

OREGON HEALTH & SCIENCE UNIVERSITY
Hospitals and Clinics
Point of Care

Troponin- I by iStat

Principle

Troponin-I values are used to assist the Emergency Department in the diagnosis of acute myocardial infarction (AMI) or to detect ischemic damage. Elevated levels of cTnI (Troponin- I) are detectable in blood within 3 to 6 hours after the onset of chest pain, reach peak concentrations in approximately 12-16 hours, and can remain elevated for 4 to 9 days post-AMI. The high specificity of cTnI measurement in identifying cardiac injury has been reported for clinical conditions involving skeletal muscle injury resulting from surgery, trauma, extensive exercise, or muscular disease.

The i-STAT cTnI test uses a two-site enzyme-linked immunosorbant assay (ELISA) method. Antibodies specific for human cardiac troponin-I are located on an electrochemical sensor fabricated on a silicon chip. Also deposited in another location on the sensor silicon chip is an antibody/alkaline phosphatase enzyme conjugate specific to a separate portion of the cTnI molecule. The sample is brought into contact with the sensors allowing the enzyme conjugate to dissolve into the sample. The cTnI in the sample becomes labeled with alkaline phosphatase and is captured onto the surface of the electrochemical sensor during an incubation period. The enzyme bound to the antibody/antigen/antibody sandwich cleaves the substrate releasing an electrochemically detectable product. The electrochemical sensor measures this enzyme product which is proportional to the concentration of cTnI within the sample.

The iStat will only be used for Troponin-I testing.

Specimen Requirements

1. Whole blood collected in a lithium heparin tube.
2. Minimum volume is 2.0 mL.
3. Mix blood and anticoagulant at least 10 times to prevent clotting.

Interferences

1. Do not test clotted samples. Clotted samples can result in elevated cTnI readings above the reference range as well as quality check code errors.
2. Grossly hemolyzed samples can cause decreased detection of cTnI, increased backgrounds, and/or quality check codes.
3. Hematocrits >65% cause increased test imprecision and quality check codes.

4. The analyzer must remain on a level surface with the display face up during testing. Motion of the analyzer during testing can increase the frequency of suppressed results or quality check codes.
5. The following substances were found to have no significant effect (less than 10%) on the cTnI method when added to a plasma pool containing approximately 2 ng/ml of cardiac troponin-I, at the concentrations indicated:

Compound	Test Level
Acetaminophen	1660 umol/L
Allopurinol	294 umol/L
Ascorbic Acid	227 umol/L
Acetyl Salicylic Acid	3330 umol/L
Atenolol	37.6 umol/L
Caffeine	23 umol/L
Chloramphenicol	155 umol/L
Diclofenac	169 umol/L
Digoxin	6.15 umol/L
Dopamine	5.87 umol/L
Enalaprilat	0.86 umol/L
Erythromycin	81.6 umol/L
Furosemide	181 umol/L
Sodium Heparin	36 U/mL
Ibuprofen	2425 umol/L
Isosorbide dinitrate	0.636 umol/L
Methyldopa	71 umol/L
Nicotine	6.2 umol/L
Nifedipine	1.156 umol/L
Phenytoin	198 umol/L
Propranolol	7.71 umol/L
Salicylic Acid	4340 umol/L
Theophylline	222 umol/L
Verapamil	4.4 umol/L
Warfarin	64.9 umol/L

- **Heparin at 90 U/mL was found to decrease the cTnI level by approximately 20%.**

Linearity

0.00 – 50.00 ng/mL

Reference Range

<0.50 ng/mL

Alert Values

Values \geq 0.50ng/mL are indicative of Cardiac Damage.

Quality Control

Internal Electronic Simulator (Daily)

The performance of the analyzer is verified by using the Internal Electronic Simulator every 8 hours of use. The Internal Electronic Simulator test cycle is automatically activated when a cartridge is inserted after the 8-hour interval is reached.

1. If the analyzer passes, the cartridge test cycle proceeds.

NOTE: "PASS" message will not be displayed on the analyzer screen. The "PASS" record will appear in the analyzer's stored results.

2. If the analyzer displays "ELECTRONIC SIMULATOR FAIL," the instrument is programmed to lock out patient testing until an Electronic simulator test passes.

a. Run the External Electronic Simulator test.

b. If External Simulator fails twice, send Troponin samples to the Core Lab for testing and call the Hotline at 1-800-366-8020 for assistance.

External Electronic Simulator

External Electronic Simulator should be run if Internal Electronic Simulator fails. External Electronic Simulator should also be run if operator suspects damage to the analyzer (for example, if analyzer is dropped). If External Electronic Simulator passes, run patient test.

1. Allow simulator and analyzer to stand in the same place, out of drafts, at room temperature for 30 minutes. The External Electronic Simulator is stored at room temperature (18-30°C).
2. Turn on analyzer
3. Press Menu key
4. Press 3 for Quality Tests
5. Press 4 for Simulator
6. Type/scan your Operator ID and press enter
7. Type/scan the simulator ID and press enter
8. Remove the cover from the Electronic Simulator and insert straight into the analyzer (inserting at an angle may cause a Quality Check message to be displayed)
9. Let the simulator run until the message reads PASS or FAIL.
10. If PASS is displayed then continue to use the analyzer.
11. If FAIL then rerun it. If the rerun fails again, send Troponin samples to the Core Lab for testing and remove the iSTAT from service.

Using an i-STAT Ceramic Conditioning Cartridge (CCC)

Use this process to resolve Quality Check Code 23.

1. Run an external Electronic Simulator - If the analyzer is configured with the Internal Electronic Simulator enabled, run an External Electronic Simulator. Running the external Electronic Simulator ensures the Internal Simulator cycle will not execute during the restoration cycle, which could lead to the premature termination of restoration cycle.
2. Run the CCC two times - Initiate the CCC cycle as you would initiate an external Electronic Simulator cycle. The instrument will identify the CCC as an external Electronic Simulator and display a Simulator Failure Code (i.e: rRGL) when the cycle is complete. Disregard the code, as this is expected behavior.
3. Return the analyzer to service

Verification of Cartridge Storage Conditions (Daily)

Refrigerated Cartridges:

1. Verify that the cartridges stored in the refrigerator are all within the expiration date printed on the boxes.
2. Dispose of any expired cartridges in the regular trash.
3. Verify that the refrigerator did not exceed the limits of 2-8°C (35-46°F).
4. Document on the Temperature Log.
5. If the temperature of the cartridge storage refrigerator is within the range of 2-8°C (35-46°F), use cartridges as required.
6. If the temperature is outside the range of 2-8°C (35-46°F):
 - a. Quarantine the cartridges in the storage refrigerator.
 - b. Notify Point of Care Department immediately.
 - c. DO NOT USE the cartridges from this refrigerator.
 - d. Record the out-of-control event in the iStat QC logbook, along with the action taken.

Room Temperature Cartridges:

1. Verify that all boxes of cartridges at room temperature (18-30°C) have been out of the refrigerator less than 2 weeks.
2. If the measured room temperature has exceeded 30°C (86°F) for any period of time:
 - a. Quarantine the cartridges.
 - b. Notify Point of Care Department immediately.
 - c. DO NOT USE the cartridges from this location.
 - d. Record the out-of-control event in the iStat QC logbook, along with the action taken.

Liquid Controls- Levels 1 and 3

Liquid QC is run every 30 days or when a new lot number arrives.

1. Liquid Control (QC) vials are stored at -18°C or colder. Call POCT @ 4-5497 when needed.
2. Let the vials warm for 30 minutes at room temperature (18-30°C).
3. Turn on the instrument and go to the Administrator Menu.
4. Press 3, Quality Tests.
5. Press 1 to select Control.
6. Enter your Operator ID number and press Enter.
7. Enter QC level and press Enter.
8. Scan the Cartridge barcode.
9. Thoroughly mix by gently swirling the bottle (avoid foaming).
10. Dispense a drop of sample directly from the vial to the cartridge.
11. Immediately seal the cartridge and insert it into the analyzer
12. Compare results to the package insert values. Record the QC results in the QC logbook.
13. Quality Control results must be within defined limits before reporting patient results. If liquid QC is not within range, rerun with new cartridge. If the rerun fails, **DO NOT USE** the iSTAT for patient testing. Send all troponin-I samples to the Core Lab for testing and call the Hotline at 1-800-366-8020 for assistance. Document all corrective actions in the iSTAT QC Logbook.

Procedure

An individual cartridge may be used after standing 5 minutes (if from refrigerator), in its pouch, to allow the cartridge to come to room temperature. Use cartridge immediately after removing it from its pouch.

Cartridge Testing

An operator starts a cartridge test cycle by selecting the iStat Cartridge option from the Test Menu.

1. Enter or scan your Employee ID number (Your 5-digit TACS ID) and press Enter.
2. Enter or scan the specimen order number and press Enter,
3. Scan the cartridge barcode by pressing the SCAN button and aim the light over the barcode located on the back side of the cartridge package.
4. Remove the cartridge from its pouch. **Avoid touching the contact pads or exerting pressure over the calibrant pack in the center of the cartridge.**
5. On a flat surface direct the dispensing tip or capillary tube containing the blood into the sample well.
6. Dispense the sample until it reaches the fill mark on the cartridge.
7. Immediately slide the snap closure over the sample well. Insert the cartridge into the instrument until it clicks into place.
The screen will read "Identifying Cartridge, Please Wait."
8. Screen will display time remaining until test completion.

9. Upon test completion, results are shown on the analyzer's display screen. **Results are displayed for 2 minutes before the analyzer turns off.**
10. If the analyzer times out, press the On/Off button to restart and select the "Last Result" option from the test menu to review the last result.
11. After use or prior to the next patient, clean the outside of the meter thoroughly.
- Gloves are to be changed and hand hygiene performed between patients.
 - Clean meter surface when visible blood or bloody fluids are present by wiping with a disposable disinfectant wipe (e.g. PDI Sani-Cloth AF or PDI Sani-Cloth HB) to remove any visible organic material. Cleaning should be followed by disinfection (see #3).
 - When no visible organic material is present, after each use disinfect the exterior surface following manufacturer's directions using a disposable bleach wipe (e.g. Clorox Germicidal Wipe or PDI Bleach Wipes).
 - Ensure that the device remains "wet" for the duration of the contact time listed on the label of the bleach wipe.
 - Alcohol should never be used because it can damage the light emitting diodes (LED) readout, causing "fogging" of the plastic screens

Alternative Procedure

Should the iStat System become inoperable for any reason, specimens should be sent to the Core Laboratory with a new Troponin request.

Calculations

- None

Reporting Results

Once test is completed, dock the iStat. The results will be transmitted to the patient's chart.

Suppressed Results

- Results outside the System's reportable ranges are flagged with a < or >, indicating that the result is below the lower limit or above the upper limit of the reportable range, respectively. '**<**' **Results are reported out as < 0.02. If a '>' result occur, send specimen(s) to the Core Laboratory for analysis.**
- Cartridge results, which are not reportable based on internal QC rejection criteria, are flagged with a '***'.
 - Analyze the sample again using another cartridge. The results that are not suppressed can be documented in the patient's chart.
 - If the result is suppressed again, send it to the Core Laboratory for analysis.
- A Quality Check message will be reported instead of results if the analyzer detects a problem with the sample, calibrant solution, sensors, mechanical, or electrical functions of the analyzer during the test cycle. **Send specimen(s) to the**

Core Laboratory for analysis. Call Point of Care Department for troubleshooting assistance.

Calibration

For cartridges, calibration is automatically performed as part of the test cycle on each cartridge. Operator intervention is not necessary.

Data Review

1. The Data Review function allows the operator to review stored results by the categories below (the 1 and 2 keys are used to scroll through the stored records):
 - a. Patient
 - b. Control
 - c. Proficiency
 - d. Cal Ver
 - e. Simulator
 - f. All
 - g. List

2. To view records, select the record and press the Enter key.

Reagents

1. Cartridges:
 - a. No preparation needed.
 - b. A single-use disposable cartridge contains microfabricated sensors, a calibration solution, fluidics system, and a waste chamber. Lactates are run on the CG4+ cartridges.
 - c. Store the main supply of cartridges at a temperature between 2 to 8°C (35 to 46°F). **Do not allow cartridges to freeze.**
 - d. Cartridges may be stored at room temperature (18 to 30°C or 64 to 86°F) for **14 days**. Cartridges should not be returned to the refrigerator once they have been at room temperature, and should not be exposed to temperatures above 30°C (86°F). Mark the calendar on the box or date individual cartridges when removed from the refrigerator to indicate the two-week room temperature expiration date. Cartridges should remain in pouches until time of use. Do not use them after the labeled expiration date.

2. i-STAT Controls Levels 1 and 3:
 - a. Store at ≤18°C until expiration date. Do not use after the expiration date on the box or vials.
 - b. Once controls thaw, they must be used within 4 hours.

3. Electronic Simulator:
 - a. Store at room temperature (18 to 30°C or 64 to 86°F) and protect contact pads from contamination by replacing the plastic cap and replacing the Electronic Simulator's protective cap after use.

References

1. Tietz, Norbert, "Tietz fundamentals of clinical chemistry", ", 5th Ed. Edited by Burtis and Ashwood, WB Saunders Co., Philadelphia, 2001, pp 450-452.
- 2 i-STAT System Manual, 2000.
3. Clinical Chemistry Theory, Analysis and Correlation, Kaplan/Pesce, 2nd Edition, pp 850-856, 884-888, 1021-1024.

