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January 2025

IMPORTANT PRODUCT INFORMATION FOR U.S. CUSTOMERS

Product Name	List Number
***i-STAT hs-TnI* cartridge (NEW)**	09P81-25
***i-STAT cTnI* cartridge**	03P90-25

Dear Valued *i-STAT System* Customer,

As the new year gets underway, we want to share an important update with you regarding changes to the *i-STAT* cartridge menu. If your facility is currently using the *i-STAT cTnI* cartridge (03P90-25), please review the information below to prepare for these changes.

We are excited to announce that on January 3, 2025, the *i-STAT hs-TnI* cartridge received clearance from the U.S. Food and Drug Administration (FDA). As the first point-of-care, high-sensitivity troponin test in the United States to provide lab-quality results at the bedside, the test enables clinicians to rapidly assess patients experiencing chest pain.

The *i-STAT hs-TnI* cartridge will be available on March 31, 2025 in the United States under list number 09P81-25. Professional societies, such as the American College of Cardiology (ACC) and American College of Emergency Physicians (ACEP), recommend the use of high-sensitivity troponin as the preferred biomarker for evaluating acute chest pain.[1]

Additional information about the *i-STAT hs-TnI* cartridge can be found at:
https://www.globalpointofcare.abbott/us/en/product-details/apoc/istat-hs-tni.html

If your facility is currently using the *i-STAT cTnI* cartridge (03P90-25), please review the information below, as there are actions you should take now to prepare to transition to the *i-STAT hs-TnI* cartridge as part of your point-of-care testing protocols. Please note that your Abbott Point of Care representative is available to support you with the transition.

With the clearance of the *i-STAT hs-TnI* cartridge, on September 30, 2025, we will end shipment in the United States of the *i-STAT cTnI* cartridge. Please work with your internal teams as well as with your Abbott Point of Care representative to begin transitioning from the *i-STAT cTnI* cartridge to the *i-STAT hs-TnI* cartridge. To help you plan for the transition from the *i-STAT cTnI* cartridge to the *i-STAT hs-TnI* cartridge, please refer to the end of this letter for a summary of activities that may be required.

[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:e368-e454.

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We understand this transition may be disruptive, so your Abbott Point of Care representative is available to discuss how we can best support the specific needs of your facility to help make this transition as seamless as possible.

For additional information on the *i-STAT hs-TnI* cartridge or the resources offered by Abbott to support the implementation of the *i-STAT hs-TnI* cartridge, please contact:

- Your local Abbott Point of Care representative
- Abbott Point of Care Technical Support via phone or email:
    - 1-844-256-9531
    - apoc_productinformation@abbott.com

For complete intended use and product information, visit the Abbott Point of Care Website (www.globalpointofcare.abbott).

We appreciate and thank you for your continued support of Abbott and the *i-STAT System*. We look forward to working with you to bring the *i-STAT hs-TnI* cartridge to your facility.

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Activities to consider in preparation for high-sensitivity troponin

Guidance/Guidelines

In preparation for the transition to high-sensitivity troponin I, we recommend reviewing applicable Clinical Laboratory Standards Institute (CLSI) guidance/guidelines which may include:

- EP05 – *Evaluation of Precision of Quantitative Measurement Procedures* (evaluating the precision performance of quantitative measurement procedures)
- EP06 - *Evaluation of Linearity of Quantitative Measurement Procedures* (analytical measurement range: linearity/calibration verification)
- EP09 - *Measurement Procedure Comparison and Bias Estimation Using Patient Samples* (the design of measurement procedure comparison experiments using patient samples and subsequent data analysis techniques used to determine the bias between two in vitro diagnostic measurement procedures)
- EP28-A3C – *Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory* (determining reference values and reference intervals for quantitative clinical laboratory test)
- EP15 – *User Verification of Precision and Estimation of Bias; Approved Guideline* (estimation of imprecision and of bias for clinical laboratory quantitative measurement)

Preparation for transition for *i-STAT cTnI* cartridge to *i-STAT hs-TnI* cartridge

The following activities may be required before using *i-STAT hs-TnI* cartridge:

- Method evaluation to obtain evidence that the accuracy (method comparison), precision and reportable range (performance verification) of the high-sensitivity test are adequate and that the reference ranges meet the needs of the patient population and clinician.
- Identification of the appropriate samples to be used for the method evaluation, precision, and evaluation of the reportable and reference ranges.
- Defining the criteria for acceptability for method evaluation (including concordance), precision and evaluation of the reportable and reference ranges.
- Ensuring an adequate number of elevated troponin samples for hs-TnI are available to complete the *Method Comparison* study in a timely manner. Determine if plasma samples can be selected from routine samples after testing on the core lab analyzer, frozen and stored in preparation for future activities.
- Determination of facility-specific accelerated diagnostic protocols (ADPs) utilizing the high-sensitivity troponin result.
- Update to Individualized Quality Control Plan (IQCP).
- Potential LIS/HIS update for capture of information in patient electronic medical record, including updates to interface software (i.e., information regarding sex specific cuts offs).
- Confirm the i-STAT data manager (*i-STAT/DE*) version being used. Contact your Abbott Point of Care Representative to determine if any changes are required.
- Updates to facility policies and procedures.
- Operator training (i.e., for interpretation of results).

Preparation for Performance Verification of *i-STAT hs-TnI* cartridge

To prepare for performance verification activities, follow your facility policies and procedures and consider collecting patient samples and obtaining *i-STAT hs-TnI* Controls and Calibration Verification Materials.

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