

i-STAT hs-TnI

cardiac markers

Cardiac troponin I results in minutes

RESULTS IN
≈15 MINUTES



ROLE OF PRODUCT

The *i-STAT hs-TnI* cartridge with the *i-STAT 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.¹ The hs-TnI test data helps healthcare providers assess patients with suspected myocardial infarction (MI).

KEY BENEFIT OF PRODUCT

The *i-STAT 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 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	154	2010	2164	7.1	13
Male	147	1088	1235	11.9	28

Table 2: Performance using whole-blood samples

>1 TO 3 HOURS*	FEMALE	MALE
No. of subjects	1745	1006
MI	117	117
Non-MI	1628	889
Sensitivity	96.58%	90.60%
Specificity	81.88%	83.58%
PPV	27.70%	42.06%
NPV	99.70%	98.54%

*Pivotal Study was conducted at 4 timepoints (in hours): 0-1, >1-3, >3-6, >6. Data on file for additional timepoints. Performance for the *i-STAT hs-TnI* cartridge in whole blood using the sex-specific 99th percentile URL (female 13 ng/L, male 28 ng/L)

INTENDED USE

The *i-STAT hs-TnI* cartridge with the *i-STAT 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 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

CARTRIDGE SPECIFICATIONS - CONTINUED

Traceability	The <i>i-STAT</i> 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>i-STAT</i> controls and calibration verification materials are traceable to the <i>i-STAT</i> 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 ($\leq -4^{\circ}\text{F}/-20^{\circ}\text{C}$) until the expiration date printed on box and vial labels
Room Temp. Equilibration	Vials, cartridges, and instruments must be at the same temperature. <i>i-STAT hs-TnI</i> 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 ($\leq -4^{\circ}\text{F}/-20^{\circ}\text{C}$) 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>i-STAT hs-TnI</i> Calibration Verification 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
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* and *i-STAT Alinity* instruments (the *i-STAT 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. *i-STAT hs-TnI* (High Sensitivity Troponin-I) Instructions for Use (Canada-REF 09P81-25).

For *in vitro* diagnostic use only.

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