



PRE-IMPLEMENTATION GUIDE **ACCESS hsTnI**

The Access hsTnI assay is designed to facilitate the diagnosis and management of patients with symptoms suggestive of myocardial infarction. The current Fourth Universal Definition of MI recommends the use of the 99th percentile upper reference limit (URL)—preferably sex-specific 99th percentile URLs—and a shorter time frame between repeat hsTn measurements for the use of hsTn assays. Implementing hsTn assays into clinical practice, however, calls for process changes to achieve efficiencies and improve quality outcomes in patient care.

In considering or planning a transition to the Beckman Coulter Access hsTnI assay, please know that cardiac experts strongly recommend against adopting hsTn assays without preparation. Implementation requires a strategy for introducing the Access hsTnI assay into your local context and workflow.



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At Beckman Coulter, we are committed to your success and are available to assist you in your transition to the Access hsTnI assay. This guide summarizes key recommendations from society experts and best practices for your reference.

Key Considerations

1. Convene a small interdisciplinary group

- > Select a maximum six decision makers to ensure efficient discussions
- > Include representatives from laboratory medicine, the emergency department, cardiology, nursing, IT and other applicable specialties

2. Put in place laboratory building blocks

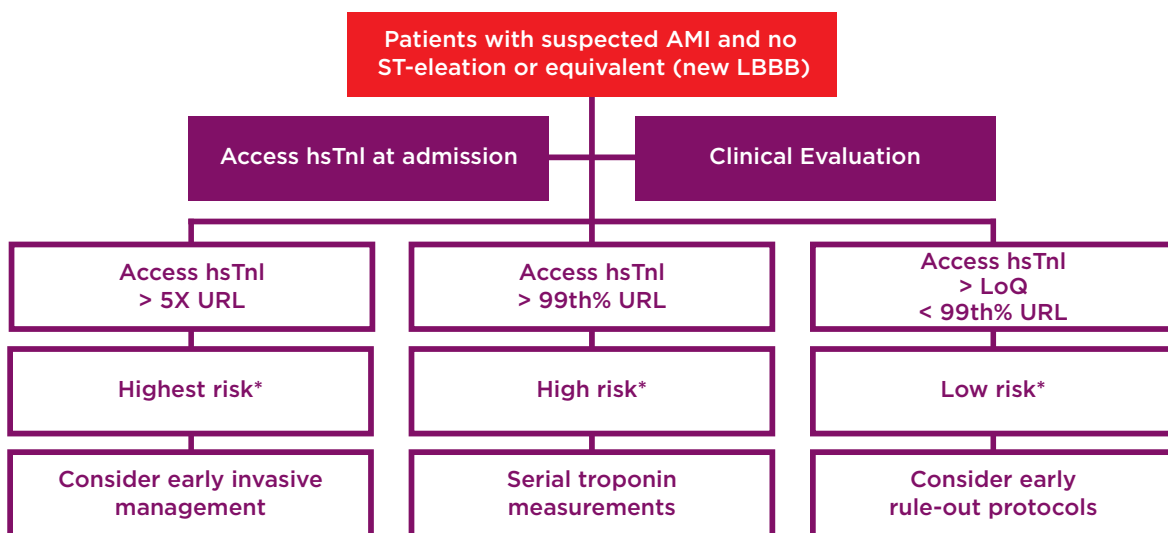
- > Validate the LoB, LoD outside the U.S., or LoQ, as applicable, per FDA regulations in the U.S.
- > Use a defined reference population to verify 99th percentile URL(s)
- > Build QC procedure following recommendations by the American Association for Clinical Chemistry (AACC) and International Federation for Clinical Chemistry and Laboratory Medicine (IFCC)
- > Understand potential sources of laboratory analytical variability when determining clinical decision limits—for example, laboratory to laboratory, instrument to instruments, lot to lot

- > Collect feedback on additional data needed to make the change—for example, serial sampling for early presenters or patients with comorbidities for observation of change patterns over time
- > Streamline the laboratory process to report Access hsTnI results within 60 minutes or less of sample receipt
- > Build an obsolescence plan for your current troponin assay; set the date by which you will begin running only Access hsTnI

3. Put in place clinical building blocks

- > Determine the clinical cutoff point(s) to aid with AMI diagnosis and consider sex differences per IFCC and clinical society recommendations
- > Employ a critical value to identify patients with a “highly abnormal” Access hsTnI result on admission in the context of a “typical presentation”—for example, five-fold the URL recommended by the 2015 ESC guidelines

Figure 1. Ranges of Diagnoses Across hs-cTn Concentrations as recommended by JACC Scientific Expert Panel (page 1064) [2]



*Risk for AMI or death

- › Develop an accelerated diagnostic protocol (ADP), incorporating Access hsTnI and clinical data to increase the efficiency and rapidity of AMI evaluations in a safe manner
 - Consider key components that impact the ADP (Figure 1)—for example, blood draw timing, change pattern, patients with comorbidities and chronic myocardial injury (Figure 2) and risk score
 - Validate the proposed ADP clinically by running Access hsTnI “behind the scenes,” while making clinical decisions based on the current assay
 - Assess the accuracy of cutoff points and change values in the proposed ADP for identifying low-risk and AMI patients, and adjust the Access hsTnI algorithm as appropriate
 - If applicable, determine if continued use of POC troponin test is appropriate; note: POC testing is not recommended if considering an accelerated protocol

4. Incorporate the ADP for Access hsTnI into the clinical electronic health record (EHR) workflow

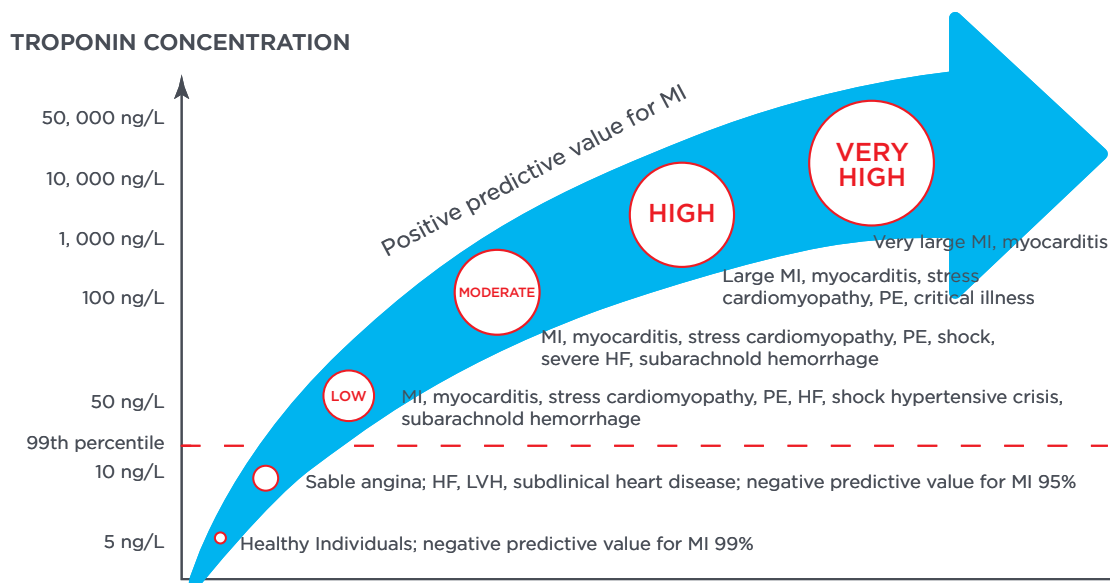
- › Create an EHR-based order set for the Access hsTnI protocol
- › Prepare a clear display of the detailed interpretation guidelines

5. Plan phased educational sessions for all clinical services affected by the transition

- › Hold a series of grand rounds, conferences and roundtable discussions to communicate the analytical and clinical benefits of having the Access hsTnI assay; the important changes, including unit changes and the new protocol; and, the differential diagnosis of an elevated Access hsTnI result
- › Distribute support tools and training materials, including emails and brochures, for continuous education; remind personnel of important dates for educational meetings, the launch event and service changes

A process change can bring uncertainty. This can be eased by organizing regular meetings among interdisciplinary members to help oversee the conversion, monitoring clinical metrics and adjusting actions and procedures, as necessary. It may be helpful to assign department champions, so they can provide decision-making support and consultation.

Figure 2. Suggested management flow chart for patients with suspicion of AMI as recommended by the Biomarker Study Group of the European Society of Cardiology Acute Cardiovascular Care Association (page 214) [1]



A broader differential diagnosis associated with lower-range elevations of hs-cTn begins to narrow as concentrations are higher. HF: heart failure; LVH: left ventricular hypertrophy; MI: myocardial infarction; PE: pulmonary embolism.



The collaborative educational process should take at least several weeks to months, to allow for preparation in the clinical laboratory and provide time for busy clinicians to familiarize themselves with the knowledge regarding the change.²



Recommended reading:

1. Hollander JE. "High-sensitivity Troponin: Time to Implement." *Ann Emerg Med*, vol. 72, no. 6. 2018, pp. 665-667.
2. Januzzi JL Jr. et al. "Recommendations for Institutions Transitioning to High-sensitivity Troponin Testing: JACC Scientific Expert Panel." *JACC*, vol. 73, no. 9. 2019, 1059-1977.
3. Wu AHB et al. "Clinical Laboratory Practice Recommendations for the Use of Cardiac Troponin in Acute Coronary Syndrome: Expert Opinion from the Academy of the American Association for Clinical Chemistry and the Task Force on Clinical Applications of Cardiac Bio-markers of the International Federation of Clinical Chemistry and Laboratory Medicine." *Clin Chem*, vol. 64, no. 4. 2018, pp. 645-655. doi: 10.1373/clinchem.2017.277186.
4. Clinical and Laboratory Standards Institute (CLSI). "Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline—Third Edition." https://clsi.org/media/1421/ep28a3c_sample.pdf, 2010. Accessed 14 Feb. 2020.
5. Thygesen K et al. "Fourth Universal Definition of Myocardial Infarction (2018)." *Eur Heart J*, vol. 40, no. 3. 2019, pp. 237-269.
6. Roffi M et al. "2015 ESC Guidelines for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation: Task Force for the Management of Acute Coronary Syndromes in Patients Presenting without Persistent ST-segment Elevation of the European Society of Cardiology (ESC)." *Eur Heart J*, vol. 37, no. 3. 2016, pp. 267-315.
7. Möckel M et al. "Editor's Choice—Rule-in of Acute Myocardial Infarction: Focus on Troponin." *Eur Heart J Acute Cardiovasc Care*, vol. 6, no. 3. 2017, pp. 212-217. doi: 10.1177/2048872616653228.
8. Boeddinghaus J et al. "High-sensitivity Cardiac Troponin I Assay for Early Diagnosis of Acute Myocardial Infarction," *Clin Chem*, vol. 65, no. 7. 2019, pp. 893-904. doi: 10.1373/clinchem.2018.300061.
9. Nestelberger T et al. "Two-hour Algorithm for Rapid Triage of Suspected Acute Myocardial Infarction Using a High-sensitivity Cardiac Troponin I Assay." *Clin Chem*, vol. 65, no. 11. 2019, pp. 1437-1447. doi:
10. McCarthy CP et al. "Myocardial Injury in the Era of High-Sensitivity Cardiac Troponin Assays", *JAMA Cardiol*. 2019;4(10):1034-1042. doi:10.1001/jamacardio.2019.2724

References

1. Möckel M. "Editor's Choice—Rule-in of acute myocardial infarction: Focus on troponin." *European Heart Journal: Acute Cardiovascular Care*, vol 6, no. 6. 2017, page 213.
2. Januzzi JL Jr. et al. "Recommendations for Institutions Transitioning to High-sensitivity Troponin Testing: JACC Scientific Expert Panel." *JACC*, vol. 73, no. 9. 2019, page 1064

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