i-STAT hs-TnI CONVERSION GUIDE

This guide provides assistance to customers transitioning from an existing testing method to testing with *i-STAT hs-TnI*, including components for conversion, testing options and a list of helpful resources. Supply orders, pricing, and service agreements can be finalized with an Abbott *i-STAT* sales specialist.

INTENDED USE FOR i-STAT hs-TnI CARTRIDGE

The *i-STAT hs-TnI* cartridge with the *i-STAT 1 System* is intended for use in the in vitro quantification of cardiac troponin I (cTnI) in whole blood or plasma samples in point of care or clinical laboratory settings. The *i-STAT hs-TnI* cartridge with the *i-STAT 1 System* is intended to be used as an aid in the diagnosis of myocardial infarction (MI).

TRANSITION CHECKLIST

HARDWARE

- *i-STAT 1* analyzer
- *i-STAT* printer (if used)
- Downloader
  (downloader cable connections)

CHECKS

- Analyzer software is updated
- Printer paper is available (if needed)
- Downloaders are programmed
- Downloaders are connected to network

NOTE: Before starting, check all equipment is available and operational. Contact *i-STAT* Technical Support if reprogramming of downloaders is needed. Connectivity may not be applicable for all facilities.

CONSUMABLES

- Cartridges
- Controls & Cal Ver
- Transfer device
- Sample collection device

CHECKS

- Storage for cartridges, controls, and Cal Ver according to IFU
- Identify the most appropriate transfer devices
- Check dates on collection devices
  (do not use expired collection devices)
- Verify collection devices are according to IFU

NOTE: New product codes/part numbers should be loaded into ordering system to eliminate ordering delays.

COMPLIANCE

METHOD EVALUATION & THE i-STAT hs-TnI CARTRIDGE

Follow internal policy and procedures approved by laboratory director; direct follow-up questions to accrediting organization.

Abbott Method Evaluation support | The method evaluation is not a manufacturer's requirement and specific details or information related to the above activities may be obtained from your accreditation or regulatory organizations.

i-STAT Supply Calculator | *i-STAT* supplies will be calculated according to the number of analyzers and method evalution plan. Optional quality control plan, training cartridges and any additional cartridges for interface testing will be calculated at the customer's request.

Data Collection Worksheets | Worksheets are available in Abbott's online *i-STAT hs-TnI* Resource Center. If a method evaluation report is needed, follow the instruction provided in the data collection worksheets. Worksheet requirements must be met for an Abbott representative to generate a report.

PROCEDURES

Review procedures and identify changes needed. Next, obtain required signatures to revised procedures.

PROCEDURE UPDATES TO CONSIDER

- Ranges: reportable, sex-specific, reference intervals
- Review necessary changes to elevated, actionable, and critical ranges
- Modify quality control plan procedures in accordance with IQCP (if applicable)
- Update reagent and control material storage conditions
- Visit the **Instructions for Use** page in the *i-STAT System Support* area of the globalpointofcare.abbott website.

INDIVIDUALIZED QUALITY CONTROL PLAN (IQCP)

- Re-evaluate risk assessment based on the addition of a new test to the plan
- Ensure controls are done in accordance with IQCP
- Re-evaluate QC Plan and Quality Assessment in accordance with changes to risk assessment
- Lab director review and approval is required for all changes

Additional information about updates /changes are available from the *i-STAT hs-TnI* Resource Center.

PROFICIENCY TESTING (PT)

Laboratories performing non-waived testing may enroll in an approved PT program for regulated analytes listed in Subpart I Proficiency, Testing Programs for Nonwaived Testing. Proficiency Testing is used to evaluate a laboratory's performance.

NOTE: Consult with your regulatory agency to determine if PT is required for hs-TnI as an unregulated analyte. Abbott has identified API and WSLH providers as most compatible with *i-STAT hs-TnI* assay. Contact your proficiency test provider to determine available material compatible with *i-STAT hs-TnI*.

RESOURCES:

- Subpart I of the CLIA regulations: Proficiency Testing programs for nonwaived testing
- CMS Brochure: Proficiency Testing and PT Referral brochure 10.15.24
- API: Cardiac Markers 5 (program 140/920) American Proficiency Institute 2025 Catalog
- WSLH: Cardiac Markers (Item PT01260) Wisconsin State Laboratory of Hygiene (WSLH) 2025 Catalog

NOTE: Catalogs listed above are subject to change. Check proficiency test provider's website for most recent catalog releases.

CONNECTIVITY

NETWORKING & INTERFACING (applies if connectivity is available or planned. Otherwise, skip this section)

Alert IT, facilities management, and biomed resources regarding the implementation of a new analyte:

- Validate device connectivity
- Update Data Manager, LIS and HIS with new test information
  - Changes can include: **Test code** **Test name** **Test Ranges** **Action ranges**
- Verify that order sets, power plans, and test batteries are updated for *i-STAT hs-TnI* testing.

DE CUSTOMIZATION CHANGES

Contact *i-STAT Technical Support* or your data management vendor for options to update your DE Customization Workspace for *i-STAT hs-TnI* compatibility.

- Links to **DE customization videos** and customization instructions (found in the *i-STAT 1 System Manual*) are linked from the *i-STAT hs-TnI* Resource Center at www.globalpointofcare.abbott: visit ***Support > product-installation-training*** to navigate to the *hs-TnI Resource Center* web page.

NOTE: Consult with your data management vendor to update to the latest DE version. If testing is not currently interfaced and will not be interfaced in the conversion, the interfacing section does not apply.

EDUCATION & TRAINING

CLINICAL AWARENESS

Inform clinicians and department leads of changes, which may include:

- Test name
- Ordering location
- Reportable ranges
- Clinical differences between conventional cTnI and high-sensitivity TnI assays (refer to *i-STAT cTnI vs hs-TnI Product Differences Flashcard*)
- Clinical support communication

TRAINING

Resources available for your staff when converting to *i-STAT hs-TnI* testing:

- Conversion eduction from *i-STAT* support team
- Real-time, interactive online trainings session: Download the training schedule from the Online Training Schedules page (found at **www.globalpointofcare.abbott > *i-STAT Customers* menu > *i-STAT System Support* page >** Training & Education **page)**

VISIT THE i-STAT hs-TnI RESOURCE CENTER TO GET STARTED

Abbott has created a dedicated online resource center with materials you need to make the transition, including:

- Conversion Guide (this document)
- Product Differences Flashcard
- Guidance On Saving hs-TnI Samples
  i-STAT hs-TnI IFU
- Interactive Remote Training schedules
- *i-STAT Learning System* (hs-TnI cartridge)
- Schedule for *Meet the Experts* sessions
- Data Collection Worksheet (must be used per the instructions in order for Abbott to generate a report)
- Suggestions for procedure updates
- Suggestions for IQCP updates

NOTE: Not all documents are required for transition, but are available for use according to your facility's needs.

SCAN THE CODE TO VISIT THE i-STAT hs-TnI RESOURCE CENTER

NEED HELP? CONTACT OUR SUPPORT TEAM AT:

MEET THE EXPERTS:

Experienced & expert staff to assist with questions & provide guidance
Calendar available HERE

DEDICATED TO hs-TnI INQUIRIES WITH RESPONSE-GOAL WITHIN 48 BUSINESS HRS.

VIA MONITORED EMAIL:

hs-TnISupport@abbott.com

DEDICATED TO i-STAT hs-TnI INQUIRIES ONLY

VIA PHONE:

1-844-256-9531

Abbott

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