always associated with pathological changes and CRP provides information for the diagnosis, therapy, and monitoring of inflammatory conditions and associated diseases.

**Methods comparison**
(y: this method; x: Siemens Stratus® CS D-Dimer)

| y = 0.99 x + 0.198; r = 0.913; n = 113 |
| y = 1.1341 x - 0.0025; r = 0.902; n = 66 |

Myoglobin
Myoglobin is one of the first markers associated with myocardial necrosis to rise above normal level. The measurement of Myoglobin can be used as a rapid and sensitive test in the early phase of AMI.

**Methods comparison**
(y: this method; x: Biomerieux Vidas® D-Dimer 2)

| y = 1.02 x + 0.058; r = 0.991; n = 110 |

CK-MB mass
CK-MB is found predominantly in cardiac muscle cells accounting for approximately 10-40 % of myocardial CK. Low concentration of CK-MB in healthy subjects is an aid for the diagnosis and monitoring of myocardial injury.

**Methods comparison**
(y: this method; x: Siemens Stratus® CS D-Dimer)

| y = 0.68x + 0.81; r = 0.992; n = 126 |

**Correlation vs. Stratus CS**
(y = 1.72 x - 0.47; r = 0.997; n = 87)
The highly precise, fast and compact chemiluminescence immunoassay analysis system

PATHFAST™ Test Principle


PATHFAST™ Technical Specifications

- Instrument type: Desktop Immunoassay Analyzer
- Throughput: Up to 6 samples or parameters per run
- Measuring time: <17 min for 6 samples using emergency markers
- Sampling material: Whole blood, plasma, serum
- Measuring principle: Analysis takes place with the help of the chemiluminescence enzyme immunoassay technology (CLEIA) and Magtration® technology.
- Reaction temperature: 37 °C
- Sample volume: 100 µl
- Data storage: Patient data: 1000, QC data: 1800, CAL data: 300
- Datatransfer: ASTM standard
- Weight: 28 kg
- EL. requirements: 100 - 240 V AC (50/60 Hz)
- Power consumption: 360 VA
- Monitor/keyboard: LCD touch-screen
- Printer: Integrated
- PC: Integrated
- Interface: RS-232C
- Calibration: Factory calibration, 2-point calibration every 4 weeks
- 24-h operation (stand-by) recommended

PATHFAST™ Dimensions

- Length: 569 mm
- Width: 343 mm
- Height: 475 mm
## Product List
**PATHFAST™ for critical care and sepsis diagnostics**

<table>
<thead>
<tr>
<th>System</th>
<th>Item number</th>
<th>Pack size</th>
</tr>
</thead>
</table>
| **PATHFAST™ Immunoanalyzer**  
Analyzer for the detection of cardiac and other emergency parameters and sepsis | 300929 | 1 x 1 |

<table>
<thead>
<tr>
<th>Consumables and Accessories</th>
<th>Item number</th>
<th>Pack size</th>
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<tbody>
<tr>
<td><strong>PATHFAST™ pipette tips</strong></td>
<td>300936</td>
<td>5 x 42 units</td>
</tr>
<tr>
<td><strong>PATHFAST™ waste box</strong></td>
<td>300950</td>
<td>10 units</td>
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### Reagent Kits for Critical Care Diagnostics

<table>
<thead>
<tr>
<th>Reagent Kits</th>
<th>Item number</th>
<th>Pack size</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PATHFAST™ hs-cTnI</strong></td>
<td>PF1241-K</td>
<td>60 tests</td>
</tr>
<tr>
<td><strong>PATHFAST™ Myoglobin</strong></td>
<td>PF1021-K</td>
<td>60 tests</td>
</tr>
<tr>
<td><strong>PATHFAST™ CK-MB</strong></td>
<td>PF1031-K</td>
<td>60 tests</td>
</tr>
<tr>
<td><strong>PATHFAST™ D-Dimer</strong></td>
<td>PF1051-K</td>
<td>60 tests</td>
</tr>
<tr>
<td><strong>PATHFAST™ NTproBNP</strong></td>
<td>PF1061-K</td>
<td>60 tests</td>
</tr>
<tr>
<td><strong>PATHFAST™ hsCRP</strong></td>
<td>PF1071-K</td>
<td>60 tests</td>
</tr>
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### Reagent Kits for Sepsis Diagnostics

<table>
<thead>
<tr>
<th>Reagent Kits</th>
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<th>Pack size</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PATHFAST™ B·R·A·H·M·S PCT</strong></td>
<td>PF1221-K</td>
<td>60 tests</td>
</tr>
<tr>
<td><strong>PATHFAST™ B·R·A·H·M·S PCT control set</strong></td>
<td>PF0221C</td>
<td>4 x 1 ml</td>
</tr>
<tr>
<td><strong>PATHFAST™ Presepsin</strong></td>
<td>PF1201-K</td>
<td>60 tests</td>
</tr>
<tr>
<td><strong>PATHFAST™ Presepsin control set</strong></td>
<td>PF0201-C</td>
<td>4 x 1 ml</td>
</tr>
</tbody>
</table>

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