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.
BIOLOGICAL PRINCIPLES OF THE PROCEDURE

The ARCHITECT STAT Troponin-I assay is a two-step immunoassay to determine the presence of cTnI in human serum and plasma using CMIA technology with flexible assay protocols, referred to as Chemiflex. In the first step, sample, assay diluent and anti-troponin-I antibody-coated paramagnetic microparticles are combined. Troponin-I present in the sample binds to the anti-troponin-I-coated microparticles. After incubation and wash, anti-troponin-I acridinium-labeled conjugate is added in the second step. Following another incubation and wash, pre-trigger and trigger solutions are then added to the reaction mixture. The resulting chemiluminescent reaction is measured as relative light units (RLUs). A direct relationship exists between the amount of troponin-I in the sample and the RLUs detected by the ARCHITECT i STAT System optics. The concentration of troponin-I is read relative to a standard curve established with calibrators of known troponin-I concentrations.

For additional information on system and assay technology, refer to the ARCHITECT System Operations Manual, Section 3.

### 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 isoform and contains additional amino acids at the N-terminus; cardiac troponin-I (cTnI) has a molecular weight of approximately 24,000 daltons.2,3 Clinical studies have demonstrated the release of cTnI into the blood stream within hours following myocardial infarction (MI) or ischemia. Their universal definition of MI is a typical rise and gradual fall of cardiac biomarkers (preferably troponin) with at least one value above the 99th percentile of the upper reference limit (URL) together with evidence of myocardial ischemia with at least one of the following: ischemic symptoms, pathological Q waves on electrocardiogram (ECG), ischemic ECG changes, or imaging evidence of new loss of viable myocardium or new regional wall motion abnormality.11 The recommended criteria are based on the principle that any reliable detectable amount of myocardial necrosis, if caused by myocardial ischemia, constitutes an MI.7 An elevated troponin value is not sufficient to make the diagnosis of myocardial infarction. Serial sampling is recommended to detect the temporal rise and fall of troponin levels characteristic of MI.52,53 In addition, other markers such as CK-MB can be used in conjunction with troponin-I results in aiding the diagnosis of MI.

Several major studies have shown that the cTnI is also useful as a predictor of cardiac risk in patients with unstable angina.14 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.15,16 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.15,17 Thus, cTnI can play an important role in identifying patients with acute coronary syndromes who are at greater risk for cardiac events. The ACCF, AHA, and the National Academy of Clinical Biochemistry (NACB) also recommend using troponin results when making treatment decisions regarding unstable angina and non-ST segment elevation MI (NSTEMI).5,18
Handling Precautions

- Do not use reagent kits beyond the expiration date.
- Do not pool reagents within a kit or between reagent kits.
- Prior to loading the ARCHITECT STAT Troponin-I Reagent Kit, reagents must be stored in an upright position and may be used immediately after removing from 2-8°C storage.
- Over time, residual liquids may dry on the septum surface. These are typically dried salts which have no effect on assay efficacy.
- For a detailed discussion of handling precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 7.

Storage Instructions

- The ARCHITECT STAT Troponin-I Reagent Kit Must be stored at 2-8°C in an upright position and may be used immediately after removal from 2-8°C storage.
- Reagents may be stored on or off the ARCHITECT
- The ARCHITECT STAT Troponin-I Reagent Kit may be stored on board the ARCHITECT i System for a maximum of 30 days. After 30 days, the reagent kit must be discarded. For information on tracking on-board time, refer to the ARCHITECT System Operations Manual, Section 5.
- For a detailed description of handling precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 7.

Indications of Reagent Deterioration

- When stored and handled as directed, reagents are stable until the expiration date.
- Reagents can be stored up to 30 days frozen at -10°C or colder. If testing will be delayed more than 8 hours, remove the plasma or serum from the cells, clot, or gel may be stored up to 72 hours at 2-8°C or stored frozen
- If testing will be delayed more than 8 hours, remove the plasma or serum from the cells, clot, or gel may be stored up to 72 hours at 2-8°C or stored frozen
- Thaw frozen specimens and mix thoroughly by LOW speed vortexing or by gently inverting, then centrifuge at 2,500-3,000 x g for 10 minutes prior to use to remove particulate matter and to ensure consistency in the results. Thaw specimens only once.
- If a lipid layer forms on the specimen surface, avoid the lipid layer when withdrawing the specimen.
- Do not use heat-inactivated specimens.
- Do not use samples with obvious microbial contamination.
- Performance has not been established using cadaver specimens or body fluids other than human heparinized plasma, EDTA plasma, or serum.
- Ensure specimens are free of fibrin, red blood cells, and other particulate matter.
- Use caution when handling patient specimens to prevent cross contamination. Use of disposable pipettes or pipette tips is recommended.
- Inspect all samples for bubbles. Remove bubbles prior to analysis.

Preparation for Analysis

- Refer to the specimen collection tube manufacturer’s instructions as well as the instructions for specimen collection and preparation for analysis. Each laboratory should follow the tube manufacturer’s processing instructions for plasma and serum collection tubes and ensure it is compatible with the ARCHITECT STAT Troponin-I assay.
- Inadequate centrifugation of the specimen may cause an erroneous result.
- Thaw frozen specimens and mix thoroughly by LOW speed vortexing or by gently inverting, then centrifuge at 2,500-3,000 x g for 10 minutes prior to use to remove particulate matter and to ensure consistency in the results. Thaw specimens only once.
- If a lipid layer forms on the specimen surface, avoid the lipid layer when withdrawing the specimen.
- Do not use heat-inactivated specimens.
- Do not use samples with obvious microbial contamination.
- Performance has not been established using cadaver specimens or body fluids other than human heparinized plasma, EDTA plasma, or serum.
- Ensure specimens are free of fibrin, red blood cells, and other particulate matter.
- Use caution when handling patient specimens to prevent cross contamination. Use of disposable pipettes or pipette tips is recommended.
- Inspect all samples for bubbles. Remove bubbles prior to analysis.

Preparing the Specimen

- When withdrawing the specimen, avoid the lipid layer when withdrawing the specimen.

Transportation

- Do not pool reagents within a kit or between reagent kits.
- Do not use heat-inactivated specimens.
- Do not use samples with obvious microbial contamination.
- Performance has not been established using cadaver specimens or body fluids other than human heparinized plasma, EDTA plasma, or serum.
- Ensure specimens are free of fibrin, red blood cells, and other particulate matter.
- Use caution when handling patient specimens to prevent cross contamination. Use of disposable pipettes or pipette tips is recommended.
- Inspect all samples for bubbles. Remove bubbles prior to analysis.

Materials Provided

- 2K41 ARCHITECT STAT Troponin-I Reagent Kit
- 2K41 ARCHITECT STAT Troponin-I Calibrators
- 2K41-10 ARCHITECT STAT Troponin-I Controls
• ARCHITECT \\
• ARCHITECT \\
• ARCHITECT \\
• ARCHITECT \\
• ARCHITECT \\
• ARCHITECT \\
• ARCHITECT \\
• ARCHITECT \\

PRE-TRIGGER SOLUTION \\
TRIGGER SOLUTION \\
WASH BUFFER \\
REACTION VESSELS \\
SAMPLE CUPS \\
SEPTUM \\
REPLACEMENT CAPS \\

For information on materials required for maintenance procedures, refer to the ARCHITECT System Operations Manual, Section 9.

Pipette or pipette tips (optional) to deliver the volumes specified on the patient or control order screen.

Assay Procedure

Before loading the ARCHITECT STAT Troponin-I Reagent Kit on the system for the first time, the microparticle bottle requires mixing to resuspend microparticles that have settled during shipment:

• Invert the microparticle bottle 30 times.

• Visually inspect the bottle to ensure microparticles are resuspended. If microparticles are still adhered to the bottle, continue to invert the bottle until the microparticles have been completely resuspended.

If the microparticles do not resuspend, DO NOT USE. Contact your local Abbott Laboratories representative.

• Once the microparticles have been resuspended, place a septum on the bottle. For instructions on placing septums on bottles, refer to the Handling Precautions section of this package insert.

Order calibration, if necessary.

• For information on ordering calibrations, refer to the ARCHITECT System Operations Manual, Section 6.

Order tests.

• For information on ordering patient specimens and controls, refer to the ARCHITECT System Operations Manual, Section 5.

Load the ARCHITECT STAT Troponin-I Reagent Kit on the ARCHITECT System with protocol capability.

• Verify that all necessary assay reagents are present. Ensure that septums are present on all reagent bottles.

The minimum sample volume is calculated by the system and is printed on the Orderlist report. No more than 10 replicates may be sampled from the same sample cup. To minimize the effects of evaporation, verify adequate sample cup volume is present prior to running the test.

• Priority: 165 µL for the first ARCHITECT STAT Troponin-I test plus 115 µL for each additional ARCHITECT STAT Troponin-I test from the same sample cup.

• ≤ 3 hours on hold: 165 µL for the first ARCHITECT STAT Troponin-I test plus 115 µL for each additional ARCHITECT STAT Troponin-I test from the same sample cup.

• If using primary or aliquot tubes, use the sample gauge to ensure sufficient patient specimen is present.

Prepare calibrators and controls.

• ARCHITECT STAT Troponin-I Calibrators and Controls should be mixed according to instructions in their respective package inserts.

• To obtain the recommended volume requirements for the ARCHITECT STAT Troponin-I Calibrators, hold the bottles vertically and dispense 9 drops of each calibrator into each respective sample cup. Dispense 165 µL of each control into each respective sample cup.

• Load samples.

• For information on loading samples, refer to the ARCHITECT System Operations Manual, Section 5.

Press RUN.

For additional information on principles of operation, refer to the ARCHITECT Operations Manual, Section 3.

For optimal performance, it is important to follow the routine maintenance procedures defined in the ARCHITECT System Operations Manual, Section 9. If your laboratory requires more frequent maintenance, follow those procedures.

Specimen Dilution Procedures

Specimens with a troponin-I value exceeding 50.00 ng/mL (50.00 µg/L) are flagged with the code “>50.00” and may be diluted with the Automated Dilution Protocol or the Manual Dilution Procedure. These specimens may be diluted by the following Manual Dilution Procedure.

Manual Dilution Procedure

Manual dilutions should be performed as follows:

• The suggested dilution for a troponin-I test is 1:20.

• Prior to diluting the specimen, dispense several drops of ARCHITECT STAT Troponin-I Calibrator A into a clean test tube for use in the next step.

• Add 10 µL of the patient specimen to 190 µL of ARCHITECT STAT Troponin-I Calibrator A.

• The operator must enter the dilution factor in the Patient or Control order screen. The system will use this dilution factor to automatically calculate the concentration of the sample before dilution. This will be the reported result. The concentration of the specimen diluted (before dilution factor is applied) should be 2.5 ng/mL (2.5 µg/L) or greater.

• For detailed information on ordering dilutions, refer to the ARCHITECT System Operations Manual, Section 5.

Calibration

To perform an ARCHITECT STAT Troponin-I calibration, test the Calibrators A, B, C, D, E, and F in duplicate. A single sample of each ARCHITECT STAT Troponin-I Control level must be tested to evaluate the assay calibration. Ensure that assay control values are within the concentration ranges specified in the control package insert. Calibrators should be priority loaded.

Calibration Range: 0.00 - 50.00 ng/mL (0.00 - 50.00 µg/L).

Once an ARCHITECT STAT Troponin-I 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.

• Controls are out of range.

• For detailed information on how to perform an assay calibration, refer to the ARCHITECT System Operations Manual, Section 6.

QUALITY CONTROL PROCEDURES

The recommended control requirement for the ARCHITECT STAT Troponin-I assay is a single sample of each control level to be tested once every 24 hours each day of use. If the quality control procedures in your laboratory require more frequent use of controls to verify test results, follow your laboratory-specific procedures.

• The ARCHITECT STAT Troponin-I Control values must be within the acceptable ranges specified in the control package insert. If a control is out of its specified range, the associated test results are invalid and must be retested. Recalibration may be indicated.

• For detailed information on how to perform an assay calibration, refer to the ARCHITECT System Operations Manual, Section 6.

Verification of Assay Claims

For protocols to verify package insert claims, refer to the ARCHITECT System Operations Manual, Appendix B. The ARCHITECT STAT Troponin-I assay belongs to method group 1. Use ARCHITECT STAT Troponin-I Calibrators in place of MasterCheck as described in the ARCHITECT System Operations Manual, Appendix B.

RESULTS Calculation

The ARCHITECT STAT Troponin-I assay uses a 4 Parameter Logistic Curve Fit (4PLC, Y-weighted) data reduction method to generate a calibration curve.

Alternate Result Units

• The default result unit for the ARCHITECT STAT Troponin-I assay is ng/mL. When the alternate result unit, µg/L, is selected, the conversion factor used by the system is 1.0. When the alternate result unit, ng/L, is selected, the conversion factor used by the system is 1000.0.

Conversion Formula: (Concentration in ng/mL) x (1.0) = µg/L

Conversion Formula: (Concentration in ng/mL) x (1000.0) = ng/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 ARCHITECT System Operations Manual, Section 5.
LIMITATIONS OF THE PROCEDURE

- Cardiac troponin-I levels can be increased in any condition resulting in cardiac cell damage. For MI diagnostic purposes, the ARCHITECT Troponin-I assay is specifically designed to minimize the effects of HAMA and heterophilic antibodies.
- Additional clinical or diagnostic information may be required to determine patient status.
- A single negative troponin-I result is not sufficient to rule out a patient who has not had a heart attack or cardiac damage. Serial negative blood draws over time are recommended before patients are classified as negative for a heart attack.
- 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. Additional information may be required for diagnosis.
- Although the ARCHITECT STAT Troponin-I assay is specifically designed to minimize the effects of HAMA and heterophilic antibodies, assay results that are not consistent with other clinical observations may require additional information for diagnosis.
- Refer to the SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS section in this package insert for specimen limitations.
- In vitro studies suggest the measured level of cardiac troponin-I in serum and plasma specimens may be decreased in the presence of streptokinase or tissue-type plasminogen activator.
- The ARCHITECT STAT Troponin-I is not intended to be used on the ARCHITECT i 2000 System.

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.

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

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 Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS) Protocol C29-A2. Apparently healthy individuals were evaluated in replicates of one using the ARCHITECT STAT Troponin-I assay. Heparinized plasma specimens were used to establish the normal ranges below. The observed 99th percentile was determined to be statistically equivalent for heparinized plasma, EDTA plasma and serum specimens based on the total population tested.

Apparent Healthy Population

<table>
<thead>
<tr>
<th>Population</th>
<th>n</th>
<th>Age Range</th>
<th>99th Percentile</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>225</td>
<td>18 - 62</td>
<td>0.013</td>
</tr>
<tr>
<td>Male</td>
<td>224</td>
<td>18 - 63</td>
<td>0.033</td>
</tr>
<tr>
<td>TOTAL</td>
<td>449</td>
<td>18 - 63</td>
<td>0.028</td>
</tr>
</tbody>
</table>

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

SPECIFIC PERFORMANCE CHARACTERISTICS

Precision

The ARCHITECT STAT Troponin-I assay precision is ≤ 10% total CV for samples ≥ 0.20 ng/mL (≥ 0.20 µg/L). A study was performed for the ARCHITECT STAT Troponin-I assay with guidance from the CLSI (formerly NCCLS) Protocol EPS-A. The ARCHITECT STAT Troponin-I Controls, Cardiac Multiconstituent Controls (MCC) and two human panels were assayed using three lots of reagents, in replicates of two at two separate times per day for 20 days on two instruments. Each reagent lot used a single calibration curve throughout the study. Data from this study are summarized in the following table.

<table>
<thead>
<tr>
<th>Sample</th>
<th>Instrument</th>
<th>Reagent Lot</th>
<th>n</th>
<th>Mean Conc. Value (ng/mL)</th>
<th>Within Run SD % CV</th>
<th>Total Run SD % CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Control</td>
<td>A</td>
<td>80</td>
<td>0.117</td>
<td>0.006</td>
<td>5.3</td>
<td>0.007</td>
</tr>
<tr>
<td>Medium Control</td>
<td>A</td>
<td>80</td>
<td>0.116</td>
<td>0.005</td>
<td>4.5</td>
<td>0.006</td>
</tr>
<tr>
<td>High Control</td>
<td>A</td>
<td>80</td>
<td>0.118</td>
<td>0.006</td>
<td>4.9</td>
<td>0.007</td>
</tr>
<tr>
<td>MCC</td>
<td>A</td>
<td>80</td>
<td>0.103</td>
<td>0.005</td>
<td>5.1</td>
<td>0.006</td>
</tr>
<tr>
<td>B</td>
<td>80</td>
<td>0.113</td>
<td>0.005</td>
<td>4.1</td>
<td>0.005</td>
<td>4.5</td>
</tr>
<tr>
<td>C</td>
<td>80</td>
<td>0.121</td>
<td>0.006</td>
<td>5.2</td>
<td>0.007</td>
<td>5.7</td>
</tr>
<tr>
<td>Low MCC</td>
<td>A</td>
<td>80</td>
<td>0.498</td>
<td>0.020</td>
<td>3.9</td>
<td>0.024</td>
</tr>
<tr>
<td>Medium MCC</td>
<td>A</td>
<td>80</td>
<td>0.478</td>
<td>0.015</td>
<td>3.1</td>
<td>0.019</td>
</tr>
<tr>
<td>High MCC</td>
<td>A</td>
<td>80</td>
<td>0.497</td>
<td>0.012</td>
<td>3.1</td>
<td>0.017</td>
</tr>
<tr>
<td>B</td>
<td>80</td>
<td>0.483</td>
<td>0.015</td>
<td>3.2</td>
<td>0.021</td>
<td>4.4</td>
</tr>
<tr>
<td>C</td>
<td>80</td>
<td>0.499</td>
<td>0.018</td>
<td>3.6</td>
<td>0.021</td>
<td>4.2</td>
</tr>
</tbody>
</table>

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

Precision Profile

The ARCHITECT STAT Troponin-I assay at 10% CV is ≤ 0.10 ng/mL (≤ 0.10 µg/L). In a study, human panels (n = 14) were prepared to concentrations ranging from 0.02 ng/mL to 0.25 ng/mL (0.02 µg/L to 0.25 µg/L). Testing was performed with guidance from the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) Protocol. Panels were tested in replicates of 20 over 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, day, and reagent lot) were calculated and plotted against the mean concentration. A reciprocal curve was fitted through the data and the 10% CV value was estimated as the concentration corresponding to the 10% CV level of the
Data from this study are summarized in the following graph.*

### Dilution Linearity

The ARCHITECT STAT Troponin-I assay recovers diluted specimens within 20% of the expected result. A dilution linearity study was performed evaluating ARCHITECT STAT Troponin-I with specimens, which had undiluted values that ranged between 10.0 and 50.4 ng/mL (10.0 and 50.4 µg/L). These specimens were diluted manually using normal human serum at various dilution factors and % recovery results are summarized in the following table.*

<table>
<thead>
<tr>
<th>Sample ID</th>
<th>Dilution Factor</th>
<th>Mean Expected Value (ng/mL, µg/L)</th>
<th>Mean Observed Value (ng/mL, µg/L)</th>
<th>% Recovery**</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>undiluted</td>
<td>9.969</td>
<td>9.969</td>
<td>–</td>
</tr>
<tr>
<td></td>
<td>1:2</td>
<td>4.984</td>
<td>4.860</td>
<td>98</td>
</tr>
<tr>
<td></td>
<td>1:20</td>
<td>0.498</td>
<td>0.483</td>
<td>93</td>
</tr>
<tr>
<td></td>
<td>1:50</td>
<td>0.199</td>
<td>0.205</td>
<td>103</td>
</tr>
<tr>
<td>2</td>
<td>undiluted</td>
<td>25.222</td>
<td>25.222</td>
<td>–</td>
</tr>
<tr>
<td></td>
<td>1:2</td>
<td>12.611</td>
<td>12.414</td>
<td>98</td>
</tr>
<tr>
<td></td>
<td>1:20</td>
<td>1.261</td>
<td>1.261</td>
<td>100</td>
</tr>
<tr>
<td></td>
<td>1:50</td>
<td>0.504</td>
<td>0.491</td>
<td>97</td>
</tr>
<tr>
<td>3</td>
<td>undiluted</td>
<td>39.023</td>
<td>39.023</td>
<td>–</td>
</tr>
<tr>
<td></td>
<td>1:2</td>
<td>19.511</td>
<td>19.206</td>
<td>98</td>
</tr>
<tr>
<td></td>
<td>1:20</td>
<td>1.951</td>
<td>1.971</td>
<td>101</td>
</tr>
<tr>
<td></td>
<td>1:50</td>
<td>0.780</td>
<td>0.762</td>
<td>98</td>
</tr>
<tr>
<td>4</td>
<td>undiluted</td>
<td>42.589</td>
<td>42.589</td>
<td>–</td>
</tr>
<tr>
<td></td>
<td>1:2</td>
<td>21.234</td>
<td>20.320</td>
<td>95</td>
</tr>
<tr>
<td></td>
<td>1:20</td>
<td>2.129</td>
<td>2.108</td>
<td>99</td>
</tr>
<tr>
<td></td>
<td>1:50</td>
<td>0.852</td>
<td>0.801</td>
<td>94</td>
</tr>
</tbody>
</table>

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

### Autodilution Verification

A study was performed evaluating the recovery of 29 serum, 27 heparinized plasma, and 90 EDTA plasma specimens using the ARCHITECT Troponin-I autodilution method resulting in a mean % Recovery** of 108.3% for serum specimens, 109.4% for heparinized plasma specimens, and 113.2% for EDTA plasma specimens.*

### Analytical Sensitivity

The ARCHITECT STAT Troponin-I assay analytical sensitivity is ≤ 0.01 ng/mL (≤ 0.01 µg/L) at the 95% level of confidence (n = 36 runs, 10 replicates of Calibrator A and 4 replicates of Calibrator B per run). Analytical sensitivity is defined as the concentration at two standard deviations above the grand mean and represents the lowest concentration of troponin that can be distinguished from zero.

### Analytical Specificity

The ARCHITECT STAT Troponin-I assay analytical specificity is ≤ 0.1% cross-reactivity with skeletal troponin-I and ≤ 1% with cardiac troponin-C and cardiac troponin-T. A study based on guidance from CLSI (formerly NCCLS) Protocol EP7-A34 was performed for the ARCHITECT STAT Troponin-I assay. Specificity of the assay was determined by studying the cross-reactivity of the following compounds in normal human serum.*

<table>
<thead>
<tr>
<th>Cross-reactant</th>
<th>Concentration (ng/mL, µg/L)</th>
<th>% Cross-reactivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skeletal troponin-I</td>
<td>100</td>
<td>0.07</td>
</tr>
<tr>
<td>Cardiac troponin-C</td>
<td>1000</td>
<td>0.00</td>
</tr>
<tr>
<td>Cardiac troponin-T</td>
<td>1000</td>
<td>0.32</td>
</tr>
</tbody>
</table>

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

### Interference

Potential interference from various drugs and elevated levels of bilirubin, hemoglobin, triglycerides, and total protein in the ARCHITECT STAT Troponin-I assay is ≤ 15% at the levels indicated. A study based on guidance from the CLSI (formerly NCCLS) Protocol EP7-A34 was performed for the ARCHITECT STAT Troponin-I assay. Troponin-I negative specimens and specimens with troponin-I levels between 0.5 and 3.0 ng/mL (0.5 and 3.0 µg/L) grand mean and represents the lowest concentration of troponin that can be distinguished from zero.
**Drug and Drug Concentration**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cinnarizine</td>
<td>400 µg/mL</td>
</tr>
<tr>
<td>Sodium Heparin</td>
<td>8 U/mL</td>
</tr>
<tr>
<td>Cocaine</td>
<td>10 µg/mL</td>
</tr>
<tr>
<td>Streptokinase*</td>
<td>31.3 U/mL</td>
</tr>
<tr>
<td>Diclofenac</td>
<td>50 µg/mL</td>
</tr>
<tr>
<td>Theophylline</td>
<td>75 µg/mL</td>
</tr>
<tr>
<td>Digoxin</td>
<td>7.5 µg/mL</td>
</tr>
<tr>
<td>t-PA*</td>
<td>2.3 µg/mL</td>
</tr>
<tr>
<td>Dopamine</td>
<td>900 µg/mL</td>
</tr>
<tr>
<td>Trinemoprim</td>
<td>75 µg/mL</td>
</tr>
<tr>
<td>Epitilbaide</td>
<td>7 µg/mL</td>
</tr>
<tr>
<td>Venasamill</td>
<td>160 µg/mL</td>
</tr>
<tr>
<td>Erythromycin</td>
<td>200 µg/mL</td>
</tr>
<tr>
<td>Warfarin</td>
<td>30 µg/mL</td>
</tr>
<tr>
<td>Furosemide</td>
<td>400 µg/mL</td>
</tr>
</tbody>
</table>

**Evaluation of Potentially Interfering Clinical Conditions**

The ARCHITECT STAT Troponin-I assay was evaluated using specimens with HAMA and Rheumatoid Factor (RF) to further assess the clinical specificity. Eleven specimens positive for HAMA and ten specimens positive for RF were evaluated for % interference with troponin-I levels spiked between 0.5 and 1.0 ng/mL (0.5 and 1.0 µg/L); % interference results are summarized in the following table.*

**Clinical Condition** | **Number of Specimens** | **% Interference**
-----------------------|------------------------|---------------------
HAMA                   | 11                     | -4.5                |
RF                     | 10                     | -5.0                |

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

**Clinical Performance**

The ARCHITECT STAT Troponin-I assay diagnostic cutoff is 0.30 ng/mL (0.30 µg/L). A study based on guidance from CLSI (formerly NCCLS) Protocol GP10-A1* was performed for the ARCHITECT STAT Troponin-I assay. Specimens from the following populations were collected from four clinical sites and evaluated using the ARCHITECT STAT Troponin-I assay:

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

All troponin-I values were 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.*

**Method Comparison**

The ARCHITECT STAT Troponin-I assay is designed to have a correlation coefficient (r) of ≥ 0.90. A study was performed where lithium heparin plasma specimens were tested in replicates of one using the ARCHITECT STAT Troponin-I assay with two reagent lots on two instruments and compared to a commercially available diagnostic kit (Comparison Assay). Data from this study were analyzed using the Passing-Bablok**38 regression method and are summarized in the following table and scatter plot.*

<table>
<thead>
<tr>
<th>ARCHITECT STAT Troponin-I vs. Comparison Assay</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Regression Method</strong></td>
</tr>
<tr>
<td>Passing-Bablok*</td>
</tr>
</tbody>
</table>

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

**Sample Range (ARCHITECT STAT Troponin-I):**

- 0.04 – 47.94 ng/mL (0.04 – 47.94 µg/L)

**Sample Range (Comparison Assay):**

- 0.02 – 51.58 ng/mL (0.02 – 51.58 µg/L)

* A linear regression method with no special assumptions regarding the distribution of the samples and measurement errors.
BIBLIOGRAPHY


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