i-STAT hs-TnI

cardiac markers

Cardiac troponin I results in minutes

ROLE OF PRODUCT

The *i-STAT hs-TnI* cartridge with the *i-STAT 1 System* is intended for use in the *in vitro* qualification of cardiac troponin I (cTnI) in whole-blood or plasma samples in point-of-care or clinical laboratory settings.[1] This cartridge's objective data helps healthcare providers assess patients with suspected myocardial infarction (MI)

KEY BENEFIT OF PRODUCT

The *i-STAT 1 System* communicates critical data to care teams and seamlessly integrates with existing clinical and laboratory workflows to support timely decision-making. the *i-STAT hs-TnI* cartridge offers:

- Lab-quality results in approximately 15 minutes
- Testing at the bedside
- Potential to optimize ED efficiency and enhance patient satisfaction

PERFORMANCE

The *i-STAT 1 System* and *hs-TnI* cartridge provide accurate results at the point-of-care when assessing patients with suspected myocardial infarctions, communicating critical data and seamlessly integrating with existing clinical and laboratory workflows to support timely decision-making. Gender-specific cutoffs for males and females enable faster patient triage, improved ED efficiency, and better outcomes for at-risk patients.

Table 1: Patient distribution for pivotal study data

SEX	MIs	NON-MIs	TOTAL SUBJECTS	% MI PREVALENCE	CUT OFF (ng/l)
Female	157	2138	2295	6.8	13
Male	150	1140	1290	11.6	28

Table 2: Performance using whole-blood samples

>1 TO 3 HOURS*	FEMALE	MALE
No. of subjects	1799	1025
MI	119	118
Non-MI	1680	907
Sensitivity	96.64%	90.68%
Specificity	82.14%	83.90%
PPV	27.71%	42.29%
NPV	99.71%	98.58%

**Pivotal Study was conducted at 4 timepoints (in hours): 0-1, >1-3, >3-6, >6. Data on file for additional timepoints."*

INTENDED USE

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).

PRODUCT CODE/LIST NUMBER

- 09P81-25 *i-STAT hs-TnI* Cartridge
- 06P17-20 *i-STAT hs-TnI* Cal Ver Set
- 06P17-21 *i-STAT hs-TnI* Control Level 1
- 06P17-22 *i-STAT hs-TnI* Control Level 2
- 06P17-23 *i-STAT hs-TnI* Control Level 3

CARTRIDGE SPECIFICATIONS

Cartridge Box	3.75" (W) x 2" (H) x 9.625" (L)
Quantity per Box	25 portion packs
Cartridge Pack	3.7" (W) x 1.95" (H) x 0.37" (D)
Shipment time-temperature indicator	Included in the shipment is; a time-temp. indicator that provides a visual non-reversible record of temperature exposure at or above 10°C and 34°C for an exposure period of 5 days at 30°C and 3 hours at 34°C
Refrigerated Storage	35-46° F/2-8° C until the date indicated on the box and portion pack.
Room Temp. Storage	64-86° F / 18-30° C for up to 14 days
Room Temp. Equilibration	5 minutes for a single cartridge 1 hour for an entire box
Sample Type	- Whole blood without anticoagulant - Whole blood or plasma with lithium heparin anticoagulant (with or without plasma separator)
Sample volume	Approximately 22 µL
Panel Name	hs-TnI
Test/Analyte(s)	Cardiac Troponin I
Analysis Time	≈15 minutes
Reportable Range	2.9 – 1000.0 ng/L
Reference Range	Each facility should establish its own reference ranges using the *i-STAT hs-TnI* test

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CARTRIDGE SPECIFICATIONS - CONTINUED

Traceability	The i-STAT System test for cardiac troponin-I (cTnI) measures cardiac troponin I amount-of-substance concentration in plasma or the plasma fraction of whole blood for in vitro diagnostic use. Cardiac troponin-I values assigned to i-STAT controls and calibration verification materials are traceable to the i- STAT System's working calibrator prepared from human cardiac troponin-ITC complex (NIST SRM2921).[1]
Latex Rubber	The "diaphragm pump" contains natural rubber latex
CLIA Categorization	Moderate complexity

CONTROL SPECIFICATIONS

Control Box	4.25" (W) x 2.406" (H) x 0.718" (D)
Quantity per box	6, clear siliconized glass vials - each includes 1 ml of frozen human plasma
Frozen Storage	Store frozen (≤ -4° F/-20 °C) until the expiration date printed on box and vial labels
Room Temp. Equilibration	Vials, cartridges, and instruments must be at the same temperature. i-STAT hs-TnI Control vials should stand at room temp. (64-86° F/18-30° C) for at least 15 minutes until completely thawed.
After Thawing	Material may be stored capped at room temperature (64-86°F /18-30°C) or refrigerated (35-46°F/2-8°C) for up to 4 hours prior to testing. DO NOT refreeze
Control Levels	Levels 1, 2 and 3

CALIBRATION VERIFICATION (CAL VER) SPECIFICATIONS

Cal Ver Box	4.25" (W) x 2.406" (H) x .718" (D)
Quantity per box	6 vials (two vials of each level) - each includes 1 ml of frozen human plasma
Frozen Storage	Store frozen (≤ -4° F/-20 °C) until the expiration date printed on the box and vial labels
Room Temp. Equilibration	Vials, cartridges, and instruments must be at the same temperature. *i-STAT hs-TnI* Calibration Verification vials should stand at room temp. (64- 86° F/18-30° C) for at least 15 minutes for thawing.
After Thawing	Material may be stored capped at room temperature (64-86° F/18-30° C) or refrigerated (35-46°F/2-8°C) for up to 4 hours prior to testing. DO NOT refreeze
Cal Ver Levels	- Levels 1, 2 and 3 - Low, mid and high result values across the reportable range

SYSTEM COMPATIBILITY

The *i-STAT hs-TnI* cartridge is part of a broad menu of tests compatible with the *i-STAT 1 System*.

To support the use of the *i-STAT hs-TnI* cartridge, updates for the *i-STAT 1* analyzer and *i-STAT/DE* software versions were released in October 2024.

TRAINING AND COMPLIANCE

Resources designed to ensure competency of *i-STAT System* users and to assist in meeting regulatory compliance requirements are available for download from the www.globalpointofcare.abbott website.

INTERACTIVE REMOTE TRAINING

- A schedule of available live, *online training* sessions related to *i-STAT System* use, *i-STAT hs-TnI* conversion and performing instrument and connectivity software updates. (e.g i-STAT DE) is available.

ADDITIONAL INFORMATION

To obtain additional product information and support, visit www.globalpointofcare.abbott.

REFERENCES

1. Abbott Point of Care, Inc. *i-STAT hs-TnI Cartridge with the i-STAT 1 System*. 510(k) Premarket Notification, K240984, U.S. Food and Drug Administration, 3 Jan. 2025. Available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K240984

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i-STAT hs-TnI - Product Specifications | 5964.1 01/25

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