Troponin-I ADV

Customer Service: Contact your local representative or find country specific contact information on www.abbottdiagnostics.com

Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

Key to symbols used

- **REF** List Number
- **IVD** In Vitro Diagnostic Medical Device
- **LOT** Lot Number
- **Store at 2-8°C** Expiration Date
- **Store at 15-30°C**
- **Manufacturer**

- **STANDARD CAL A** Standard Calibrator (A-F)
- **CONTROL L** Control Low, Medium, High (L, M, H)
- **REAGENT PACK** Reagent Pack
- **REACTION VESSELS** Reaction Vessels
- **MATRIX CELLS** Matrix Cells
- **SAMPLE CUPS** Sample Cups
- **Consult instructions for use**

See REAGENTS section for a full explanation of symbols used in reagent component naming.
**NAME**
AxSYM Troponin-I ADV

**INTENDED USE**
AxSYM Troponin-I ADV is a Microparticle Enzyme Immunoassay (MEIA) for the quantitative determination of cardiac troponin-I (cTnI) in human serum or plasma on the AxSYM System. Troponin-I values are used to assist in the diagnosis of myocardial infarction (MI) and in the risk stratification of patients with acute coronary syndromes (including unstable angina and non-ST elevation) with respect to relative risk of mortality, myocardial infarction, or increased probability of ischemic events.

**SUMMARY AND EXPLANATION OF TEST**
Troponin-I (TnI) is a regulatory subunit of the troponin complex associated with the actin thin filament within muscle cells. TnI, in conjunction with troponin-C and troponin-T, plays an integral role in the regulation of muscle contraction. Three distinct tissue specific isoforms of TnI have been identified from skeletal and cardiac muscles. The cardiac isoform exhibits only 60% similarity with the skeletal muscle isoforms and contains additional amino acids at the N-terminus; cTnI has a molecular weight of approximately 24,000 daltons. Clinical studies have demonstrated the release of cTnl into the blood stream within hours following acute myocardial infarctions (AMI) or ischemic damage. Elevated levels of cTnI (above the values established for non-AMI specimens) are detectable in serum within 4 to 6 hours after the onset of chest pain, reach peak concentrations in approximately 8 to 24 hours, and remain elevated for 3 to 10 days following AMI. The temporal pattern of cTnl release following an infarction thus extends across the diagnostic windows of both creatine kinase-MB (CK-MB) and lactate dehydrogenase (LD). The clinical utility of cTnI measurements for the assessment of myocardial damage has been demonstrated in several clinical studies indicating improved cardiac specificity of cTnI over CK-MB. The high specificity of cTnI measurements is beneficial in identifying cardiac injury for clinical conditions involving skeletal muscle injury resulting from surgery, trauma, extensive exercise, or muscular disease.

The World Health Organization (WHO) criteria for defining AMI are the presence of two of the following three elements: unequivocal ECG changes, unequivocal serum cardiac enzyme changes, and prolonged chest pain. The Joint European Society of Cardiology/American College of Cardiology Committee current guideline redefines MI and supports the use of cTnl as a preferred marker for myocardial injury. Their definition of MI is a typical rise and gradual fall of cardiac troponin (or more rapid fall of CK-MB) with at least one of the following: ischemic symptoms, pathological Q waves on electrocardiogram (ECG), ischemic ECG changes, or coronary artery intervention. Serial sampling is recommended to detect the temporal rise and fall of troponin levels characteristic of MI. An elevated troponin alone is not sufficient to make the diagnosis of myocardial infarction. Other markers such as CK-MB and myoglobin can be used in conjunction with troponin-I results in aiding the diagnosis of MI. Several major studies have shown that cTnI is also useful as a predictor of cardiac risk in patients with unstable angina. Previous studies showed that during a 30-day follow-up, patients with acute coronary syndromes (including unstable angina) were at greater risk of progressing to MI if cTnI is elevated. Results from the PRISM trial showed that elevated cTnI levels could help to identify patients with unstable angina who had additional cardiac risk (especially within the first 72 hours after onset of symptoms) and who could benefit from treatment with a glycoprotein IIb/IIIa-receptor antagonist. Thus, cTnI can play an important role in identifying patients with acute coronary syndromes who are at greater risk for cardiac events. The American College of Cardiology and the American Heart Association current guidelines also recommend using troponin results when making treatment decisions regarding unstable angina and non-ST segment elevation MI (NSTEMI).

**BIological PRINCIPLES OF THE PROCEDURE**
AxSYM Troponin-I ADV is a three-step assay based on the Microparticle Enzyme Immunoassay (MEIA) technology. The AxSYM Troponin-I ADV reagents and sample are pipetted in the following sequence:

**Sampling Center**
- Sample and all AxSYM Troponin-I ADV reagents required for one test are pipetted by the Sampling Probe into various wells of a Reaction Vessel (RV).
- Sample and Pre-Incubation Diluent are combined in one well of the RV. Components in the Pre-Incubation Diluent bind with and inactivate factors in the sample that might otherwise cause falsely elevated or falsely depressed troponin readings.
- The RV is immediately transferred into the Processing Center. Further pipetting is done in the Processing Center with the Processing Probe.

**Processing Center**
- An aliquot of the sample/diluent mixture is transferred to the well containing microparticles coated with monoclonal antibodies recognizing the cTnI molecule. The cTnI in the sample binds to the microparticles forming an antibody-antigen complex.
- An aliquot of the sample/diluent/microparticle mixture, containing the antibody-antigen complex bound to the microparticles, is transferred to the Matrix Cell. The microparticles bind irreversibly to the glass fiber matrix.
- The Matrix Cell is washed to remove unbound materials.
- The Conjugate 1 (biotin labeled anti-cTnI monoclonal antibody) is then dispensed onto the Matrix Cell and allowed to bind to the troponin-I of the antibody-antigen complex, forming an antibody-antigen-antibody complex.
- The Matrix Cell is washed to remove unbound materials.
- The Conjugate 2 (anti-biotin monoclonal antibody linked to alkaline phosphatase) is then dispensed onto the Matrix Cell and allowed to bind to the biotin of the antibody-antigen-antibody complex, forming an antibody-antigen-antibody-antibody complex.
- The Matrix Cell is washed to remove unbound materials.
- The substrate, 4-Methylumbelliferyl Phosphate, is added to the Matrix Cell, and the fluorescent product is measured by the MEIA optical assembly.

For further information, refer to the AxSYM System Operations Manual, Section 3.

**REAGENTS**

**Reagent Pack, 100 Tests**
AxSYM Troponin-I ADV Reagent Pack (8K19-20*)

- 1 Bottle (13.1 mL) Conjugate 2, Anti-biotin (mouse monoclonal)-alkaline phosphatase (E. coli) conjugate in TRIS buffer with protein (mouse and bovine) stabilizers. Minimum concentration: 0.5 μg/mL. Preservatives: Sodium Azide and antimicrobial agents. (Reagent Bottle 1)
- 1 Bottle (4.9 mL) Microparticles, Anti-tropion-I (mouse monoclonal) coated microparticles in TRIS buffer with protein (mouse, goat, and bovine) stabilizers. Minimum concentration: 0.2% solids. Preservatives: ProClin and Sodium Azide. (Reagent Bottle 2)
- 1 Bottle (13.7 mL) Conjugate 1, Anti-tropion-I (mouse monoclonal): biotin conjugate in TRIS buffer with protein (mouse and bovine) stabilizers. Minimum concentration: 1.5 μg/mL. Preservatives: ProClin and Sodium Azide. (Reagent Bottle 3)
- 1 Bottle (14.5 mL) Pre-Incubation Diluent, Diluent containing protein (mouse, goat, bovine, and E. coli lysate) stabilizers in TRIS buffer. Preservatives: ProClin and Sodium Azide. (Reagent Bottle 4)

* 8K19-20 includes an AxSYM Troponin-I ADV Reagent Pack (100 tests), Reaction Vessels (100 each), and Matrix Cells (100 each).

**Calibrators**
AxSYM Troponin-I ADV Standard Calibrators (8K19-01)
6 Bottles (4 mL each) of AxSYM Troponin-I ADV Standard Calibrators. Calibrator A contains gelatin (porcine) solution and Calibrators B through F contain a recombinant human cardiac troponin I-C complex in a protein (bovine) solution to yield the following concentrations:

1. Bottle (13.1 mL) Conjugate 2, Anti-biotin (mouse monoclonal)-alkaline phosphatase (E. coli) conjugate in TRIS buffer with protein (mouse and bovine) stabilizers. Minimum concentration: 0.5 μg/mL. Preservatives: Sodium Azide and antimicrobial agents. (Reagent Bottle 1)
2. Bottle (4.9 mL) Microparticles, Anti-tropion-I (mouse monoclonal) coated microparticles in TRIS buffer with protein (mouse, goat, and bovine) stabilizers. Minimum concentration: 0.2% solids. Preservatives: ProClin and Sodium Azide. (Reagent Bottle 2)
3. Bottle (13.7 mL) Conjugate 1, Anti-tropion-I (mouse monoclonal): biotin conjugate in TRIS buffer with protein (mouse and bovine) stabilizers. Minimum concentration: 1.5 μg/mL. Preservatives: ProClin and Sodium Azide. (Reagent Bottle 3)
4. Bottle (14.5 mL) Pre-Incubation Diluent, Diluent containing protein (mouse, goat, bovine, and E. coli lysate) stabilizers in TRIS buffer. Preservatives: ProClin and Sodium Azide. (Reagent Bottle 4)
The AxSYM Troponin-I ADV assay standardization is traceable to materials with a National Institute of Standards and Technology (NIST) assigned value.

AxSYM Troponin-I ADV Standard Calibrators are gravimetrically prepared from recombinant troponin-I-C complex and tested against internal working calibrators. The AxSYM internal working calibrators were value assigned by specimen correlation to the Abbott ARCHITECT STAT Troponin-I assay calibrated using its internal working calibrators. The ARCHITECT STAT Troponin-I internal working calibrators were prepared from recombinant troponin-I-C complex which has a concentration traceable near the AMI medical decision point to a NIST value-assigned native human troponin I-T-C complex.

Controls

AxSYM Troponin-I ADV Controls (8K19-10)

3 Bottles (8 mL each) of AxSYM Troponin-I ADV Controls contain a recombinant human cardiac troponin-I-C complex in a protein (bovine) solution to yield the following concentrations:

<table>
<thead>
<tr>
<th>Control</th>
<th>Troponin-I Concentration (ng/mL, μg/L)</th>
<th>Range (ng/mL, μg/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CONTROL L</td>
<td>0.28</td>
<td>0.17 - 0.39</td>
</tr>
<tr>
<td>CONTROL M</td>
<td>1.14</td>
<td>0.68 - 1.60</td>
</tr>
<tr>
<td>CONTROL H</td>
<td>9.49</td>
<td>5.69 - 13.29</td>
</tr>
</tbody>
</table>

Preservative: ProClin.

The AxSYM Troponin-I ADV default result unit is ng/mL. The alternate result unit, μg/L, may be selected for reporting results (Assay Parameter 45).

Other Reagents

Solution 1 (MUP) (8A47-04)

SOLUTION 1 [MUP] 4 Bottles (230 mL each) Solution 1 (MUP) containing 4-Methylumbelliferyl Phosphate, 1.2 mM, in AMP buffer. Preservative: Sodium Azide.

Solution 3 (Matrix Cell Wash) (8A81-04)

SOLUTION 3 [MATRIX CELL WASH] 4 Bottles (1000 mL each) Solution 3 (Matrix Cell Wash) containing 0.3 M Sodium Chloride in TRIS Buffer. Preservatives: Sodium Azide and antimicrobial agents.

Solution 4 (Line Diluent) (8A46)

SOLUTION 4 [LINE DILUENT] 1 Bottle (10 L) Solution 4 (Line Diluent) containing 0.1 M Phosphate Buffer. Preservatives: Sodium Azide and antimicrobial agent.

AxSYM Probe Cleaning Solution (9A35-05)

PROBE CLEANING SOLUTION 2 Bottles (220 mL each) AxSYM Probe Cleaning Solution containing 2% Tetraethylammonium Hydroxide (TEAH).

Warnings and Precautions

- **IVD**
- **For In Vitro Diagnostic Use**

Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

Safety Precautions

CAUTION: This product requires the handling of human specimens. It is recommended that all human sourced materials be considered potentially infectious and handled in accordance with the OSHA Standard on Bloodborne Pathogens.19 Biosafety Level 220 or other appropriate biosafety practices21,22 should be used for materials that contain or are suspected of containing infectious agents.

This product contains sodium azide; for a specific listing, refer to the REAGENTS section. Contact with acids liberates very toxic gas. This material and its container must be disposed of in a safe way.

For product not classified as dangerous per European Directive 1999/45/EC as amended - Safety data sheet available for professional user on request.

Handling Precautions

- AxSYM Troponin-I ADV reagents are susceptible to bubbles/foaming and require inspection for and removal of bubbles before loading. Refer to the AxSYM System Operations Manual, Section 9.
- Do not use Solution 1 (MUP) beyond the expiration date or a maximum of 14 days on-board the AxSYM System. When loading new Solution 1 (MUP), it is important to immediately tighten the instrument cap for MUP to minimize exposure to air. Prolonged exposure of MUP to air may compromise performance.
- Do not use the reagent pack beyond the expiration date or a maximum of 112 cumulative hours on-board the AxSYM System.
- Do not mix reagents from different reagent packs.

Refer to the AxSYM System Operations Manual, Sections 7 and 8, for a more detailed discussion of the safety and handling precautions during System operation.

Mixing Instructions

Mix AxSYM Troponin-I ADV Standard Calibrators and Controls by gentle inversion prior to use.

Storage Instructions

- Store Solution 1 (MUP) at 2-8°C and Solution 2 (MUP) at 15-30°C.

Solution 1 (MUP), Solution 2 (MUP), Standard Calibrators B through F, and Controls contain a mixture of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one (3:1), which is a component of ProClin, and are classified per applicable European Community (EC) Directives as: Irritant (Xi). The following are the appropriate Risk (R) and Safety (S) phrases.

- R43 May cause sensitization by skin contact.
- S24 Avoid contact with skin.
- S35 This material and its container must be disposed of in a safe way.
- S37 Wear suitable gloves.
- S46 If swallowed, seek medical advice immediately and show this container or label.

The AxSYM Troponin-I ADV Reagent Pack, Standard Calibrators, and Controls must be stored at 2-8°C. The AxSYM Troponin-I ADV Standard Calibrators and Controls should be returned to 2-8°C storage immediately after use. Reagents are stable until expiration when stored and handled as directed.

The AxSYM Troponin-I ADV Standard Calibrators and Controls are light sensitive; protect from light during storage.

The AxSYM Troponin-I ADV Reagent Pack may be on-board the AxSYM System for a maximum of 112 cumulative hours; for example, 14 eight-hour shifts. After 112 hours, the reagent pack must be discarded. Refer to the AxSYM System Operations Manual, Sections 2 and 5, for further information on tracking on-board time.

Solution 1 (MUP) must be stored at 2-8°C (do not freeze). It may be used immediately after removing it from the refrigerator. MUP may be on-board the AxSYM System for a maximum of 14 days. After 14 days, it must be discarded.

- Store Solution 2 (MUP) at 15-30°C.

The AxSYM Troponin-I ADV Reagent Pack contains a component of ProClin, and are classified per applicable European Community (EC) Directives as: Irritant (Xi). The following are the appropriate Risk (R) and Safety (S) phrases.

- R43 May cause sensitization by skin contact.
- S24 Avoid contact with skin.
- S35 This material and its container must be disposed of in a safe way.
- S37 Wear suitable gloves.
- S46 If swallowed, seek medical advice immediately and show this container or label.

The AxSYM Troponin-I ADV Control value is out of the expected range, it may indicate deterioration of the reagents or errors in technique. Associated test results may be invalid and require retesting. Assay recalibration may be indicated. Refer to the AxSYM System Operations Manual, Section 10, for further troubleshooting information.

The AxSYM System has the capability to generate a Levey-Jennings plot of each assay’s quality control performance. Refer to the AxSYM System Operations Manual, Section 5.

<table>
<thead>
<tr>
<th>Calibrator</th>
<th>Troponin-I Concentration (ng/mL, μg/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>STANDARD CAL A</td>
<td>0.00</td>
</tr>
<tr>
<td>STANDARD CAL B</td>
<td>0.38</td>
</tr>
<tr>
<td>STANDARD CAL C</td>
<td>1.90</td>
</tr>
<tr>
<td>STANDARD CAL D</td>
<td>2.85</td>
</tr>
<tr>
<td>STANDARD CAL E</td>
<td>7.59</td>
</tr>
<tr>
<td>STANDARD CAL F</td>
<td>22.78</td>
</tr>
</tbody>
</table>


d | Microparticles, Conjugate 1, Pre-Incubation Diluent, Standard Calibrators B through F, and Controls contain a mixture of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one (3:1), which is a component of ProClin, and are classified per applicable European Community (EC) Directives as: Irritant (Xi). The following are the appropriate Risk (R) and Safety (S) phrases.

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- S24 Avoid contact with skin.
- S35 This material and its container must be disposed of in a safe way.
- S37 Wear suitable gloves.
- S46 If swallowed, seek medical advice immediately and show this container or label.

The AxSYM Troponin-I ADV Reagent Pack, Standard Calibrators, and Controls must be stored at 2-8°C. The AxSYM Troponin-I ADV Standard Calibrators and Controls should be returned to 2-8°C storage immediately after use. Reagents are stable until expiration when stored and handled as directed.

The AxSYM Troponin-I ADV Standard Calibrators and Controls are light sensitive; protect from light during storage.

The AxSYM Troponin-I ADV Reagent Pack may be on-board the AxSYM System for a maximum of 112 cumulative hours; for example, 14 eight-hour shifts. After 112 hours, the reagent pack must be discarded. Refer to the AxSYM System Operations Manual, Sections 2 and 5, for further information on tracking on-board time.

Solution 1 (MUP) must be stored at 2-8°C (do not freeze). It may be used immediately after removing it from the refrigerator. MUP may be on-board the AxSYM System for a maximum of 14 days. After 14 days, it must be discarded.

- Store Solution 2 (MUP) at 15-30°C.

The AxSYM Troponin-I ADV Reagent Pack contains a component of ProClin, and are classified per applicable European Community (EC) Directives as: Irritant (Xi). The following are the appropriate Risk (R) and Safety (S) phrases.

- R43 May cause sensitization by skin contact.
- S24 Avoid contact with skin.
- S35 This material and its container must be disposed of in a safe way.
- S37 Wear suitable gloves.
- S46 If swallowed, seek medical advice immediately and show this container or label.

The AxSYM Troponin-I ADV Control value is out of the expected range, it may indicate deterioration of the reagents or errors in technique. Associated test results may be invalid and require retesting. Assay recalibration may be indicated. Refer to the AxSYM System Operations Manual, Section 10, for further troubleshooting information.

The AxSYM System has the capability to generate a Levey-Jennings plot of each assay’s quality control performance. Refer to the AxSYM System Operations Manual, Section 5.
Fluorescence Background Acceptance Criteria
Quality Control for the MUP substrate blank is automatically determined by the instrument and checked under Assay Parameter 64 Max Intercept. If the MUP intercept value is greater than the maximum allowable value, the result is invalid. The test request will be moved to the Exceptions List where it will appear with the message “1064 Invalid test result, intercept too high” and the calculated intercept value. Refer to the AxSYM System Operations Manual, Section 10, when this error message is obtained.

Refer to the AxSYM System Operations Manual, Section 2, for further information on this parameter.

INSTRUMENT PROCEDURE

Assay File Installation
Install the TnI_ADV assay file from the AxSYM Metabolic/Cardiac Assay Disk. List Number 7G53-02 or higher, on the AxSYM System before performing Troponin-I ADV assays. This assay file must be run with AxSYM System Software Version 3.60 or higher.

Refer to the AxSYM System Operations Manual, Section 2, for installation procedures.

AxSYM Troponin-I ADV Assay Parameters
Assay parameters can be displayed and edited according to the procedure in the AxSYM System Operations Manual, Section 2. Selected assay parameters used for the AxSYM Troponin-I ADV assay are listed below.

<table>
<thead>
<tr>
<th>Assay Parameters</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
</tr>
<tr>
<td>6</td>
</tr>
<tr>
<td>11</td>
</tr>
<tr>
<td>45</td>
</tr>
<tr>
<td>46</td>
</tr>
<tr>
<td>80</td>
</tr>
</tbody>
</table>

NOTE: Parameter 45 can be edited to the alternate result unit, μg/L. Parameter 80 cannot be edited.

Instrument Procedure
Refer to the AxSYM System Operations Manual for a detailed description of instrument procedures.

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS
- The following specimen collection tubes may be used for the AxSYM Troponin-I ADV assay:

<table>
<thead>
<tr>
<th>Glass</th>
<th>Plastic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum</td>
<td>No Additive</td>
</tr>
<tr>
<td>Plasma</td>
<td>Lithium Heparin</td>
</tr>
<tr>
<td></td>
<td>Plasma separator tubes with Lithium Heparin</td>
</tr>
<tr>
<td></td>
<td>Sodium Heparin</td>
</tr>
</tbody>
</table>

Other anticoagulants have not been verified for use with the AxSYM Troponin-I ADV assay.
- Abbott Laboratories recommends the use of heparinized plasma specimens for the AxSYM Troponin-I ADV assay.
- Refer to the specimen collection tube manufacturer’s instructions as well as these package insert instructions for specimen collection and preparation for analysis. Each laboratory should determine the acceptability of its own specimen collection and processing procedures.
- Inadequate centrifugation of the specimen may cause an erroneous result.
- For serum specimens, ensure that complete clot formation has taken place prior to centrifugation. Some specimens, especially those from patients receiving anticoagulant or thrombolytic therapy, may exhibit increased clotting times. If the specimen is centrifuged before complete clot formation, the presence of fibrin may cause erroneous results.

- If a lipid layer forms on the specimen surface, transfer the specimen to a sample cup and avoid the lipid layer when withdrawing the specimen.
- If testing will be delayed more than 8 hours, remove the plasma or serum from the cells, clot, or gel. Specimens removed from the cells, clot, or gel may be stored up to 24 hours at 2-8°C or stored frozen (-10°C or colder) prior to being tested.
- All specimens stored longer than 24 hours must be recenterfuged prior to testing.
- Specimens can be stored up to 30 days frozen at -10°C or colder.
- Thaw frozen specimens and mix thoroughly by LOW speed vortexing or by gently inverting, then centrifuge at 3,000 x g for 10 minutes or 2,000 x g for 15 minutes prior to use to remove particulate matter and to ensure consistency in the results. Thaw specimens only once.
- Ensure specimens are free of fibrin, red blood cells, and other particulate matter.
- Inspect all samples for bubbles. Remove bubbles prior to analysis.
- When serial specimens are being evaluated, use the same specimen type throughout the evaluation.
- The AxSYM System does not provide the capability to verify specimen type. It is the responsibility of the operator to verify the correct specimen type is used in the AxSYM Troponin-I ADV assay.
- Test all samples (patient specimens, controls, and calibrators) within 2.5 hours of being placed on-board the AxSYM System. Refer to the AxSYM System Operations Manual, Section 5, for a more detailed discussion of on-board sample storage constraints.
- Performance has not been established using cadaver specimens or body fluids other than human plasma or serum.
- Do not use samples with obvious microbial contamination.
- Do not use heat-inactivated specimens.
- When shipping specimens, package and label specimens in compliance with applicable state, federal, and international regulations covering the transport of clinical specimens and infectious substances. Prior to shipping, remove the plasma or serum specimen from the cells, clot, or gel. Ship specimens frozen on dry ice.

Sample Volume
The sample volume required to perform a single undiluted Troponin-I ADV test on the AxSYM System varies depending on the type of sample container used.

For specimen volume requirements in primary or aliquot tubes and for calibrator/control volume requirements for multiple reagent lots, refer to the AxSYM System Operations Manual, Section 5.

For sample cups, the initial ROUTINE or STAT test requires 271 μL. For every additional Troponin-I ADV test performed (ROUTINE or STAT) from the same container, an additional 221 μL of sample is required. The sample cup minimum volumes for both ROUTINE and STAT tests are calculated by the AxSYM System. They are displayed on the Order screen at the time the test is ordered and printed on the Orderlist Report. When using Host Order Query, the Order screen information and the Orderlist Report are not available. Refer to the AxSYM System Operations Manual, Section 5, for a description of the Host Order Query option.

If the assay is configured for auto retest, the additional specimen volume needed for the retest will not be displayed on the Order screen at the time the test is ordered. Therefore, the total specimen volume requires an additional 221 μL of specimen. Refer to the AxSYM System Operations Manual, Section 2, for details on Automatic Sample Retest Configuration.

If the assay is configured for auto dilution, the total specimen volume requires an additional 94 μL of specimen. If more than one auto-dilution replicate is desired from the same specimen, each additional auto-dilution replicate will require an additional 44 μL of specimen.

To obtain the recommended volume requirements for the AxSYM Troponin-I ADV Standard Calibrators and Controls, hold the bottles vertically and dispense 16 drops of each calibrator or 8 drops of each control into each respective sample cup.
AxSYM TRO PonIN-I ADV PROCEDURE
Materials Provided
- 8K19-20 AxSYM Troponin-I ADV Reagent Kit, containing:
  100 REA TION VESSELS
  100 MAT RIX CELLS

Materials Required But Not Provided
- AxSYM System
- 8K19-01 AxSYM Troponin-I ADV Standard Calibrators
- 8K19-10 AxSYM Troponin-I ADV Controls
- 8A47-04 SOLUTION 1 MUP
- 8A81-04 SOLUTION 3 MATRIX CELL WASH
- 8A46 SOLUTION 4 LINE DILUENT
- 9A35-05 AxSYM PROBE CLEANING SOLUTION
- 8A76-01 SAMPLE CUPS
- Pipettes/pipette tips (optional) to deliver the volumes specified on the Order screen.

CAUTION:
- When manually dispensing sample into sample cups, verify that dispensing equipment does not introduce cross contamination and that it delivers the specified sample volume. Use a separate pipette tip for each sample.
- For optimal performance, it is important to follow the routine maintenance procedures defined in the AxSYM System Operations Manual, Section 9. If your laboratory requires more frequent maintenance, follow those procedures.

Assay Procedure
**NOTE:** The AxSYM Troponin-I ADV Reagent Pack, Standard Calibrators, and Controls may be used immediately after removing them from the refrigerator.

Manually open the cap of reagent bottle 4 prior to loading the reagent pack on the system.

Sections 5 and 6 of the AxSYM System Operations Manual contain detailed steps for performing assay calibration and sample testing procedures. Prior to ordering tests, confirm that the System inventory of Matrix Cells, bulk solutions, and waste levels are acceptable.

The Orderlist Report contains sample placement information and sample cup volume requirements for all ordered tests. It is recommended that this report be referenced when loading samples into sample segments. When using Host Order Query, the Orderlist Report is not available. Refer to the AxSYM System Operations Manual, Section 5, for a description of the Host Order Query Option.

When testing is completed, it is recommended that the AxSYM Troponin-I ADV Reagent Pack be removed from the Sampling Center to maximize the on-board reagent pack use. If not empty, close reagent bottle 4. Store the reagent pack at 2-8°C.

CAUTION: When operating the AxSYM System, always observe the following:
- The System status must be WARMING, PAUSED, READY, or STOPPED before adding or removing sample segments, reagent packs, or RVs.
- Do not open the Interior Waste Door or the AxSYM Processing Center Cover while any test is in process. If opened, all processing will stop. In-process tests will be terminated and must be repeated.

**SPECIMEN DILUTION PROCEDURES**

Patient specimens with a troponin-I assay value exceeding 22.78 ng/mL (HIGH RANGE assay parameter 92) are flagged with the code “>22.78 ng/mL.” To quantitate the concentration of these specimens, perform the Automated Dilution Protocol or the Manual Dilution Procedure.

**Automated Dilution Protocol**

The Automated Dilution Protocol is provided to assist in quantitating test results greater than 22.78 ng/mL and up to 227.80 ng/mL. The AxSYM System performs a 1:10 dilution of the unknown specimen using one RV. The AxSYM System automatically calculates the concentration of the diluted specimen and reports the result.

If the assay is configured for auto dilution, the total specimen volume requires an additional 94 μL of specimen. If more than one auto-dilution replicate is desired from the same specimen, each additional auto-dilution replicate will require an additional 44 μL of specimen.

Refer to the AxSYM System Operations Manual, Section 5, for additional information on ordering specimen dilutions.

**Manual Dilution Procedure**

A manual dilution of 1:50 is suggested for patient specimens with troponin-I concentrations greater than 227.80 ng/mL. Add 10 μL of the patient specimen to 490 μL of AxSYM Troponin-I ADV Standard Calibrator A (0.00 ng/mL). This dilution should be performed so that the diluted test results read greater than the AxSYM Troponin-I ADV Standard Calibrator B (0.38 ng/mL). The concentration reported by the AxSYM System must be multiplied by the manual dilution factor (e.g., 50) to obtain the final specimen concentration.

**Volume of Specimen**

\[ \text{Final Specimen Concentration} = \frac{\text{Printed Concentration} \times \text{Manual Dilution Factor}}{\text{Volume of Specimen}} \]

**QUALITY CONTROL PROCEDURES**

**Calibration**

The AxSYM Troponin-I ADV assay must be calibrated using a Standard Calibration (6-point) procedure.

**Standard Calibration**

To perform an AxSYM Troponin-I ADV standard calibration, test Standard Calibrators A, B, C, D, E, and F in duplicate. A single sample of all levels of troponin-I controls must be tested as a means of evaluating the assay calibration.

Once the AxSYM Troponin-I ADV calibration is accepted and stored, all subsequent samples may be tested without further calibration unless:
- A reagent pack with a new lot number is used.
- Controls are out of range.
- The MEIA Optics Verification Update has been performed.

Refer to the AxSYM System Operations Manual, Section 6, for:
- Setting up an assay calibration
- When recalibration may be necessary
- Calibration verification

The AxSYM System verifies that the results of an assay calibration meet the specifications assigned to selected validity parameters. An error message occurs when the calibration fails to meet a specification. Refer to the AxSYM System Operations Manual, Section 10, for an explanation of the corrective actions for the error code. Refer to the AxSYM System Operations Manual, Appendix E, for an explanation of the calibration validity parameters that may be used by the AxSYM System.

**Quality Control**

The minimum control requirement for the AxSYM Troponin-I ADV assay is a single sample of all control levels tested once every 24 hours each day of use. Ensure that control values are within the concentration ranges specified in the package insert. Refer to the REAGENTS, Controls section of this package insert for AxSYM Troponin-I ADV Control Ranges.

If the quality control procedures in your laboratory require laboratory generated process control limits and/or more frequent use of controls to verify test results, follow your laboratory-specific procedures. If non-Abbott controls are used, one control level should be near the MI diagnostic decision limit established by your laboratory.

**RESULTS**

**Calculation**

The AxSYM Troponin-I ADV assay uses a Y-weighted, four-parameter logistic curve (4PLC) fit to generate a standard calibration curve. Refer to the AxSYM System Operations Manual, Appendix F, for further information.
Alternate Result Units

- The default result unit for AxSYM Troponin-I ADV is ng/mL. When the alternate result unit, μg/L, is selected, the conversion factor used by the AxSYM System is 1.0.
- Conversion formula: (concentration in ng/mL) x 1.0 = μg/L.

Flags

Some results may contain information in the Flags field. For a description of the flags that may appear in this field, refer to the AxSYM System Operations Manual, Sections 1 and 2.

LIMITATIONS OF THE PROCEDURE

- Cardiac troponin-I levels can be increased in any condition resulting in cardiac cell damage. For MI diagnostic purposes, the AxSYM Troponin-I ADV results should be used in conjunction with other information such as cardiac marker results (e.g., CK-MB and/or myoglobin), ECG, clinical observations and symptoms, etc.
- Specimens from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain human anti-mouse antibodies (HAMA).23 Such specimens may show either falsely elevated or depressed values when tested with assay kits such as AxSYM Troponin-I ADV that employ mouse monoclonal antibodies.24 For more information, refer to the SPECIFIC PERFORMANCE CHARACTERISTICS, Clinical Performance section in this package insert.
- Anti-E. coli antibodies in human serum may react with AxSYM Troponin-I ADV reagent components and cause anomalous values to be observed. For more information, refer to the SPECIFIC PERFORMANCE CHARACTERISTICS, Clinical Performance section in this package insert.
- Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with in vitro immunoassays. The presence of heterophilic antibodies in a patient specimen may cause anomalous values to be observed.25,26
- Although the AxSYM Troponin-I ADV assay is specifically designed to minimize the effects of HAMA, anti-E. coli, and heterophilic antibodies, assay results that are not consistent with other clinical observations may require additional information for diagnosis.
- In vitro studies suggest the measured level of cardiac troponin-I in serum and plasma specimens may decrease over time in the presence of streptokinase or tissue-type plasminogen activator.
- Refer to the SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS section in this package insert for specimen limitations.

EXPECTED VALUES

It is recommended that each laboratory establish its own reference range, which may be unique to the population it serves depending upon geographical, patient, dietary, or environmental factors.

Any condition resulting in myocardial cell damage can potentially increase cardiac troponin-I levels. Published studies have documented that these conditions include, but are not limited to, angina, unstable angina, congestive heart failure, myocarditis, cardiac surgery, or invasive testing and non-cardiac related causes such as pulmonary embolism, renal failure, and sepsis.6,27,28,29

Serial sampling is recommended to detect the temporal rise and fall of troponin levels characteristic of MI.12,13

For diagnostic cutoff and additional information, refer to the SPECIFIC PERFORMANCE CHARACTERISTICS, Clinical Performance section in this package insert.

A reference range study was conducted based on guidance from the Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS) protocol C28-A2.30 Apparently healthy individuals contributed one sample which was evaluated in replicates of one using the AxSYM Troponin-I ADV assay. The data from this study are summarized in the table below.*

<table>
<thead>
<tr>
<th>Sample</th>
<th>Instru-</th>
<th>Reagent</th>
<th>Lot</th>
<th>Instrument</th>
<th>Mean</th>
<th>Within Run SD</th>
<th>CV(%)</th>
<th>Total SD</th>
<th>CV(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>A</td>
<td>80</td>
<td>1</td>
<td>3</td>
<td>2.63</td>
<td>0.021</td>
<td>8.2</td>
<td>0.036</td>
<td>9.8</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>80</td>
<td>2</td>
<td>3</td>
<td>0.27</td>
<td>0.006</td>
<td>5.9</td>
<td>0.018</td>
<td>6.6</td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>80</td>
<td>3</td>
<td>3</td>
<td>0.29</td>
<td>0.006</td>
<td>5.9</td>
<td>0.018</td>
<td>6.6</td>
</tr>
</tbody>
</table>

Low Control

<table>
<thead>
<tr>
<th>Sample</th>
<th>Instru-</th>
<th>Reagent</th>
<th>Lot</th>
<th>Instrument</th>
<th>Mean</th>
<th>Within Run SD</th>
<th>CV(%)</th>
<th>Total SD</th>
<th>CV(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>A</td>
<td>80</td>
<td>1</td>
<td>3</td>
<td>0.018</td>
<td>0.004</td>
<td>4.0</td>
<td>0.016</td>
<td>3.6</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>80</td>
<td>2</td>
<td>3</td>
<td>0.016</td>
<td>0.004</td>
<td>4.0</td>
<td>0.016</td>
<td>3.6</td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>80</td>
<td>3</td>
<td>3</td>
<td>0.016</td>
<td>0.004</td>
<td>4.0</td>
<td>0.016</td>
<td>3.6</td>
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</table>

Medium Control

<table>
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<tr>
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<th>Instru-</th>
<th>Reagent</th>
<th>Lot</th>
<th>Instrument</th>
<th>Mean</th>
<th>Within Run SD</th>
<th>CV(%)</th>
<th>Total SD</th>
<th>CV(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>A</td>
<td>80</td>
<td>1</td>
<td>3</td>
<td>0.054</td>
<td>0.004</td>
<td>7.7</td>
<td>0.012</td>
<td>2.3</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>80</td>
<td>2</td>
<td>3</td>
<td>0.054</td>
<td>0.004</td>
<td>7.7</td>
<td>0.012</td>
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<td>C</td>
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<td>3</td>
<td>3</td>
<td>0.054</td>
<td>0.004</td>
<td>7.7</td>
<td>0.012</td>
<td>2.3</td>
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</tbody>
</table>

High Control

<table>
<thead>
<tr>
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<th>Instru-</th>
<th>Reagent</th>
<th>Lot</th>
<th>Instrument</th>
<th>Mean</th>
<th>Within Run SD</th>
<th>CV(%)</th>
<th>Total SD</th>
<th>CV(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>A</td>
<td>80</td>
<td>1</td>
<td>3</td>
<td>0.48</td>
<td>0.021</td>
<td>4.9</td>
<td>0.037</td>
<td>7.7</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>80</td>
<td>2</td>
<td>3</td>
<td>0.48</td>
<td>0.021</td>
<td>4.9</td>
<td>0.037</td>
<td>7.7</td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>80</td>
<td>3</td>
<td>3</td>
<td>0.48</td>
<td>0.021</td>
<td>4.9</td>
<td>0.037</td>
<td>7.7</td>
</tr>
</tbody>
</table>

SPECIFIC PERFORMANCE CHARACTERISTICS

Precision

The AxSYM Troponin-I ADV assay is designed to have a precision ≤ 10% with 95% confidence for concentrations from 0.27 ng/mL up to 4.00 ng/mL. A study was performed for the AxSYM Troponin-I ADV assay based on guidance from CLSI protocol EP5-A.31 The AxSYM Troponin-I ADV Controls and three cardiac multiconstituent controls (MCC) were assayed in replicates of two at two separate times of day for 20 days. Testing was performed on three instruments using three lots of reagents. The instruments were calibrated at the start of the study. The data from this study are summarized in the following table.*
Precision Profile

In five studies, the median AxSYM Troponin-I ADV concentration that demonstrated a 10% CV was 0.16 ng/mL with a range of 0.16 ng/mL to 0.27 ng/mL. These studies were performed based upon guidance from the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) protocol. 32 Human panels (n=10 or 12) were prepared to concentrations ranging from 0.02 to 0.98 ng/mL. For each study, the panels were assayed in replicates of two over ten days on one instrument using two reagent lots and three calibrations for a total of 40 replicates per panel. The total %CVs (combining variance components for replicate, run, and day) were calculated and plotted against the mean concentration. A parametric curve was fitted through the data and the 10% CV value was estimated as the concentration corresponding to the 10% CV level of the fitted curve. The median precision profile graph with 95% confidence limits of the fitted curve follows.*

Analytical Specificity

The AxSYM Troponin-I ADV assay is designed to have ≤ 0.1% cross-reactivity with skeletal troponin-I and ≤ 1% cross-reactivity with cardiac troponin-C and cardiac troponin-T. A study based on guidance from CLSI protocol EP7-A 34 was performed for the AxSYM Troponin-I ADV assay. Data from this study are summarized in the following table.*

Interference

The AxSYM Troponin-I ADV assay was designed to have ≤ 10% interference for specimens containing troponin-I concentrations between 0.27 and 3.00 ng/mL and ≤ 15% for specimens containing troponin-I ≥ 3.00 ng/mL. As demonstrated by a study* based on guidance from CLSI protocol EP7-A 34, the following was observed:

Carryover

The AxSYM Troponin-I ADV assay is designed to have a mean carryover of ≤ 0.04 ng/mL. In a study, carryover from a sample with a troponin-I concentration ≥ 227.80 ng/mL to an adjacent sample of AxSYM Troponin-I ADV Standard Calibrator A (0.00 ng/mL) was determined to be ≤ 0.04 ng/mL.

Analytical Sensitivity

The analytical sensitivity of the AxSYM Troponin-I ADV assay, defined as the concentration at two standard deviations above the AxSYM Troponin-I ADV Standard Calibrator A (0 ng/mL), was calculated to be 0.02 ng/mL at the 95% level of confidence (n=21 runs, 10 replicates of Calibrator A and 4 replicates of Calibrator B per run).

Linearity

The AxSYM Troponin-I ADV assay is linear between 0.02 and 22.78 ng/mL based on a study performed with guidance from CLSI protocol EP6-A. 33

* Representative data; results in individual laboratories may vary from these data.

<table>
<thead>
<tr>
<th>Sample</th>
<th>Instrument</th>
<th>Lot</th>
<th>n</th>
<th>Mean (ng/mL)</th>
<th>Within Run SD</th>
<th>Within Run CV(%)</th>
<th>Total SD</th>
<th>Total CV(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>A</td>
<td>80</td>
<td>3.57</td>
<td>0.180</td>
<td>5.0</td>
<td>0.235</td>
<td>6.6</td>
<td></td>
</tr>
<tr>
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<td>B</td>
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<td>3.40</td>
<td>0.170</td>
<td>5.0</td>
<td>0.186</td>
<td>5.5</td>
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</tr>
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<td>C</td>
<td>80</td>
<td>3.55</td>
<td>0.214</td>
<td>6.0</td>
<td>0.227</td>
<td>6.4</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>A</td>
<td>80</td>
<td>3.99</td>
<td>0.242</td>
<td>6.1</td>
<td>0.235</td>
<td>6.6</td>
<td></td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>80</td>
<td>3.74</td>
<td>0.194</td>
<td>5.2</td>
<td>0.223</td>
<td>6.0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>80</td>
<td>3.53</td>
<td>0.215</td>
<td>6.1</td>
<td>0.222</td>
<td>6.3</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>A</td>
<td>80</td>
<td>3.63</td>
<td>0.219</td>
<td>6.0</td>
<td>0.238</td>
<td>6.6</td>
<td></td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>80</td>
<td>3.53</td>
<td>0.179</td>
<td>5.1</td>
<td>0.179</td>
<td>5.1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>80</td>
<td>3.69</td>
<td>0.161</td>
<td>4.3</td>
<td>0.194</td>
<td>5.3</td>
<td></td>
</tr>
</tbody>
</table>

* Representative data; results in individual laboratories may vary from these data.

<table>
<thead>
<tr>
<th>Cross-reactant Substance</th>
<th>Cross-reactant Concentration (ng/mL)</th>
<th>% Cross-reactivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skeletal troponin-I</td>
<td>100</td>
<td>0.0</td>
</tr>
<tr>
<td>Cardiac troponin-C</td>
<td>1000</td>
<td>0.0</td>
</tr>
<tr>
<td>Cardiac troponin-T</td>
<td>1000</td>
<td>0.1</td>
</tr>
</tbody>
</table>

* Representative data; results in individual laboratories may vary from these data.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Drug Concentration (μg/mL)</th>
<th>Drug</th>
<th>Drug Concentration (μg/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abciximab</td>
<td>20</td>
<td>Furomide</td>
<td>400</td>
</tr>
<tr>
<td>Acetaminophen</td>
<td>250</td>
<td>Ibuprofen</td>
<td>500</td>
</tr>
<tr>
<td>Acetylsalicylic Acid</td>
<td>600</td>
<td>Low MW Heparin</td>
<td>5</td>
</tr>
<tr>
<td>Allpurinol</td>
<td>40</td>
<td>Metyldopa</td>
<td>15</td>
</tr>
<tr>
<td>Ambroxol</td>
<td>18</td>
<td>Nifedipine</td>
<td>600</td>
</tr>
<tr>
<td>Ampicillin</td>
<td>50</td>
<td>Nitrofurantoin</td>
<td>4</td>
</tr>
<tr>
<td>Ascorbic Acid</td>
<td>40</td>
<td>Nystatin</td>
<td>7.5</td>
</tr>
<tr>
<td>Atenolol</td>
<td>10</td>
<td>Oxytetracycline</td>
<td>5</td>
</tr>
<tr>
<td>Caffeine</td>
<td>100</td>
<td>Phenytin</td>
<td>60</td>
</tr>
<tr>
<td>Captopril</td>
<td>5</td>
<td>Propranolol</td>
<td>5</td>
</tr>
<tr>
<td>Cinnarizine</td>
<td>2.7</td>
<td>Quinidine</td>
<td>20</td>
</tr>
<tr>
<td>Cocaine</td>
<td>1.0</td>
<td>Sodium Heparin</td>
<td>8</td>
</tr>
<tr>
<td>Diclofenac</td>
<td>50</td>
<td>Theophylline</td>
<td>60</td>
</tr>
<tr>
<td>Digoxin</td>
<td>7.5 ng/mL</td>
<td>Trimethoprim</td>
<td>40</td>
</tr>
<tr>
<td>Dopamine</td>
<td>900</td>
<td>Verapamil</td>
<td>2</td>
</tr>
<tr>
<td>Epitilbiodate</td>
<td>7</td>
<td>Warfarin</td>
<td>30</td>
</tr>
<tr>
<td>Erythromycin</td>
<td>60</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* All specimens were serum except plasma was used to evaluate red blood cells.

<table>
<thead>
<tr>
<th>Potentially Interfering Substance</th>
<th>Potentially Interfering Substance Concentration (mg/dL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bilirubin</td>
<td>20</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>500</td>
</tr>
<tr>
<td>Red Blood Cells</td>
<td>0.4% (v/v)</td>
</tr>
<tr>
<td>Total Protein</td>
<td>9</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>1000</td>
</tr>
</tbody>
</table>
Clinical Performance

The AxSYM Troponin-I ADV assay diagnostic cutoff for AMI (WHO criteria) is 0.40 ng/mL. A study based on guidance from CLSI protocol GP10-A36 was performed for the AxSYM Troponin-I ADV assay. Specimens from the following populations were collected from five clinical sites and evaluated using the AxSYM Troponin-I ADV assay:

- 174 specimens from 77 AMI patients diagnosed according to WHO criteria.
- 778 specimens from 366 non-AMI patients diagnosed according to WHO criteria.

The maximum troponin-I value for each patient was used to determine the diagnostic cutoff by receiver operator characteristics (ROC) curve analysis and to determine the optimum clinical sensitivity and specificity. The following graph depicts the ROC curve using these specimens.*

Risk Stratification

The National Academy of Clinical Biochemistry recommends that patients suspected of acute coronary syndromes should undergo a diagnostic workup including biochemical markers for risk stratification with troponin being the preferred marker. Elevated troponin levels above the 99th percentile with acceptable precision provide prognostic information in terms of identifying patients at risk of having a future cardiac event or mortality.

As with all diagnostic tests, each laboratory should establish its own diagnostic cutoff to assure proper representation of specific populations and to reflect current practice and criteria for MI diagnosis at their institution.

Evaluation of Other Potential Interferents

Specimens from patients with anti- E. coli antibodies, chronic renal failure, HAMA, rheumatoid factor, or skeletal muscle injury were evaluated to further assess the clinical specificity of the AxSYM Troponin-I ADV assay. Data from this study are summarized in the following table.*

Method Comparison

The AxSYM Troponin-I ADV assay is designed to have a correlation \( r \geq 0.90 \) with the comparison assay. The AxSYM Troponin-I ADV assay was compared to a commercially available diagnostic kit (Comparison Assay). Specimens were tested in replicates of one with two reagent lots and a total of five calibrations on one instrument. Data from this study were analyzed using the Passing Bablok regression method and are summarized in the following tables and scatterplot.*

* Representative data; results in individual laboratories may vary from these data.

<table>
<thead>
<tr>
<th>Method Comparison</th>
<th>n</th>
<th>Slope (95% CI)</th>
<th>Intercept (95% CI)</th>
<th>Correlation Coefficient (r)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Passing-Bablok(^a)</td>
<td>546</td>
<td>1.47 (1.44, 1.52)</td>
<td>-0.05 (-0.06, -0.04)</td>
<td>0.97 (0.96, 0.98)</td>
</tr>
</tbody>
</table>

Sample Range (AxSYM Troponin-I ADV): 0.02 - 67.32 ng/mL
Sample Range (Comparison Assay): 0.03 - 59.56 ng/mL

* Representative data; results in individual laboratories may vary from these data.
AxSYM Troponin-I ADV vs. Comparison Assay
(Specimens in the AxSYM Troponin-I ADV Dynamic Range)

<table>
<thead>
<tr>
<th>Method</th>
<th>n</th>
<th>Slope (95% CI)</th>
<th>Intercept (95% CI)</th>
<th>Correlation Coefficient (r)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Passing-Bablok a</td>
<td>531</td>
<td>1.47 (-0.06, -0.04)</td>
<td>0.95 (-0.06, -0.04)</td>
<td>0.95 (-0.06, -0.04)</td>
</tr>
</tbody>
</table>

Sample Range (AxSYM Troponin-I ADV): 0.02 - 22.67 ng/mL
Sample Range (Comparison Assay): 0.03 - 19.53 ng/mL
* Representative data; results in individual laboratories may vary from these data.

BIBLIOGRAPHY

AxSYM, ARCHITECT and PRISM are trademarks of Abbott Laboratories in various jurisdictions. ProClin is property of its respective owner.