PATHFAST™

EMERGENCY & CRITICAL CARE

Diagnostics in Emergency & Critical care

- up to 6 samples in parallel
- in less than 17 minutes
- out of whole blood, plasma or serum
- in high-sensitive central lab quality

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

PATHFAST™
ESC GUIDELINES 2020
hs-cTn I

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 < 17 minutes.

Parallel Processing for fast action Six parallel channels. Six quantitative analysis simultaneously. Six results in < 17 minutes. This gives PATHFAST TM 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.

Concept and Application Its compact design and low weight make PATHFAST TM 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 TM 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.

Equipment and Networking The PATHFAST TM 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.

Principle and Precision PATHFAST TM is a fully automatic immunoassay analyzer, which combines the progressive chemiluminescence technology with the patented Magtration TM 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.

Operation and Safety Insert the reagent cartridge, apply the samples and press the „Start" button. PATHFAST TM 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.

Biomarker and Diagnosis PATHFAST TM 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 therapeutical decision. Basis for a safe diagnosis on-site for patients with acute coronary syndrome, venous thromboembolism and suspected coronary insufficiency.

Diagnostic safety through parallel scanning of all significant markers

High sensitivity Troponin 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]

Assay range	2.33 - 50 000 ng/L
Total % CV at the 99	th 6.1 at 29 ng/L
Correlation vs. Stratus CS	y = 0.947 x + 4.29, r = 0.995; n = 79 plasma samples

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:

		Plasma (ng/L)			
		#1	#2	#3	#4
Precision	mean	21.3	25.9	34.9	44.9
Within-run	SD	1.25	1.27	1.56	1.43
	CV	5.9%	4.9 %	4.5%	3.2%
Total	SD	1.45	1.25	1.72	2.01
	CV	6.8%	4.8%	4.9%	4.5%

Sensitivity and measurable normal value

The limit of blank (LoB) and the limit of detection (LoD) of the PATHFAST TM 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 TM hs-cTnI was classified as a high sensitive assay according to IFCC guidelines. With PATHFAST TM 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]

	N	Gender specific 99th percentile (ng/L)	% measurable concentrations > LoD
Overall	734	27.9	66.3%
Males	382	29.7	78.8%
Females	352	20.3	52.8%

Reference ranges

The reference interval for the PATHFAST TM 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 TM 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]

Time point after admission	0h	1h	3h
RO-AUC	0.901	0.949	0.964
Sensitivity, % (95% CI)	64 (58-72)	81 (75-86)	91 (86-94)
Specificity, % (95% CI)	92 (90-97)	93 (90-94)	91 (89-93)
PPV, % (95% CI)	73 (66-79)	77 (71-82)	75 (69-80)
NPV, % (95% CI)	89 (86-91)	94 (92-96)	97 (96-98)

Quantitative results within < 17 minutes

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]

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.[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.

	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

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).14 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 TM 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).[12]

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.[13]

Secured results of all biomarkers in critical care

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

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

Myoglobin

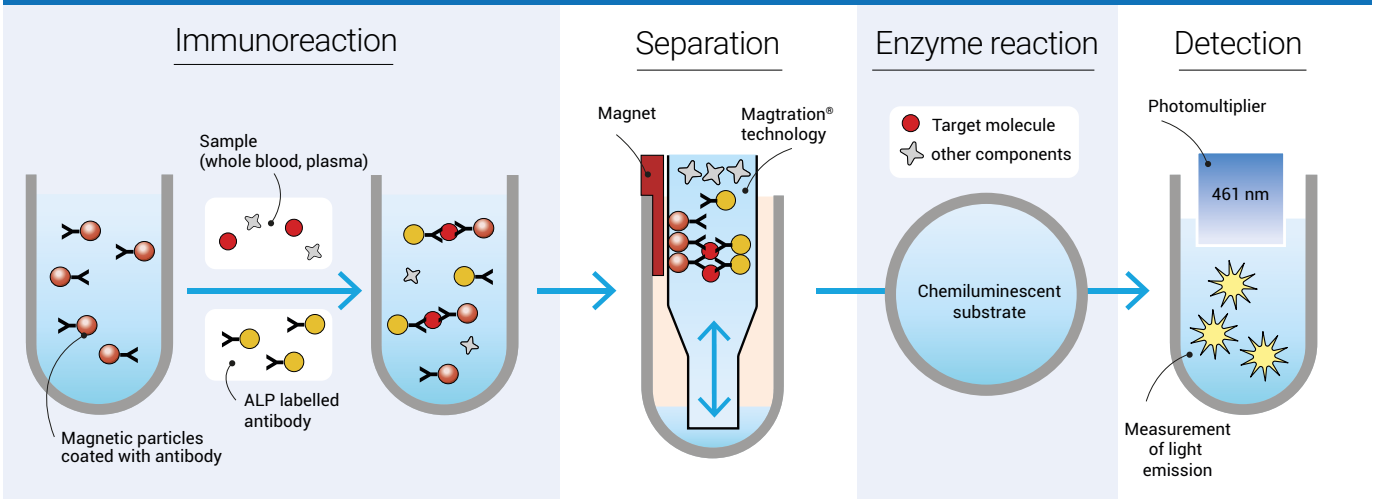
Myoglobin is one of the first markers associated with myocardial necrosis to rise above normal level. The measurement of Myoglobin can be used as a rapid and sensitive test in the early phase of AMI.

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

Easy and quick operation

The highly precise, fast and compact chemiluminescence immunoassay analysis system

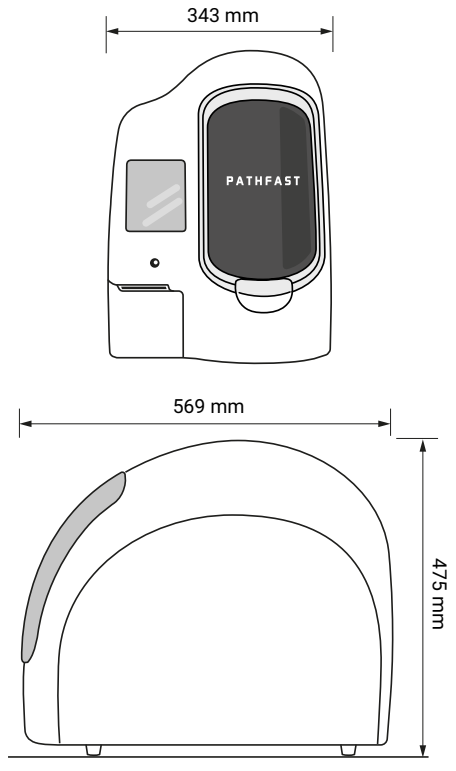
PATHFAST™ Test principle



PATHFAST™ Technical Specifications

Instrument type	Desktop Immunoassay Analyzer
Throughput	Up to 6 samples or parameters per run
Measuring time	<17 minutes for 6 samples using emergency markers or PATHFAST™ Presepsin
Sampling material	Whole blood, plasma, serum
Measuring principle	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 and Fixed 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, Handheld Barcodereader included
Interface	RS-232C and Ethernet Port
Calibration	Factory calibration, 2-point calibration every 4 weeks
24-h operation (stand-by)	Recommended

PATHFAST™ Dimensions



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	300929	1 x 1
CONSUMABLES AND ACCESSORIES		
PATHFAST™ pipette tips	300936	5 x 42 units
PATHFAST™ waste box	300950	10 units
REAGENT KITS FOR CRITICAL CARE DIAGNOSTICS		
PATHFAST™ hs-cTnI	PF1241-K	60 tests
PATHFAST™ Myoglobin	PF1021-K	60 tests
PATHFAST™ CK-MB	PF1031-K	60 tests
PATHFAST™ D-Dimer	PF1051-K	60 tests
PATHFAST™ NTproBNP	PF1061-K	60 tests
PATHFAST™ hsCRP	PF1071-K	60 tests
REAGENT KITS FOR SEPSIS DIAGNOSTICS		
PATHFAST™ B·R·A·H·M·S PCT	PF1221-K	60 tests
PATHFAST™ B·R·A·H·M·S PCT control set	PF0221C	4 x 1 ml
PATHFAST™ Presepsin	PF1201-K	60 tests
PATHFAST™ Presepsin control set	PF0201-C	4 x 1 ml

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