i-STAT hs-TnI Control Levels 1, 2, and 3

NAME

i-STAT hs-TnI Control Level 1 (REF 06P17-21)

i-STAT hs-TnI Control Level 2 (REF 06P17-22)

i-STAT hs-TnI Control Level 3 (REF 06P17-23)

INTENDED USE

The i-STAT High Sensitivity Troponin-I (i-STAT hs-TnI) controls are available to monitor the performance of the i-STAT hs-TnI test.

REAGENTS

Contents: Each box contains 6 vials, and each vial contains 1 mL of frozen human plasma.

Composition:

Ingredient Name	Concentration (% by weight)
Human Source Material	30-60%
Buffers and Preservatives	40-70%
Cardiac Troponin I Antigen	<0.01%

Warnings and Precautions

- For *in vitro* diagnostic use.
- Handle this product using the same safety precautions used when handling any potentially infectious material. The human plasma used in the preparation of this product has been tested following FDA accepted test methods and found nonreactive for the presence of Hepatitis B antigen (HBsAg), antibody to Human Immunodeficiency Virus (HIV 1/2), antigen to Human Immunodeficiency Virus (HIV-1), antibody to Hepatitis C

Virus (HCV), and Syphilis. However, no known test method can offer complete assurance that products derived from human blood will not transmit infectious disease.

- Do not use if arrived thawed or uncapped. Do not refreeze. Bacterial contamination can cause an increase in turbidity. Do not use the control if there is visible evidence of microbial growth or gross contamination.
- Dispose of this product as biohazardous waste according to all local, state, and national regulations.
- Safety Data Sheets are available in the Support section of the website at www.globalpointofcare.abbott.

Storage Conditions

- Store frozen at ≤ -20 °C (-4°F) until the expiration date printed on the box and vial labels.
- Do not use beyond the expiration date on the box and vial labels.

INSTRUMENTS

The i-STAT hs-TnI Control Levels 1, 2 and 3 are intended for use with the i-STAT System which includes the i-STAT 1 analyzer and the i-STAT Alinity instrument. The i-STAT System should be used by healthcare professionals trained and certified to use the system and should be used according to the facility's policies and procedures.

The i-STAT System incorporates a comprehensive group of components needed to perform sample analysis. A portable instrument and a cartridge with the required tests, using 2-3 drops of a sample will allow the operator to view the results.

For a detailed description of the instrument and system procedures, refer to the i-STAT Alinity System Operations Manual or i-STAT 1 System Manual located at www.globalpointofcare.abbott.

PROCEDURE

Preparation for Analysis:

Prior to testing, the i-STAT hs-TnI Control vials should stand at room temperature (18-30°C or 64-86°F) for a minimum of 15 minutes until completely thawed. After thawing, do not refreeze. Material may be stored capped at room temperature 18-30°C (64-86°F) or refrigerated 2-8°C (35-46°F) for up to 4 hours prior to testing.

For best results, vials, cartridges, and instruments should be at the same temperature.

Directions for Use:

1. The controls are housed in dropper vials to enable convenient transfer of the fluid from the vial into the cartridge. Before transferring the fluid to the cartridge, gently invert the vial at least 10 times to ensure homogeneity.

Note: To minimize foaming of the control sample, avoid vigorous or rapid mixing motion.

2. Remove the cap and direct the dropper tip into the cartridge sample well. Fill the cartridge to the fill mark.
3. Close the cartridge.
4. Refer to the i-STAT Alinity System Operations Manual or the i-STAT 1 System Manual for how to perform quality control testing.
5. When prompted, insert the sealed cartridge into the instrument's cartridge port.
6. Push the sealed cartridge into the instrument port until it clicks into place. Wait for the test to complete.

ACCEPTABLE CRITERIA

Target Value

Target values (determined by testing multiple vials of each level using multiple lots of i-STAT cartridges and instruments that have passed the Electronic Simulator test) are printed on a value assignment sheet and are also provided in an electronic file, electronic value assignment sheet (eVAS) posted on the APOC website at www.globalpointofcare.abbott.

Ensure that the lot number printed on the value assignment sheet matches the lot number on the label of the vial and that the software version above the target value table matches the software version in the instrument.

Ranges

Refer to value assignment sheet (VAS) or electronic version (eVAS) for the target (mean), the acceptable range and units of measurement for:

Assay	Unit
hs-TnI	ng/L

The ranges displayed represent the maximum deviation expected when controls and cartridges are performing properly.

Should results outside the ranges be obtained, refer to the Limitation section below.

Limitation

Target values are specific to the i-STAT System. Results may differ if used with other methods.

If a result for a level is outside the range published in the value assignment sheet, verify the following conditions are met and repeat the test.

- The correct value assignment sheet is being used and the correct cartridge type and lot number listing is being used.
- Expiration date printed on cartridge portion pack and control vial label have not been exceeded.
- Room temperature expiration date for cartridge has not been exceeded.

- Cartridge and control have been stored correctly.
- The control has been handled correctly–see the directions for use.
- The instrument being used passes the Electronic Simulator test.

If the results are still out of range despite meeting the above criteria, repeat the test using a new box of control fluids and/or cartridges. If the results are still out of range, contact your local support service provider.

Note: Follow facility policy regarding control results that do not fall within assigned ranges.

METROLOGICAL 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's controls are traceable to i-STAT's working calibrator prepared from human cardiac troponin-ITC complex (NIST SRM2921).

i-STAT System controls are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from Abbott Point of Care Inc.

To obtain additional information and technical support, refer to the company website at www.globalpointofcare.abbott.

KEY TO SYMBOLS

Symbol	Definition/Use
	Use by or expiration date An expiration date expressed as YYYY-MM-DD means the last day the product can be used
	The Manufacturer lot number/batch will appear adjacent to this symbol
	Contains sufficient for <n> tests
	Temperature limitations. The upper and lower limits for storage are adjacent to upper and lower arms.
	Catalog number, list number, or reference
	Single use only. Do not refreeze.
	Manufacturer
	Consult instructions for use or see System Manual for instructions.
	*In vitro* diagnostic medical device
	U.K. Conformity Assessed (UKCA) marking in accordance with the UK Medical Device Regulations 2002.
	Control
	Biological risks
	Device for near-patient testing
	Caution: Read all warnings and precautions in instructions for use.

EC REP	Authorized Representative in the European Community
	Importer in the European Community

ADDITIONAL INFORMATION

To obtain additional product information and technical support, refer to the Abbott company website at www.globalpointofcare.abbott.

Product issues and adverse events should be reported to Abbott through your Abbott Point of Care support service. For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/746/EU on In vitro Diagnostic Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to Abbott and its authorized representative and to your national authority.

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UK Responsible Person
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IVD

CONTROL

EC REP **EMERGO EUROPE**
Westervoortsedijk 60,
6827 AT Arnhem
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Technical Support: please contact your local service provider for service information.

For customers in the European Union: A summary of safety and performance (SSP) for this device is available at https://ec.europa.eu/tools/eudamed/ after the launch of the European Database on Medical Devices. Search for the device using the UDI-DI provided on the outer packaging of the device. A copy of the SSP can also be requested from the European Authorized Representative or the manufacturer.