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PATHFAST®

Cardiac & Sepsis Biomarker Analyzer

FDA CLEARED
FDA
FDA CLEARED

Lab-Quality
CLEIA
Technology

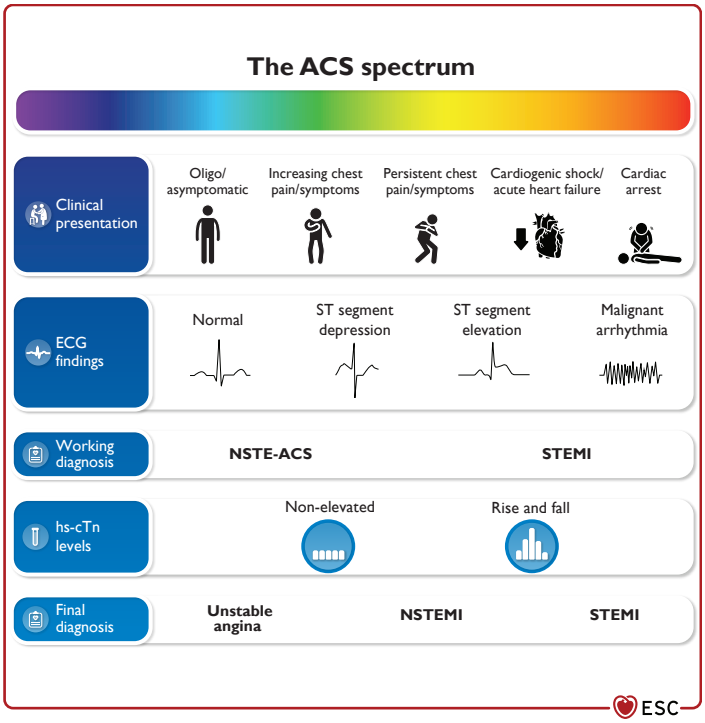
17 min

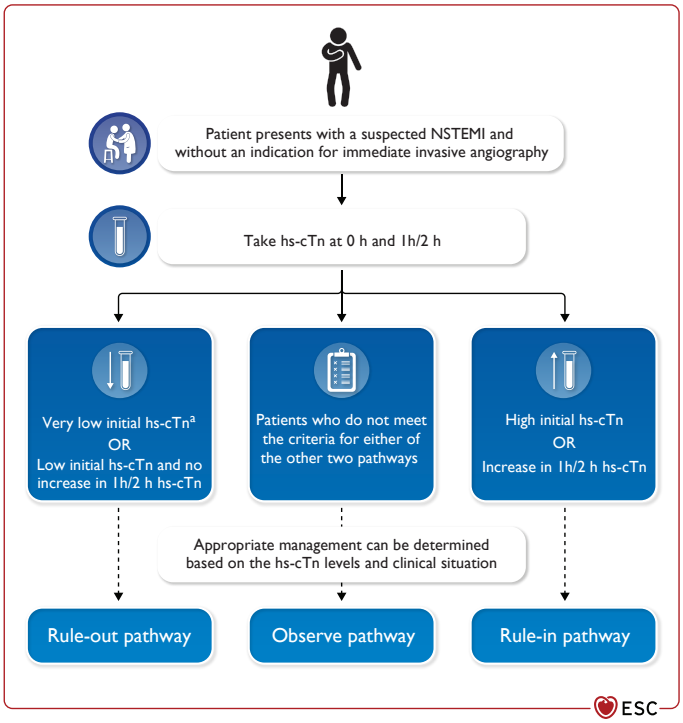
Quantitative Results
in < 17 Minutes.

PATHFAST®

Follow the Gold Standard, Follow the Guidelines.

ESC
European Society of Cardiology





It is recommended to measure cardiac troponins with high-sensitivity assays immediately after presentation and to obtain the results within 60 min of blood sampling

The use of biomarkers other than cTn for the diagnosis of ACS is not recommended.

American Heart Association®

AMERICAN COLLEGE of CARDIOLOGY

The AHA/ACC guidelines recognize hs-cTnI as the preferred biomarker for the detection of myocardial injury and endorse the assay-specific overall 99th percentile upper reference limits.

PATHFAST hs-cTnI

PATHFAST hs-cTnI assay fits for the recommendations on the IFCC and ESC guidelines for the early detection of AMI.

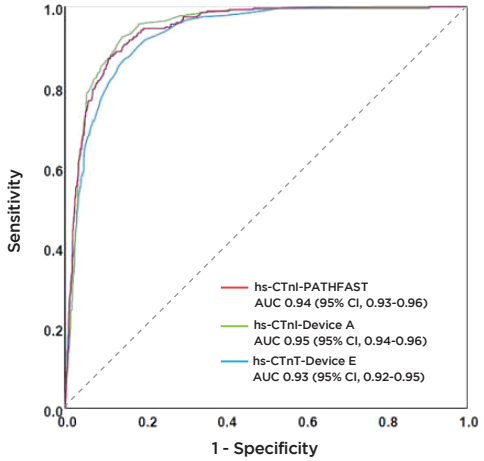
99th Percentile **29.0 ng/L**

CV **6.1 %**

In clinical studies PATHFAST hs-cTnI has been evaluated for a 99th percentile upper reference limit of 29.0 ng/L at an imprecision of 6.1%, which is less than 10% and fits for the criteria of hs-cTnI, declared by IFCC.

Criteria for a high sensitivity cTn assay

Recommendation from IFCC	
99th percentile of hs assays should be measured with an analytical imprecision of <10% CV	✓
hs-cTnI assays should measure cTn above the limit of detection (LOD) in 50% of healthy individuals	✓
Gender specific 99th percentile values should be established for men and women.	✓
Recommendation from IESC guideline	
New ESC guidelines of 2023 recommend to use an ESC algorithmic approach with serial hs-cTnI measurements (0 h/1 h or 0 h/2 h) to rule in and rule out NSTEMI.	✓



Diagnostic discrimination of hs-CTnI-PATHFAST, hs-CTnI-Device A and hs-CTnT-Device E concentrations at presentation of NSTEMI. NSTEMI, non-ST-segment elevation myocardial infarction.

Source: Koechlin et al. Am Heart J 2024 2026 20104-113.

Study reference - American Heart Journal, Feb 2024.

Study objective: American Heart Journal study on 1,500+ ED patients validates PATHFAST hs-cTnI for rapid NSTEMI rule-in/rule-out.

Conclusions: The POC hs-cTnI-PATHFAST assay allows rapid and effective rule-out and rule-in of NSTEMI using both a 0/1h- and a 0/2h-algorithm with high NPV/sensitivity for rule-out and high PPV/specificity for rule-in.

PATHFAST demonstrated equivalent performance to central laboratory systems based on CLEIA.

Assay and Time Point	ROC AUC (95% CI)
hs-cTnI-PATHFAST	
Presentation (=0h)*	0.94 (0.93–0.96)
1h**	0.97 (0.96–0.98)
2h***	0.97 (0.96–0.98)

Assay and Time Point	ROC AUC (95% CI)
Hs-cTnI-Device A	
Presentation (=0h)*	0.95 (0.94–0.96)
1h**	0.97 (0.96–0.98)
2h***	0.97 (0.96–0.98)

Assay and Time Point	ROC AUC (95% CI)
hs-cTnT-Device E	
Presentation (=0h)*	0.93 (0.92–0.95)
1h**	0.96 (0.94–0.97)
2h***	0.96 (0.94–0.97)

1. Insert the reagent cartridge into the cartridge rack.
2. Apply 100µL of samples to the sample well with a pipet or dropper.
3. Place the cartridge rack in the PATHFAST.
4. Set the dedicated chips to each cartridge.
5. Close the cover and press the "Start" button.

Available Markers

Cardiac Markers

hs-cTnI
hsCRP
NTproBNP
CK-MB
Myo

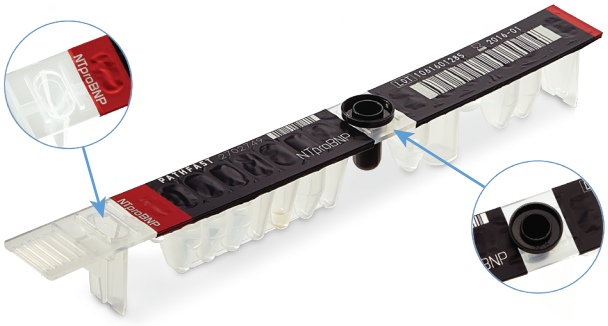
Sepsis Markers

P-SEP
PCT

DVT Marker

D-Dimer

Reagent Cartridge



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

PATHFAST®

Technical Specifications

Instrument type	Cardiac and Sepsis 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	37.5º C	**Dimensions**	13.5 in. W x 22.4 in. D x 18.7 in. H
Sample volume	100 µL	**Electrical requirements**	100 – 240 Voltage
Wavelength	300 – 650 nm	**Monitor/keyboard**	LCD Touchscreen
Data storage	Patient data: 1000	**Printer & PC**	Integrated
QC data	1800	**Interface**	RS-232C
CAL data	300	**24-h operation (standby)**	Yes
Data transfer	ASTM standard	**Calibration**	Factory calibration, 2-point calibration every 4 weeks
Weight	62 lbs		

Manufacturer:
PHC Corporation
2131-1 Minamigata, Toon, Ehime 791-0395, Japan

Marketed by:
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