

PATHFAST[®]

Cardiac Biomarker Analyzer

The PATH to better cardiac care starts here



precision



quality and
compatibility



flexibility



easy to use



- **#1** for precision among point-of-care analyzers*
- Affordable, core-lab quality results – in under 17 minutes
- Test menu: Troponin I, NTproBNP, CK-MB, D-Dimer, hsCRP and Myoglobin
- Unaffected by hemolysis†

* 5.1%CV at the 99th percentile for Troponin I. Source: IFCC Table of analytical characteristics of commercial cardiac Troponin I and T assay declared by the manufacturer – November 2014 (www.ifcc.org)

† Up to 1000mg/dL



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The PATH to better cardiac care starts here.

PATHFAST is an easy to use, bench-top chemiluminescent immunoassay analyzer providing affordable, core-lab quality results from whole blood samples in under 17 minutes. With the flexibility to run up to six tests simultaneously, and results that are unaffected by hemolysis[†], PATHFAST ensures accurate results are available to the caregiver quickly – improving patient outcomes, and overall cardiac care.

Industry-leading precision and accuracy

- Core-lab quality results – 5.1% CV for Troponin I at 99th percentile cutoff
- High level of accuracy from combination of chemiluminescence technology and proprietary Magtration[®] technology

Flexible, reliable testing – fast

- Ability to run whole blood or plasma samples
- Testing and results unaffected by hemolysis[†]
- Six simultaneous tests in under 17 minutes
- Flexibility to perform any of the assays – from one to six tests per run

Simple. User-friendly.

- Single test reagent cartridge
- Color touchscreen controls
- Fewer than five steps to potentially life-saving results:
 - Scan patient ID with barcode reader
 - Add sample to sample well
 - Place cartridge rack in analyzer
 - Press start. Results will be printed out in under 17 minutes.

Quality and Compatibility

- Manufactured in Japan under strict quality control standards
- Easily interfaces with Laboratory Information Systems (LIS)

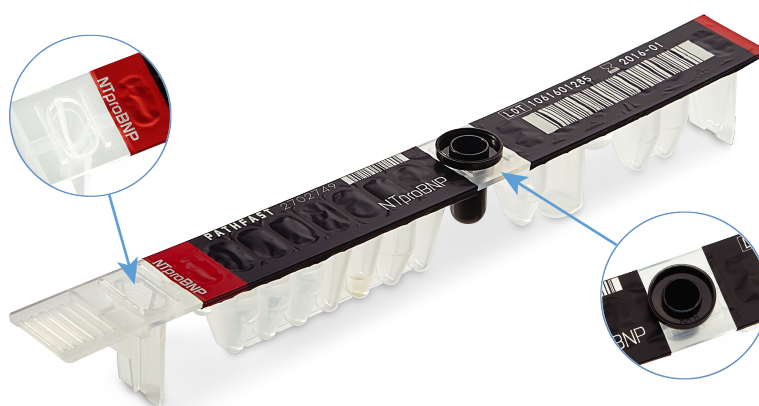
Compact design, big impact. Ideal for:

- Emergency departments
- Stat laboratories
- Core laboratories
- Stand alone emergency rooms
- Urgent care facilities



[†] Up to 1000mg/dL

Reagent Cartridge



- Magnetic particles
- ALP-conjugated antibody
- Chemiluminescent substrate
- Sample diluent
- Washing buffer

Technical Specifications

Instrument type	Bench-top Cardiac Biomarker Analyzer
Throughput	Up to 6 samples or assays per run
Measuring time	<17 minutes for up to six simultaneous samples
Sampling material	Whole blood, plasma
Measuring principle	Chemiluminescence enzyme immunoassay technology (CLEIA) combined with proprietary Magtration™ technology
Reaction temperature	37.5° C
Sample volume	100µL
Wavelength	300 – 650 nm
Data storage	Patient data: 1000
QC data	1800
CAL data	300
Data transfer	ASTM standard
Dimensions	13.5 in. W x 22.4 in. D x 18.7 in. H
Weight	62 lbs
Electrical requirements:	100 – 240 Vac
Monitor/keyboard	LCD Touchscreen
Printer	Integrated
PC	Integrated
Interface	RS-232C
Calibration	Factory calibration, 2-point calibration every 4 weeks
24-h operation (standby)	24-h operation (standby)

From a single whole blood sample, PATHFAST determines the quantity of Troponin I, NTproBNP, CK-MB, D-Dimer hsCRP and Myoglobin present, providing results within minutes, and facilitating critical care decisions for patients with acute myocardial infarction, deep vein thrombosis, pulmonary embolism and congestive heart failure.

Available Markers

Troponin I

Measurement of cardiac Troponin I is used as an aid in the diagnosis of acute myocardial infarction (AMI). Troponin I is released rapidly in blood circulation after the onset of AMI.

Sample	#1	#2	#3	#4
Total % CV in plasma	7.1%	6.1%	5.4%	3.9%
Troponin means in ng/ml	0.022	0.029	0.086	0.251

Myoglobin

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

	QC-L	QC-M	QC-H
Total % CV in plasma	4.3%	3.8%	2.4%
MYO means in ng/ml	33.8	102	688

CK-MB

CK-MB is found predominantly in cardiac muscle cells, accounting for approximately 10-40% of myocardial CK. Concentration levels of CK-MB in blood aids in the diagnosis and monitoring of myocardial injury.

	QC-L	QC-M	QC-H
Total % CV in plasma	8.4%	6.4%	6.9%
CK-MB means in ng/ml	2.69	36.0	211

D-Dimer

Elevated concentrations of D-Dimer indicate increased coagulation and fibrinolytic activity. D-Dimer assay may be useful in assisting with the diagnosis of deep vein thrombosis and pulmonary embolism.

	QC-LL	QC-L	QC-M	QC-H
Total % CV in plasma	6.1%	6.0%	4.5%	7.1%
D-Dimer means in g/ml	0.024	0.249	0.654	2.45

NTproBNP

The result from NTproBNP assay aids in the diagnosis and assessment of severity of congestive heart failure (CHF) and risk stratification in patients with acute coronary syndrome.

	QC-LL	QC-L	QC-M	QC-H
Total % CV in plasma	4.7%	3.4%	4.6%	5.4%
NTproBNP means in pg/ml	101	425	2388	12058

hsCRP

Measurement of high sensitivity CRP may add to the predictive value of other markers used to assess the risk of cardiovascular and peripheral vascular diseases.

	QC-LL	QC-L	QC-M	QC-H
Total % CV in serum	7.4%	8.1%	8.5%	5.3%
hsCRP means in mg/L	0.916	4.63	15.1	25.6

Diagnostic safety through parallel assays of all significant cardiac biomarkers.

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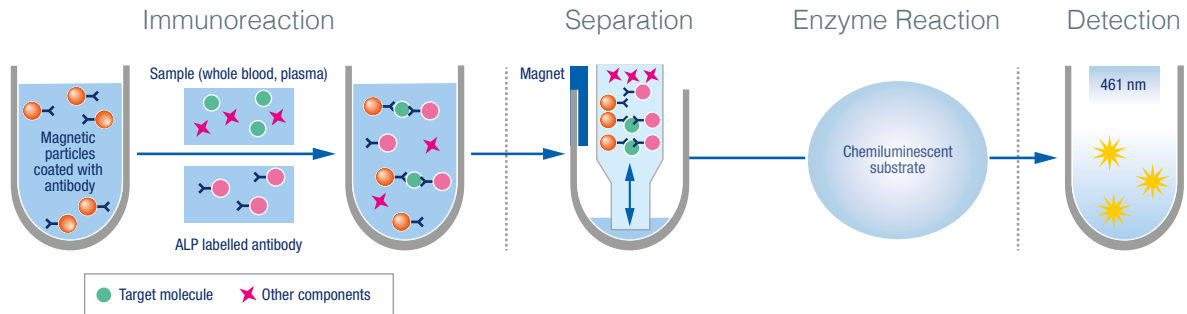


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PATHFAST[®] Test Principle



**Troponin I, NTproBNP,
CK-MB, D-Dimer,
hsCRP, Myoglobin**

Diagnostic safety through parallel
assays of all significant cardiac
biomarkers.





Product Listing

PATHFAST for critical care diagnostics

System	Item number	Pack size
PATHFAST Cardiac Biomarker Analyzer Analyzer for the measurement of cardiac and other emergency markers.	300646	1 X 1
Reagent Kits	Item Number	Pack Size
PATHFAST cTnI-II	PF1101-K	60 tests
PATHFAST Myo-II	PF1111-K	60 tests
PATHFAST CK-MB-II	PF1121-K	60 tests
PATHFAST D-Dimer	PF1051-KUS	60 tests
PATHFAST NTproBNP	PF1061-KUS	60 tests
PATHFAST hsCRP	PF1071-KUS	60 tests
Consumables and Accessories	Item Number	Pack Size
PATHFAST Tips	300936	5 x 42 units
PATHFAST Waste Box	300950	10 units
PATHFAST Roll Paper	300943	10 rolls

Pathfast.com

email: info@polymedco.com

phone: 800-431-2123

www.polymedco.com

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