Quantitative measurement of 6 analytes in parallel

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

PATHFAST™

EMERGENCY & CRITICAL CARE

- » 6 samples in parallel
- » in 15 minutes
- » from whole blood
- » in central lab quality

LSI Medience Corporation

MITSUBISHI CHEMICAL EUROPE

PATHFAST™

Central lab quality at the point of care

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 make 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 only 15 minutes.

Parallel Processing for fast action

Six parallel channels. Six quantitative analysis simultaneously. Six results in 15 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 Troponin I, NTproBNP, D-Dimer, hsCRP, Myoglobin, HCG and CK-MB mass from one single whole blood sample. The quantitative data of the parallel analyses provide results within minutes, which facilitate the therapeutical decision. Basis for a safe diagnosis on-site for patients with acute coronary syndrome, venous thromboembolism and suspected coronary insufficiency.

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

Diagnostic safety through parallel scanning of all significant markers

Troponin I sensitive

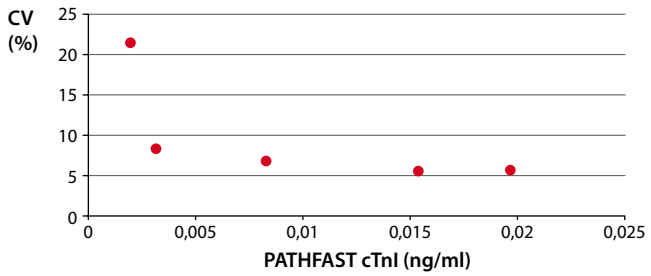
cTnI results are used to assist in the diagnosis of acute myocardial infarction and to aid in the risk stratification of patients with acute coronary syndromes with respect to their relative risk of mortality.[1-3,8]

Assay range	0.001 – 50 ng/ml
Total % CV in plasma	QC-L = 3.9%, QC-M = 3.1%, QC-H = 3.7%
Correlation vs. Stratus CS	y = 0.37x – 0.007; r = 0.975; n = 80

Precision

The imprecision profile was determined by control samples. The within-run and total standard deviations were calculated by NCCLS EP5-A2 guidelines.

Imprecision profile of PATHFAST cTnI according to NCCLS



Reference ranges

Reference ranges were determined from 119 healthy subjects, in whom cardiovascular diseases were exluded by cardiac magnetic resonance imaging including a dobutamine stress test. Plasma samples were measured yielding only values below 0.020 ng/ml. Upper reference limit (99th percentile) for cTnI concentration is 0.020 ng/ml. The lowest concentration with a CV less than or equal 10% (LoQ) was 0.0031 ng/ml.

Clinical performance

Troponin level of patients with non-ST-elevation myocardial Infarction (NSTEMI), unstable angina pectoris, ST-elevation myocardial infarction, non cardiac chest pain, and others were measured.

Comparison of predictive values from ROC analysis		
PATHFAST TnI (cut-off ≥ 0.02 ng/ml)	NPV (%)	PPV (%)
Admission	86.1	93.4
3 hours	94.6	94.4
6 hours	93.6	90.3

Detection of NSTEMI was analyzed by ROC curves and the corresponding negative predictive values (NPV) and positive predictive values (PPV) are displayed in the table comparision of predictive value from ROC analysis.[4]

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).[5-7]

Assay range	15 – 30,000 pg/ml
Total % CV in plasma	QC-L = 5.0%, QC-M = 4.6%, QC-H = 5.4%
Correlation vs. Elecsys	y = 1.01 x + 2.6; r = 0.99; n = 795

Reference ranges

Outpatients with symtoms 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.[6,7]

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.

	All CHF	NYHA I	NYHA II	NYHA III	NYHA IV
Mean	3350	732	1314	2872	8721
SD	4737	756	1350	2700	7055
Median	1531	595	715	2254	6431
95th	11538	1678	4988	9123	25797
% > cut-off	94.4	81.3	100	95.8	100
n	72	16	16	24	16

Quantitative results within 15 minutes

Secured results of all biomarkers in critical care

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.

Assay range	0.005 – 5 µg/ml FEU
Total % CV in plasma	QC-L = 6.9%, QC-M = 6.0%, QC-H = 7.1%
Methods comparison (plasma samples)	y = 0.99 x + 0.198, r = 0.913, n = 113 (y: this method; x: Siemens Stratus® CS D-Dimer) y = 1.1341 x – 0.0025, r = 0.902, n = 66 (y: this method; x: Biomerieux Vidas® D-Dimer 2)

The plasma concentration of D-Dimer is elevated in several clinical conditions including DVT, PE and disseminated intravascular coagulation (DIC). The exclusion of the diagnosis of acute venous thromboembolism (DVT and/or PE) is possible when the D-Dimer concentration is below the cut-off established by clinical studies. D-Dimer measurement can also be used as an aid in diagnosis and monitoring of DIC.

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).[9]

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.[10]

Reagent Cartridge

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.

Assay range	0.05 – 30 mg/l
Total % CV in plasma	QC-L = 4.1%, QC-M = 5.4%, QC-H = 5.6%
Correlation vs. Dade Behring	y = 1.02 x + 0.058; r = 0.991; n = 110

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.

Assay range	5 – 1000 ng/ml
Total % CV in plasma	QC-L = 4.3%, QC-M = 3.8%, QC-H = 2.4%
Correlation vs. Stratus CS	y = 0.68x + 0.81; r = 0.992; n = 126

HCG

ßHCG is the preferred biomarker for diagnosis of pregnancy. The ability to quantitate low levels of ßHCG out of whole blood helps to savely exclude a possible pregnancy at the point of care.

Assay range	1 - 500 mIU/ml
Total % CV in plasma	QC-L = 3.3%, QC-M = 4.1%, QC-H = 3.8%
Correlation vs. IMMULITE	y = 1.022 x + 2.10; r = 0.997, n = 120

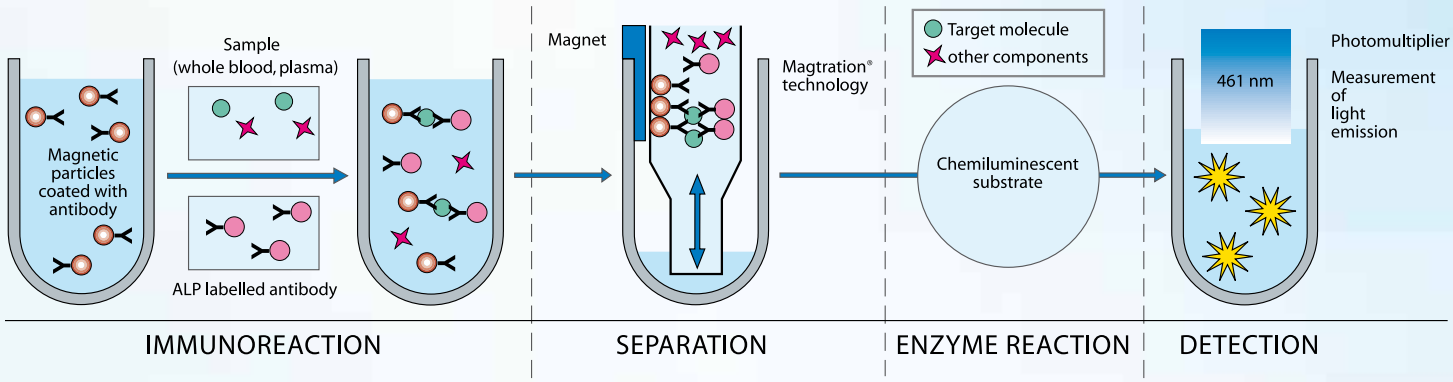
CK-MB mass

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.

Assay range	2 – 500 ng/ml
Total % CV in plasma	QC-L = 8.3%, QC-M = 6.4%, QC-H = 6.8%
Correlation vs. Stratus CS	y = 1.72 x – 0.47; r = 0.997; n = 87

PATHFAST™ 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	15 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

References

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2) The Task Force for the Diagnosis and Treatment of Non-ST-Segment Elevation Acute Coronary Syndromes of the European Society of Cardiology. Guidelines for the diagnosis and treatment of non-ST-elevation acute coronary syndromes. Eur Heart J 2007;28:1598-1660.
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4) 21st International Congress of Clinical Chemistry and Laboratory Medicine, IFCC-WorldLab – EuroMedLab, Berlin, 15-19 May 2011.
5) Nielsen LS et al. N-terminal pro-brain natriuretic peptide for discriminating between cardiac and non-cardiac dyspnea. Eur heart J Fail 2004;6:63-70.
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7) Zaninotto M et al. PATHFAST NTproBNP (N-terminal- pro B type natriuretic peptide) : a multicenter evaluation of a new point-of care assay. Clin Chem Lab Med 2010; 48:1029-1034.
8) Peetz D et al. Method comparison of cardiac marker assays on PATHFAST, StratusCS, Axsym, Immulite 2000, Triage, Elecsys and Cardiac reader. Clin Lab 2006;52:605-14.
9) Fukuda T, Kasai H. A rapid and quantitative D-dimer assay in whole blood and plasma on the point-of-care PATHFAST analyser. Thromb Res (2007); 10 :1016-1020.
10) Ivandic BT, Spanuth E, Giannitsis E. PATHFAST D-Dimer vs. VIDAS D-dimer Exclusion – a comperative evaluation in emergency patients with post hoc confirmed pulmonary embolism, Poster at 55th Annual meeting of the Society of Thrombosis and Haemostasis Research 16-19 Feb. 2011, Wiesbaden.

Product List **PATHFAST™ for critical care and sepsis diagnostics**	Item number	Pack size
SYSTEM		
PATHFAST™ Immunoanalyser Analyzer for the detection of cardiac and other emergency parameters and sepsis	1114-0000	1 x 1
CONSUMABLES AND ACCESSORIES		
PATHFAST™ pipette tips	1114-1000	5 x 42 units
PATHFAST™ waste box	1114-1001	10 units
REAGENT KITS FOR CRITICAL CARE DIAGNOSTICS		
PATHFAST™ cTnI	1110-2000	60 tests
PATHFAST™ Myoglobin	1110-2001	60 tests
PATHFAST™ CK-MB	1110-2002	60 tests
PATHFAST™ D-Dimer	1110-2003	60 tests
PATHFAST™ NTproBNP	1110-2004	60 tests
PATHFAST™ hsCRP	1110-2005	60 tests
PATHFAST™ HCG	1110-2009	60 tests
PATHFAST™ HCG control set	1110-2010	4 x 1 ml
REAGENT KITS FOR SEPSIS DIAGNOSTICS		
PATHFAST™ Presepsin	1110-4000	60 tests
PATHFAST™ Presepsin control set	1110-4001	4 x 1 ml

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