hsTropI – High Sensitivity Troponin-I

Intended Use

The Alinity i STAT High Sensitivity Troponin-I assay is a chemiluminescent microparticle immunoassay (CMIA) used for the quantitative determination of cardiac troponin I (cTnI) in human plasma (lithium heparin) on the Alinity i system. The Alinity i STAT High Sensitivity Troponin-I assay is to be used as an aid in the diagnosis of myocardial infarction (MI).

Clinical Significance

Cardiac troponin I is a regulatory subunit of the troponin complex associated with the actin thin filament within cardiac muscle cells. Troponin I, in conjunction with troponin C and troponin T, plays an integral role in the regulation of muscle contraction. High sensitivity assays can detect elevated levels of cTnI (above the 99th percentile of an apparently healthy reference population) within 3 hours after the onset of chest pain.6 Cardiac troponin I reaches peak concentrations in approximately 8 to 28 hours and remains elevated for 3 to 10 days following MI. Cardiac troponin is the preferred biomarker for the detection of myocardial infarction based on improved sensitivity and superior tissue-specificity compared to other available biomarkers of necrosis, including CK-MB, myoglobin, lactate dehydrogenase, and others. The high tissue specificity of cTnI measurements is beneficial for identifying myocardial infarction in clinical conditions involving skeletal muscle injury resulting from surgery, trauma, extensive exercise, or muscular disease.

Methodology

This assay is an automated, two-step immunoassay for the quantitative determination of cTnI in human plasma (lithium heparin) using chemiluminescent microparticle immunoassay (CMIA) technology. Sample and anti-troponin I antibody-coated paramagnetic microparticles are combined and incubated. The cTnI present in the sample binds to the anti-troponin I coated microparticles. The mixture is washed. Anti-troponin I acridinium-labeled conjugate is added to create a reaction mixture and incubated. Following a wash cycle, Pre-Trigger and Trigger Solutions are added. The resulting chemiluminescent reaction is measured as a relative light unit (RLU). There is a direct relationship between the amount of cTnI in the sample and the RLU detected by the system optics.

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Specimen

Type of Specimen

Specimen Type	Collection Vessel
Plasma	Lithium heparin Lithium heparin separator

Specimen Storage and Stability

1. Tubes of blood are to be kept closed at all times and in a vertical position. It is recommended that the plasma be physically separated from contact with cells within two hours from the time of collection.
2. Do not use: heat-inactivated specimens, pooled specimens, grossly hemolyzed specimens, specimens with obvious microbial contamination, specimens with fungal growth, frozen specimens
3. For accurate results, plasma specimens should be free of fibrin, red blood cells, and other particulate matter, including cryoprecipitate.
4. To ensure consistency in results, recentrifuge specimens prior to testing if they contain fibrin, red blood cells, or other particulate matter.
5. **Recentrifugation of Specimens**: Transfer mixed specimens to a centrifuge tube and centrifuge at a r elative centrifugal force (RCF) of 3000 to 3500 x g for 30 minutes before testing. Transfer clarified specimen to a sample cup or secondary tube for testing. For centrifuged specimens with a lipid layer, transfer only the clarified specimen and not the lipemic material.

Specimen Type	Temperature	Maximum Storage Time	Special Instructions
Plasma	Room temperature (15 to 30°C)	8 hours	Specimens may be stored on the red blood cells or separator gel.

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Sample Dilution Procedures
Plasma
Samples with a cTnI value exceeding 3600.0 ng/L (pg/mL) are flagged with the code "> 3600.0 ng/L" ("> 3600.0 pg/mL") and may be diluted with the Automated Dilution Protocol.

Automated Dilution Protocol
The system performs a 1:30 dilution of the sample and automatically calculates the concentration by multiplying the result by the dilution factor. Automated dilution samples with a cTnI value exceeding 60 000.0 ng/L (pg/mL) will not be reported and are flagged with the code "> 60 000.0 ng/L" ("> 60 000.0 pg/mL").

Reagents

Reagent Handling

- Upon receipt, gently invert the unopened reagent kit by rotating it over and back for a full 180 degrees, 5 times with green label stripe facing up and then 5 times with green label stripe facing down. This ensures that liquid covers all sides of the bottles within the cartridges. During reagent shipment, microparticles can settle on the reagent septum.
  – Place a check in the square on the reagent kit to indicate to others that the inversions have been completed.
  • After mixing, place reagent cartridges in an upright position for 1 hour before use to allow bubbles that may have formed to dissipate.
- If a reagent cartridge is dropped, place in an upright position for 8 hours before use to allow bubbles that may have formed to dissipate.
- Reagents are susceptible to the formation of foam and bubbles. Bubbles may interfere with the detection of the reagent level in the cartridge and cause insufficient reagent aspiration that may adversely affect results.

Reagent Storage and Stability

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
Unopened	2 to 8°C	Until expiration date	Store in upright position. If cartridge does not

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			remain upright, gently invert the cartridge 10 times and place in an upright position for 1 hour before use.
Onboard	System Temperature	30 days	
Opened	2 to 8°C	Until expiration date	Store in upright position. Do not reuse original reagent caps or replacement caps due to the risk of contamination and the potential to compromise reagent performance.

Calibration

Calibration Required

For instructions on performing a calibration, refer to the Alinity ci-series Operations Manual, Section 5.
Each assay control must be tested to evaluate the assay calibration. Once a calibration is accepted and stored, all subsequent samples may be tested without further calibration unless:
• A reagent kit with a new lot number is used.
• Daily quality control results are outside of statistically-based quality control limits used to monitor and control system performance, as described in the Quality Control Procedures section of this package insert. Recalibration is recommended every 30 days. A calibration may be extended based on acceptable verification of the calibration by the laboratory. This assay may require recalibration after maintenance to critical parts or subsystems or after service procedures have been performed.

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Calibration Preparation

Calibration material is the 04Z2101 Alinity i STAT High Sensitivity Troponin-I Calibrators. Remove from carton and allow calibrators to stand room temp (15 to 30C) until completely thawed. (90 to 120mins). Gently invert; prior to use.

Calibration Storage and Stability

	Calibrator Storage	Stability Once OPEN
Troponin Cal (CAL A to Cal F)	Unopened: -20 (Until expiration date)	**-20 °C: For up to 3 freeze/thaw cycles, not to exceed the expiration date printed on the bottle**

Calibration Information

1. Calibrator lots may be configured using the bar code label on the calibrator carton.
2. Verify that the correct calibrator values have been entered into the calibration file.
3. Calibration is performed by running Alinity i STAT High Sensitivity Troponin-I Calibrators
4. For information on configuring calibrator data, refer to the Alinity ci-series Operations Manual, Section 5.

Quality Control

See Policy Chemistry Quality Control Policy

Sample Processing

See Policy RIV-PPP-1199

Reference Range

Test unit= pg/mL for all ages and both sexes.

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Test	Sex	Age Year Low	Age Year High	Ref Low	Ref High
HSTNI	M	0	250	0	35
HSTNI	F	0	250	0	14
HSTNI	U	0	56	0	14

Analytic Range

AMR Low	AMR High	CRR Low	CRR High
3	3600	3	6000

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