PATHFAST®
Analyzer

High sensitivity cardiac troponin I testing on the PATHFAST analyzer

Todd W. Kelley, MD | VP Medical Affairs, Polymedco

Every year, millions of Americans present to emergency departments (EDs) with chest pain and must be evaluated for acute myocardial infarction (AMI).

The various causes of chest pain represent a spectrum of urgency, from relatively benign issues to critical, life-threatening conditions.

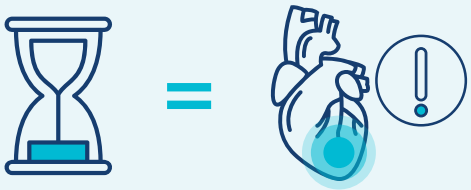
AMI is at the top of the list for dangerous conditions. Although many chest pain patients are found to have non-cardiac causes for their symptoms, a thorough diagnostic work-up is required to determine the appropriate course of care.

Only ~5%

of ED patients who present with chest pain are ultimately diagnosed with AMI.[1]

Timely treatment recommendations and challenges

Troponin as a biomarker of cardiac injury



Guidelines from the American Heart Association (AHA), American College of Cardiology (ACC) and Society for Cardiovascular Angiography and Interventions (SCAI) recommend percutaneous coronary intervention (PCI), the process by which occluded or narrowed coronary arteries are reopened to blood flow, within the first 2 hours of hospital presentation.[3]

For accurate and timely diagnosis of AMI, ACC/AHA guidelines recommend chest radiography, electrocardiography, and **high sensitivity cardiac troponin (hs-cTn) as the preferred diagnostic biomarker**.[4]

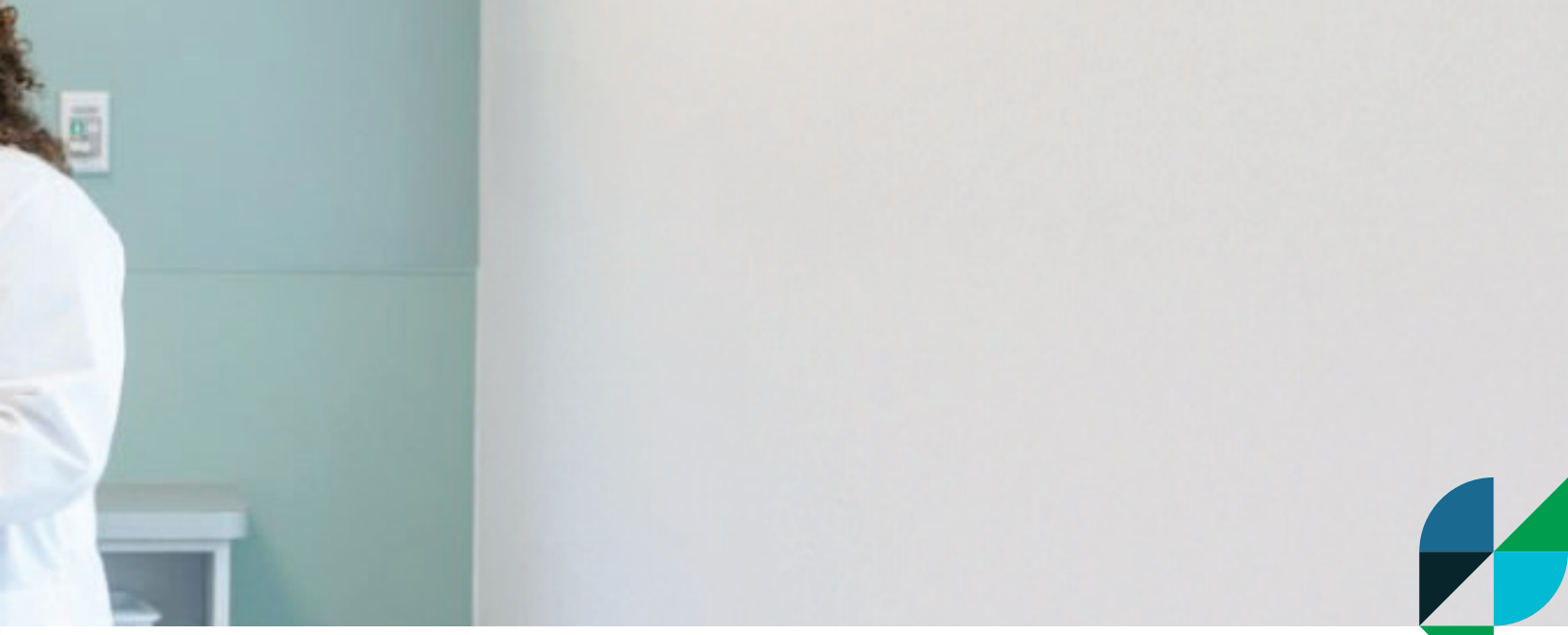
In the context of the urgency associated with clinical evaluation of patients with chest pain, logistical and turnaround time **challenges may arise when sending blood samples to a centralized laboratory located remotely to the ED for troponin testing**.

The potentially extended time to result associated with centralized testing may lead to delays in diagnosis and ultimately, delays in PCI and restoration of coronary artery blood flow.

The detection of elevated levels of cardiac troponin (cTn) has become the standard of care for the laboratory diagnosis of AMI. In 2017, the first hs-cTn tests were cleared by the FDA. Clinical algorithms utilizing hs-cTn are more sensitive and specific in ruling in or out the presence of AMI versus contemporary (non-high sensitivity) cTn tests (graphic 1).

However, the kinetics and patterns of release of cTn as measured by a hs-cTn assay are complex and incorporation into clinical workflows can be somewhat confusing, especially when clinical management has relied on contemporary cTn testing.

> **By utilizing point-of-care (POC) hs-cTn tests in the ED or other acute care settings to minimize hs-cTn turnaround times, providers can discover a faster route to definitive treatment.**



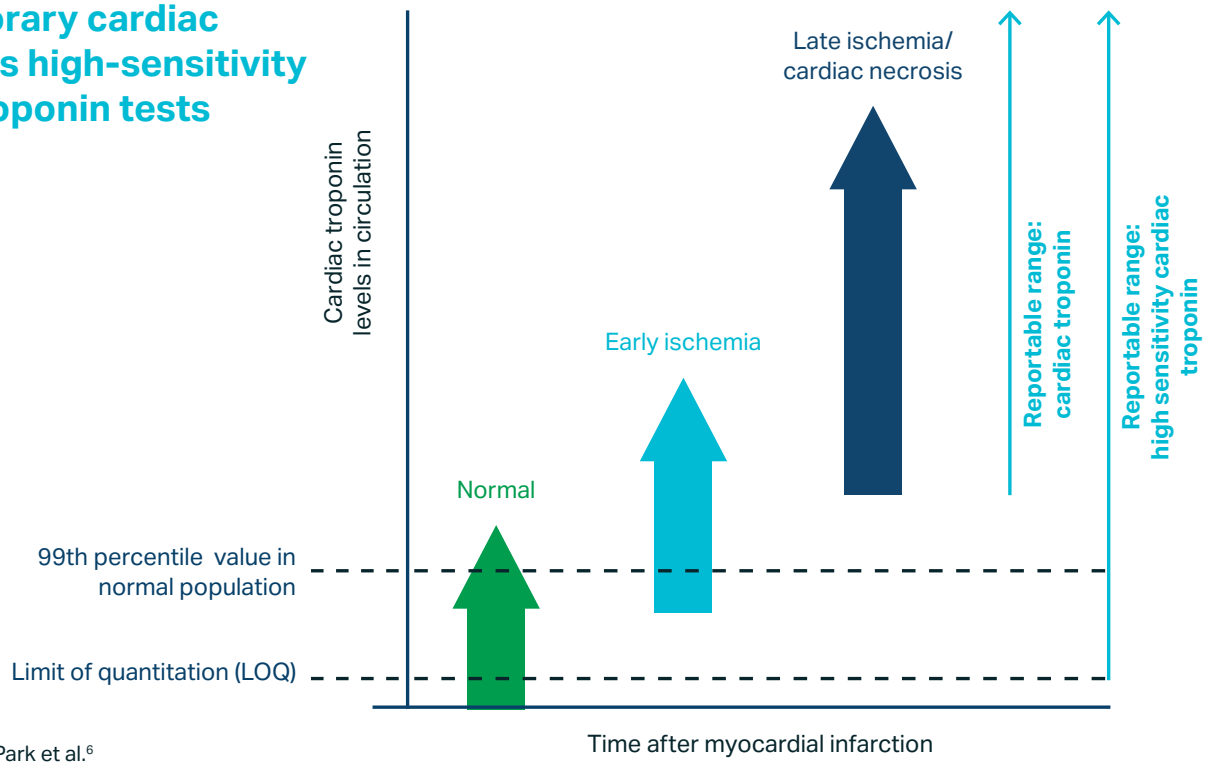
Skeletal and cardiac muscles utilize the **troponin-tropomyosin complex** to regulate contraction. The troponin complex consists of tissue specific isoforms of troponins I, T and C. When muscle cells are injured and begin to undergo necrosis, complexed troponins degrade and are released into the circulation.

Troponin release exhibits slightly delayed kinetics compared to release of cytosolic proteins such as creatine kinase (CK) which may be detected more quickly. Thus, the testing characteristics of cardiac biomarkers can vary considerably, and this variation should be well understood when implementing these assays for clinical care.

For detection of cardiac injury, cardiac troponin I (cTnI) and cardiac troponin T (cTnT) are comparably sensitive in the acute care setting but may have differing associations with outcome in other clinical contexts.[5]

Graphic 1

Contemporary cardiac troponin vs high-sensitivity cardiac troponin tests



Graphic based on Park et al.[6]

Clinical algorithms utilizing hs-cTn are more sensitive and specific in ruling the presence of AMI in or out versus contemporary cardiac troponin tests.

Use of single hs-cTn values to rule out AMI

hs-cTn tests typically designate a minimum reportable cTn value (the limit of quantitation, or LOQ) and a 99th percentile upper value (derived from a normal reference population) to represent a clinical threshold for early myocardial injury.

For patients who present late after onset of chest pain (>2 hours), a single "very low" hs-cTn value can be used to identify those at low risk for AMI. This value may be the LOQ for the test, or a slightly higher value that has been appropriately clinically validated.[4]

Algorithms to diagnose AMI with hs-cTn testing

The European Society of Cardiology (ESC) recommends 0-hour (at presentation) and 1-hour sample draws for hs-cTn testing in symptomatic patients.[7] **This is referred to as the 0/1h algorithm**.

If the first two measurements are inconclusive (ie below the 99th percentile value) and there is persistent clinical concern for AMI, an additional 3-hour test is recommended.

0/2h and 0/3h algorithms are also available in addition to the 0/1h algorithm. All three of these algorithms described in the ESC guidelines are also endorsed by the AHA/ACC.[4]

hs-cTn testing at the point of care

POC testing has already been incorporated into ED workflows for some non-cardiac clinical indications, particularly for patients with symptoms of respiratory infectious diseases. However, for the management of patients with acute chest pain, hs-cTn tests designed to reduce the time to results – and potentially the time to treatment or discharge – have not previously been available in the United States.

The benefits of POC hs-cTn testing may include:

1	2	3	4
Reduced time to rule in or rule out AMI	More efficient use of valuable ED and cardiology resources	**Reduced time to PCI for patients with cardiac ischemia**	**Rapid disposition of chest pain patients with non-cardiac diagnoses**

The wait is over: PATHFAST hs-cTnI-II at the POC

Polymedco is excited to announce the addition of PATHFAST hs-cTnI-II to the existing menu of assays available on the PATHFAST Analyzer.

Precision | **Quality and compatibility** | **Flexibility** | **Easy to use**

The release of PATHFAST's hs-cTnI-II represents the availability of **the first hs-cTnI test suitable for POC use in the United States**.

In Europe, the PATHFAST hs-cTnI-II assay has been shown to support successful validation of 0/1, 0/2, and 0/3h algorithms for clinical management of patients with chest pain at the POC.[8]

Educational points to consider when converting to hs-cTn

Appropriate communication and education are necessary to minimize confusion and ensure that differences in test features are well understood. Clinicians including ED physicians, cardiologists, hospitalists, nurse practitioners and other acute care providers must be informed and aware of the features of hs-cTn testing.

hs-cTn testing may necessitate a change in the frequency of sample draws as new clinical algorithms are applied to patients undergoing evaluation for chest pain in the ED.

hs-cTn testing may lead to more accurate recognition of cardiac injury and consequently more efficient utilization of cardiology care resources.

hs-cTn testing is reported in ng/L rounded to whole integers without decimals, in contrast to contemporary cTn testing which is reported in ng/mL.

New reference ranges and new clinical cutoffs (i.e. LoQ and 99th percentile cutoffs) will need to be implemented requiring institutional communication and education.

Implementing PATHFAST hs-cTnI-II: A suggested approach

- Establish a timeline to phase out the previous troponin test, transitioning exclusively to PATHFAST hs-cTnI-II
- Integrate hs-cTnI-II data and diagnostic protocols into the clinical EHR, including standing orders and order sets
- Create an institution-specific AMI evaluation protocol based on guidelines, incorporating PATHFAST hs-cTnI-II and clinical data
- Validate this protocol by comparing decisions made using the new hs-cTnI-II assay against those made with the previous assay
- After implementation, monitor hs-cTnI-II ordering patterns, evaluate results, provide ongoing education and collaborate with lab/point of care personnel and clinicians to enhance the efficiency of AMI evaluation

Make the change.
Make a difference.

PATHFAST hs-cTnI-II is the newest assay in a comprehensive suite of cardiac tests designed for use at the point of care. The PATHFAST Analyzer offers fast turnaround times, core lab-quality results, and the flexibility and precision necessary for acute care settings.

Other FDA-cleared PATHFAST assays:

- NT-proBNP
- D-dimer
- hs-CRP
- Myoglobin
- CK-MB

Learn more about hs-cTnI-II testing with the PATHFAST Analyzer

Polymedco.com

PATHFAST INTENDED USE

PATHFAST® hs-cTnI-II is an in vitro diagnostic test for the quantitative measurement of cardiac Troponin I (cTnI) in heparinized or EDTA whole blood and plasma. Measurements of cardiac Troponin I are used as an aid in the diagnosis of acute myocardial infarction (AMI). PATHFAST® hs-cTnI-II is for use in clinical laboratory or point of care (POC) settings.

References 1. Gulati M, Levy PD, Mukherjee D, et al. 2021 AHA/ACC/ASE/CHEST/SAEM/SCCT/SCMR guideline for the evaluation and diagnosis of chest pain: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation. 2021;144(22):e368-e454. doi:10.1161/CIR.0000000000001029 **2.** Lawani O, Gorman N, Gorman F, Ganim J, Sdringola-Maranga S. Correlates of delayed initial contact to emergency services among patients with Suspected ST-elevation myocardial infarction. Cardiol Res Pract. 2021;2021:8483817. Published 2021 Sep 14. doi:10.1155/2021/8483817 **3.** Lawton JS, Tamis-Holland JE, Bangalore S, et al. 2021 ACC/AHA/SCAI guideline for coronary artery revascularization: executive summary: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation. 2022;145(3):e4-e17. doi:10.1161/CIR.0000000000001039 **4.** Sandoval Y, Apple FS, Mahler SA, et al. High-sensitivity cardiac troponin and the 2021 AHA/ACC/ASE/CHEST/SAEM/SCCT/SCMR guidelines for the evaluation and diagnosis of acute chest pain. Circulation. 2022;146(7):569-581. doi:10.1161/CIRCULATIONAHA.122.059678 **5.** Welsh P, Preiss D, Hayward C, et al. Cardiac troponin T and troponin I in the general population. Circulation. 2019;139(24):2754-2764. doi:10.1161/CIRCULATIONAHA.118.038529 **6.** Park KC, Gaze DC, Collinson PO, Marber MS. Cardiac troponins: from myocardial infarction to chronic disease. Cardiovasc Res. 2017;113(14):1708-1718. doi:10.1093/cvr/cvx183 **7.** Byrne RA, Rossello X, Coughlan JJ, et al. 2023 ESC Guidelines for the management of acute coronary syndromes. Eur Heart J. 2023;44(38):3720-3826. doi:10.1093/eurheartj/ehad191 **8.** Koechlin L, Boeddinghaus J, Lopez-Ayala P, et al. External validation of the 0/1h-algorithm and derivation of a 0/2h-algorithm using a new point-of-care hs-cTnI assay. Am Heart J. 2024;268:104-113. doi:10.1016/j.ahj.2023.11.0141. **9.** Gulati M, Levy PD, Mukherjee D, et al. 2021 AHA/ACC/ASE/CHEST/SAEM/SCCT/SCMR guideline for the evaluation and diagnosis of chest pain: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation. 2021;144(22):e368-e454. doi:10.1161/CIR.0000000000001029

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Polymedco, LLC
510 Furnace Dock Road
Cortlandt Manor, NY 10567
polymedco.com

polymedco

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