Customer Service
United States: 1-877-4ABBOTT
International: Call your Abbott Representative

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

---

Key to symbols used

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>REF</td>
<td>List Number</td>
</tr>
<tr>
<td>IVD</td>
<td>In Vitro Diagnostic Medical Device</td>
</tr>
<tr>
<td>Store at 2-8°C</td>
<td></td>
</tr>
<tr>
<td>Consult instructions for use</td>
<td></td>
</tr>
<tr>
<td>Serial Number</td>
<td></td>
</tr>
<tr>
<td>Authorized Representative</td>
<td></td>
</tr>
<tr>
<td>Manufacturer</td>
<td></td>
</tr>
<tr>
<td>Lot Number</td>
<td></td>
</tr>
<tr>
<td>Expiration Date</td>
<td></td>
</tr>
<tr>
<td>Reaction Vessels</td>
<td></td>
</tr>
<tr>
<td>Sample Cups</td>
<td></td>
</tr>
<tr>
<td>Septum</td>
<td></td>
</tr>
<tr>
<td>Replacement Caps</td>
<td></td>
</tr>
<tr>
<td>Reagent Lot</td>
<td></td>
</tr>
<tr>
<td>Assay CD-ROM</td>
<td></td>
</tr>
<tr>
<td>Control Number</td>
<td></td>
</tr>
</tbody>
</table>

See REAGENTS section for a full explanation of symbols used in reagent component naming.
CK-MB is a Chemiluminescent Microparticle Immunoassay (CMA) for the quantitative determination of the MB isoenzyme of creatine kinase (CK-MB) in human serum and plasma on the ARCHITECT i System with STAT protocol capability. CK-MB values are used to assist in the diagnosis of myocardial infarction (MI).

**SUMMARY AND EXPLANATION OF TEST**

CK-MB is an 84,000 molecular weight enzyme that represents a significant fraction of the creatine kinase present in myocardial tissue.1,2 CK-MB is also present in a variety of other tissues, although at much lower levels.3-5 The appearance of CK-MB in serum, in the absence of major muscle trauma, may be indicative of cardiac damage and thus, myocardial infarction (MI).5,6 MI is defined as myocardial cell death due to re-perfused ischemia.8 The magnitude and temporal course of CK-MB elevation and decline may clarify the timing of the myocardial insult, allow an estimate of infarct size, and contribute to the non-invasive assessment of reperfusion.9

**BIOLOGICAL PRINCIPLES OF THE PROCEDURE**

The ARCHITECT STAT CK-MB assay is a two-step assay to determine the presence of the MB isoenzyme of creatine kinase (CK-MB) in human serum and plasma using CMA technology with flexible assay protocols, referred to as Chemiflex. In the first step, sample and anti-CK-MB coated paramagnetic microparticles are combined. CK-MB present in the sample binds to the anti-CK-MB coated microparticles. After incubation and washing, anti-CK-MB acridinium-labeled conjugate is added in the second step. Following another incubation and wash, pre-trigger and trigger solutions are added to the reaction mixture. The resulting chemiluminescent reaction is measured as relative light units (RLUs). A direct relationship exists between the amount of CK-MB in the sample and the RLUs detected by the ARCHITECT i System optics.

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

**REAGENTS**

Reagent Kit, 100 Tests/500 Tests

Note: Some kit sizes are not available in all countries or for use on all ARCHITECT i Systems. Please contact your local distributor.

**ARCHITECT STAT CK-MB Reagent Kit (2K42)**

- **MICROPARTICLES** 1 or 4 Bottles (6.6 mL/27.0 mL) Anti-CK-MB (mouse, monoclonal) coated microparticles in TRIS buffer with protein (bovine) stabilizer. Preservatives: antimicrobial agents.
- **CONJUGATE** 1 or 4 Bottles (5.9 mL/26.3 mL) Anti-CK-MB (mouse, monoclonal) acridinium-labeled conjugate in MES buffer with protein (bovine) stabilizer. Preservatives: antimicrobial agents.

Other Reagents

ARCHITECT i Pre-Trigger Solution

- **PRE-TRIGGER SOLUTION** Pre-Trigger Solution containing 1.32% (w/v) hydrogen peroxide.

ARCHITECT i Trigger Solution

- **TRIGGER SOLUTION** Trigger Solution containing 0.35 N sodium hydroxide.

ARCHITECT i Wash Buffer

- **WASH BUFFER** Wash Buffer containing phosphate buffered saline solution. Preservative: antimicrobial agent.

**WARNINGS AND PRECAUTIONS**

For In Vitro Diagnostic Use.

**Safety Precautions**

- **CAUTION:** This product requires the handling of human specimens. It is recommended that all human sourced materials are considered potentially infectious and be handled in accordance with the OSHA Standard on Bloodborne Pathogens.10 Biosafety Level 211 or other appropriate biosafety practices12,13 should be used for materials that contain or are suspected of containing infectious agents.

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

For a detailed discussion of safety precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 8.
SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

- The following specimen collection tubes may be used in the ARCHITECT STAT CK-MB assay.

<table>
<thead>
<tr>
<th>Serum</th>
<th>Plastic</th>
</tr>
</thead>
<tbody>
<tr>
<td>No additive (uncoated)</td>
<td>Serum separator tubes</td>
</tr>
<tr>
<td>Lithium heparin</td>
<td>Lithium heparin</td>
</tr>
<tr>
<td>Plasma separator tubes with lithium heparin</td>
<td>Plasma separator tubes with lithium heparin</td>
</tr>
<tr>
<td>Sodium heparin</td>
<td></td>
</tr>
</tbody>
</table>

NOTE: Evaluation of serum samples may result in up to a -18% bias compared with plasma samples.

When serial specimens are being evaluated, the same type of specimen should be used throughout the study.

Other anticoagulants have not been validated for use with the ARCHITECT STAT CK-MB assay. Follow the manufacturer’s processing instructions for plasma or serum collection tubes.

- The ARCHITECT / System does not provide the capability to verify specimen type. It is the responsibility of the operator to verify the correct specimen types are used in the ARCHITECT STAT CK-MB assay.
- Do not use heat-inactivated specimens.
- Performance has not been established using cadaver specimens or body fluids other than human serum or plasma.
- Specimens with obvious microbial contamination should not be used.
- 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 with an applicator stick prior to analysis. Use a new applicator stick for each sample to prevent cross contamination.
- Plasma and serum specimens should be free of fibrin, red blood cells or other particulate matter.
- Ensure that complete clot formation in serum specimens has taken place prior to centrifugation. Some specimens, especially those from patients receiving anticoagulant or thrombolytic therapy, may exhibit increased clotting time. If the specimen is centrifuged before a complete clot forms, the presence of fibrin may cause erroneous results.
- Patient specimens with a cloudy or turbid appearance must be centrifuged prior to testing. Following centrifugation, avoid the lipid layer, if present, when pipetting the specimen.
- If testing will be delayed more than 8 hours, remove plasma or serum from the red blood cells, clot or separator gel.
- Specimens removed from the red blood cells, clot or separator gel may be stored up to 72 hours at 2-8°C.
- Specimens can be stored up to 30 days frozen at -10°C or colder.
- Specimens must be mixed THOROUGHLY after thawing, by LOW speed vortex or by gentle inversion, and centrifuged prior to use to remove red blood cells or particulate matter to ensure consistency in the results. Multiple freeze-thaw cycles of specimens should be avoided.
- All samples (patient specimens, controls, and calibrators) should be tested within 3 hours of being placed on board the ARCHITECT / System. Refer to the ARCHITECT System Operations Manual, Section 5, for a more detailed discussion of on-board sample storage constraints.
- When shipped, specimens must be packaged and labeled in compliance with applicable state, federal and international regulations covering the transport of clinical specimens and infectious substances. Specimens must be shipped frozen (dry ice). Prior to shipment, it is recommended that specimens be removed from the red blood cells, clot or separator gel.

PROCEDURE

Materials Provided

- 2K42 ARCHITECT STAT CK-MB Reagent Kit

Materials Required but not Provided

- ARCHITECT / System with STAT protocol capability
- 3K51 ARCHITECT / ASSAY CD-ROM - US - Addition B
- 3K53 ARCHITECT / ASSAY CD-ROM - WW (excluding US) - Addition B
- 2K42-01 ARCHITECT STAT CK-MB Calibrators

- 2K42-10 ARCHITECT STAT CK-MB Controls
- ARCHITECT / PRE-TRIGGER SOLUTION
- ARCHITECT / TRIGGER SOLUTION
- ARCHITECT / WASH BUFFER
- ARCHITECT / REACTION VESSELS
- ARCHITECT / SAMPLE CUPS
- ARCHITECT / SEPTUM
- ARCHITECT / REPLACEMENT CAPS
- Pipettes or pipette tips (optional) to deliver the volumes specified on the patient or control order screen.
- For information on materials required for maintenance procedures, refer to the ARCHITECT System Operations Manual, Section 9.

Assay Procedure

Before loading the ARCHITECT STAT CK-MB 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 remain 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, remove and discard the cap. Wearing clean gloves, remove a septum from the bag. Squeeze the septum in half to confirm that the slits are open. Carefully snap the septum onto the top of the bottle.

- 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 CK-MB Reagent Kit on the ARCHITECT / System with STAT 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. Verify adequate sample cup volume is present prior to running the test.
- Priority: 80 μL for the first ARCHITECT STAT CK-MB test plus 30 μL for each additional ARCHITECT STAT CK-MB test from the same sample cup.
- ≤ 3 hours on-board: 150 μL for the first ARCHITECT STAT CK-MB test plus 30 μL for each additional ARCHITECT STAT CK-MB test from the same sample cup.
- To minimize the effects of evaporation, all samples (patient specimens, calibrators and controls) must be tested within 3 hours of being placed on board the ARCHITECT / System.
- If using primary or aliquot tubes, use the sample gauge to ensure sufficient patient specimen is present.
- Prepare Calibrators and Controls.
- ARCHITECT STAT CK-MB Calibrators and Controls should be prepared according to their respective package inserts.
- To obtain the recommended volume requirements for the ARCHITECT STAT CK-MB Calibrators, hold the bottles vertically and dispense 8 drops of each calibrator into each respective sample cup. Dispense 150 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. The system performs the following functions:
  - Moves the sample to the aspiration point.
  - Loads a reaction vessel (RV) into the process path.
  - Aspirates and transfers sample into the RV.
  - Advances the RV one position and transfers microparticles into the RV.
  - Mixes, incubates and washes the reaction mixture.
  - Adds conjugate to the RV.
  - Mixes, incubates and washes the reaction mixture.
Manual dilutions should be performed as follows:

- Adds pre-trigger and trigger solutions.
- Measures chemiluminescent emission to determine the quantity of CK-MB in the sample.
- Aspirates contents of RV to liquid waste and unloads RV to solid waste.
- Calculates the result.
- 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 CK-MB value exceeding 300.0 ng/mL are flagged with the code “>300.0” and may be diluted with the Automated Dilution Protocol or the Manual Dilution Procedure.

Automated Dilution Protocol

- If using the Automated Dilution Protocol, the system performs a 1:2 dilution of the specimen and automatically calculates the concentration of the specimen before dilution and reports the result.
- Specimens with a CK-MB value exceeding 600.0 ng/mL are flagged with the code “>600.0” when run using the Automated Dilution Protocol. These specimens may be diluted with the Manual Dilution Procedure.

Manual Dilution Procedure

Manual dilutions should be performed as follows:

- The suggested dilution for CK-MB is 1:10.
- Prior to diluting the specimen, dispense approximately 15 drops of ARCHITECT STAT CK-MB Calibrator A into a clean test tube for use in the next step.
- Transfer 180 μL of ARCHITECT STAT CK-MB Calibrator A from the test tube prepared in the prior step into another clean test tube and add 20 μL of the patient specimen.
- 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 dilution should be performed so that the diluted result reads greater than 3.0 ng/mL.
- For detailed information on ordering dilutions, refer to the ARCHITECT System Operations Manual, Section 5.

Calibration

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

- Calibration Range: 0.0 – 300.0 ng/mL.
- Once an ARCHITECT STAT CK-MB 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 CK-MB 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 CK-MB 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 CK-MB assay belongs to method group 1. Use ARCHITECT STAT CK-MB Calibrators in place of MasterCheck as described in the ARCHITECT System Operations Manual, Appendix B.

RESULTS

Calculation

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

Alternate Result Units

- The default result unit for the ARCHITECT STAT CK-MB assay is ng/mL. When the alternate result unit, μg/L, is selected, the conversion factor used by the system is 1.0.
- Conversion Formula: (Concentration in ng/mL) \times (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 ARCHITECT System Operations Manual, Section 5.

LIMITATIONS OF THE PROCEDURE

- CK-MB levels can be increased in any conditions resulting in myocardial cell damage. For MI diagnostic purposes, the ARCHITECT STAT CK-MB results should be used in conjunction with other information such as cardiac marker results (e.g., troponin-I 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). Such specimens may show either falsely elevated or depressed values when tested with assay kits that employ mouse monoclonal antibodies. Although the ARCHITECT STAT CK-MB assay is specifically designed to minimize the effects of HAMA, assay results that are not consistent with other clinical observations may require additional information for diagnosis.
- 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.

ARCHITECT STAT CK-MB is not intended to be used on an ARCHITECT System without STAT protocol capability.

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, environmental factors, or sample type utilized. Since CK-MB is released from damaged myocardium, CK-MB levels in normal individuals are often low or undetectable. A reference range study was conducted based on guidance from National Committee for Clinical Laboratory Standards (NCCLS) Protocol C28-A2. Plasma samples from apparently healthy individuals were evaluated in replicates of using the ARCHITECT STAT CK-MB assay. The observed values are summarized in the following table.*

<table>
<thead>
<tr>
<th>Population</th>
<th>n</th>
<th>99th Percentile (ng/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>153</td>
<td>3.4</td>
</tr>
<tr>
<td>Male</td>
<td>157</td>
<td>7.2</td>
</tr>
<tr>
<td>TOTAL</td>
<td>310</td>
<td>6.6</td>
</tr>
</tbody>
</table>

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

The concentration of CK-MB in serum rises rapidly subsequent to myocardial infarction. It is recommended that serial samples be drawn at intervals subsequent to initial symptoms for most accurate results. Correlation with other clinical findings (e.g., ECG, symptoms, etc.) should be sought in evaluating the determined CK-MB levels. Values for CK-MB generally peak at 10-24 hours subsequent to the initial symptom of chest pain and decline to normal range within 72-96 hours. CK-MB values which increase rapidly or which show an early time to peak may be indicative of reperfusion.

Since low levels of CK-MB are present in other tissues and total CK is not always indicative of MI or reperfusion. It has also been shown to be elevated following long distance running or vigorous exercise due to CK-MB present in skeletal muscle. Additionally, patients with acute skeletal muscle trauma, dermatomyositis, polymyositis and muscular dystrophy may exhibit elevated CK-MB values. Renal failure, tissue damage following surgery, and cardiac contusion may also cause an elevation of CK-MB. In these cases, the relative percent (%) index of CK-MB may be helpful in differentiating MI from non-MI specimens. The relative percent index of CK-MB is calculated by the following equation.

\[
\text{Relative Percent Index} = \left( \frac{\text{Observed Value}}{\text{Reference Value}} \right) \times 100
\]
Relative % Index = \( \frac{\text{ARCHITECT STAT CK-MB value (ng/mL)}}{\text{Total CK (U/L)}} \times 100 \)

Due to differences in total CK methods and CK-MB levels in hospital populations, the normal range for the relative % index must be established at each laboratory. Use of relative % index may not be appropriate for all samples.36

### SPECIFIC PERFORMANCE CHARACTERISTICS

#### Precision

The ARCHITECT STAT CK-MB assay precision is ≤ 10% total CV for samples ≥ 3 ng/mL. A study was performed using the ARCHITECT STAT CK-MB assay with guidance from the NCCCLS Protocol EPS-A.37 ARCHITECT STAT CK-MB Controls and two human plasma 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>Instrument Lot</th>
<th>n</th>
<th>Conc. (ng/mL)</th>
<th>SD % CV</th>
<th>SD % CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 A</td>
<td>80</td>
<td>7.1</td>
<td>0.24</td>
<td>3.3</td>
</tr>
<tr>
<td>1 B</td>
<td>80</td>
<td>7.2</td>
<td>0.29</td>
<td>4.1</td>
</tr>
<tr>
<td>Low C</td>
<td>80</td>
<td>7.0</td>
<td>0.25</td>
<td>3.6</td>
</tr>
<tr>
<td>Control 2 A</td>
<td>80</td>
<td>7.6</td>
<td>0.27</td>
<td>3.5</td>
</tr>
<tr>
<td>B</td>
<td>80</td>
<td>7.5</td>
<td>0.28</td>
<td>3.7</td>
</tr>
<tr>
<td>C</td>
<td>80</td>
<td>7.3</td>
<td>0.29</td>
<td>3.9</td>
</tr>
<tr>
<td>Medium C</td>
<td>80</td>
<td>30.3</td>
<td>0.94</td>
<td>3.1</td>
</tr>
<tr>
<td>Control 2 A</td>
<td>80</td>
<td>31.9</td>
<td>1.39</td>
<td>4.4</td>
</tr>
<tr>
<td>B</td>
<td>80</td>
<td>30.4</td>
<td>1.12</td>
<td>3.7</td>
</tr>
<tr>
<td>C</td>
<td>80</td>
<td>30.3</td>
<td>1.21</td>
<td>4.0</td>
</tr>
<tr>
<td>1 A</td>
<td>80</td>
<td>80.1</td>
<td>2.45</td>
<td>3.1</td>
</tr>
<tr>
<td>B</td>
<td>80</td>
<td>85.8</td>
<td>2.64</td>
<td>3.1</td>
</tr>
<tr>
<td>High C</td>
<td>80</td>
<td>80.6</td>
<td>2.92</td>
<td>3.6</td>
</tr>
<tr>
<td>Control 2 A</td>
<td>80</td>
<td>80.0</td>
<td>3.24</td>
<td>4.0</td>
</tr>
<tr>
<td>B</td>
<td>80</td>
<td>79.8</td>
<td>3.15</td>
<td>3.9</td>
</tr>
<tr>
<td>C</td>
<td>80</td>
<td>81.6</td>
<td>3.92</td>
<td>3.6</td>
</tr>
<tr>
<td>1 A</td>
<td>80</td>
<td>5.4</td>
<td>0.13</td>
<td>2.5</td>
</tr>
<tr>
<td>B</td>
<td>80</td>
<td>5.4</td>
<td>0.16</td>
<td>3.0</td>
</tr>
<tr>
<td>Panel 1 C</td>
<td>80</td>
<td>5.4</td>
<td>0.19</td>
<td>3.6</td>
</tr>
<tr>
<td>2 A</td>
<td>80</td>
<td>5.8</td>
<td>0.20</td>
<td>3.4</td>
</tr>
<tr>
<td>B</td>
<td>80</td>
<td>5.8</td>
<td>0.20</td>
<td>3.5</td>
</tr>
<tr>
<td>C</td>
<td>80</td>
<td>5.6</td>
<td>0.17</td>
<td>3.0</td>
</tr>
<tr>
<td>1 A</td>
<td>80</td>
<td>14.1</td>
<td>0.34</td>
<td>2.4</td>
</tr>
<tr>
<td>B</td>
<td>80</td>
<td>15.1</td>
<td>0.46</td>
<td>3.0</td>
</tr>
<tr>
<td>Panel 2 C</td>
<td>80</td>
<td>14.3</td>
<td>0.33</td>
<td>2.3</td>
</tr>
<tr>
<td>2 A</td>
<td>80</td>
<td>14.7</td>
<td>0.40</td>
<td>2.7</td>
</tr>
<tr>
<td>B</td>
<td>80</td>
<td>14.8</td>
<td>0.35</td>
<td>2.4</td>
</tr>
<tr>
<td>C</td>
<td>80</td>
<td>14.7</td>
<td>0.55</td>
<td>3.7</td>
</tr>
</tbody>
</table>

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

#### Dilution Linearity

The ARCHITECT STAT CK-MB assay recovers diluted specimens within 20% of the expected result. A dilution linearity study was performed evaluating ARCHITECT STAT CK-MB using specimens with undiluted values that ranged between 190.5 and 274.6 ng/mL. These specimens were diluted manually using normal human plasma at various dilution factors and representative percent recovery results are summarized in the following table.*

<table>
<thead>
<tr>
<th>Sample ID</th>
<th>Dilution Factor</th>
<th>Mean Observed Value (ng/mL)</th>
<th>Mean Endogenous Value (ng/mL)</th>
<th>Mean Recovered Value (ng/mL)</th>
<th>Mean Expected Value (ng/mL)</th>
<th>% Recovery***</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>undiluted</td>
<td>190.5</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>1:2</td>
<td>97.2</td>
<td>0.7</td>
<td>96.5</td>
<td>95.3</td>
<td>101</td>
</tr>
<tr>
<td></td>
<td>1:10</td>
<td>20.6</td>
<td>1.2</td>
<td>19.4</td>
<td>19.1</td>
<td>102</td>
</tr>
<tr>
<td></td>
<td>1:50</td>
<td>5.3</td>
<td>1.3</td>
<td>4.0</td>
<td>3.8</td>
<td>104</td>
</tr>
<tr>
<td>2</td>
<td>undiluted</td>
<td>242.3</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>1:2</td>
<td>124.9</td>
<td>0.7</td>
<td>124.2</td>
<td>121.1</td>
<td>103</td>
</tr>
<tr>
<td></td>
<td>1:10</td>
<td>25.7</td>
<td>1.2</td>
<td>24.5</td>
<td>24.2</td>
<td>101</td>
</tr>
<tr>
<td></td>
<td>1:50</td>
<td>6.0</td>
<td>1.3</td>
<td>4.7</td>
<td>4.8</td>
<td>97</td>
</tr>
<tr>
<td>3</td>
<td>undiluted</td>
<td>274.6</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>1:2</td>
<td>136.3</td>
<td>0.7</td>
<td>135.6</td>
<td>137.3</td>
<td>99</td>
</tr>
<tr>
<td></td>
<td>1:10</td>
<td>28.5</td>
<td>1.2</td>
<td>27.3</td>
<td>27.5</td>
<td>99</td>
</tr>
<tr>
<td></td>
<td>1:50</td>
<td>6.4</td>
<td>1.3</td>
<td>5.1</td>
<td>5.5</td>
<td>93</td>
</tr>
</tbody>
</table>

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

** Mean Recovered Value = Mean Observed Value (ng/mL) - Mean Endogenous Value (ng/mL)

*** % Recovery = (Mean Recovered Value (ng/mL) / Mean Expected Value (ng/mL)) x 100

#### Autodilution Verification

Recovery performance was evaluated for the autodilution method of the ARCHITECT STAT CK-MB assay by testing specimens with undiluted values that ranged between 128.3 and 278.2 ng/mL. The observed percent recovery results are summarized in the following table.*

<table>
<thead>
<tr>
<th>Sample ID</th>
<th>Mean Undiluted Value (ng/mL)</th>
<th>Mean Observed Value (ng/mL)</th>
<th>% Recovery**</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>128.3</td>
<td>119.4</td>
<td>93</td>
</tr>
<tr>
<td>2</td>
<td>168.7</td>
<td>164.0</td>
<td>97</td>
</tr>
<tr>
<td>3</td>
<td>260.8</td>
<td>268.1</td>
<td>103</td>
</tr>
<tr>
<td>4</td>
<td>273.3</td>
<td>304.6</td>
<td>111</td>
</tr>
<tr>
<td>5</td>
<td>278.2</td>
<td>264.2</td>
<td>95</td>
</tr>
</tbody>
</table>

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

** % Recovery = (Mean Observed Value (ng/mL) / Mean Undiluted Value (ng/mL) x 100

#### Analytical Sensitivity

The ARCHITECT STAT CK-MB analytical sensitivity is ≤ 0.1 ng/mL at the 95% level of confidence (n=38 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 ARCHITECT STAT CK-MB Calibrator A (0.0 ng/mL) grand mean and represents the lowest concentration of CK-MB that can be distinguished from zero.

#### Analytical Specificity

The ARCHITECT STAT CK-MB assay analytical specificity is ≤ 0.01% cross-reactivity with CK-MM and CK-BB. A study based on guidance from NCCCLS Protocol EPS-A39 was performed using the ARCHITECT STAT CK-MB 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)</th>
<th>% Cross-reactivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>CK-BB</td>
<td>10,000</td>
<td>0.01</td>
</tr>
<tr>
<td>CK-MM</td>
<td>10,000</td>
<td>0.00</td>
</tr>
</tbody>
</table>

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

Potential interference from elevated levels of bilirubin, hemoglobin, triglycerides, and total protein in the ARCHITECT STAT CK-MB assay is ≤ 15% at the levels indicated in the following table. A study performed using the NCLLS Protocol EP7-A2 was performed for the ARCHITECT STAT CK-MB assay. Specimens with CK-MB levels between 7.2 and 23.6 ng/mL were supplemented with the following potentially interfering compounds.

<table>
<thead>
<tr>
<th>Substance</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bilirubin</td>
<td>20 mg/dL</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>500 mg/dL</td>
</tr>
<tr>
<td>Total Protein (Low)</td>
<td>4 g/dL</td>
</tr>
<tr>
<td>Total Protein (High)</td>
<td>10 g/dL</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>1000 mg/dL</td>
</tr>
</tbody>
</table>

**Evaluation of Potentially Interfering Clinical Conditions**

The ARCHITECT STAT CK-MB assay was evaluated by testing specimens with HAMA and rheumatoid factor (RF) to further assess clinical specificity. Ten specimens positive for HAMA and ten specimens positive for RF were evaluated for % interference with CK-MB added to between 25.0 and 32.9 ng/mL. Mean Absolute % Interference is summarized in the following table.*

<table>
<thead>
<tr>
<th>Clinical Condition</th>
<th>Number of Specimens</th>
<th>% Interference</th>
</tr>
</thead>
<tbody>
<tr>
<td>HAMA Positive</td>
<td>10</td>
<td>5.6</td>
</tr>
<tr>
<td>RF Positive</td>
<td>10</td>
<td>3.9</td>
</tr>
</tbody>
</table>

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

**Method Comparison**

The ARCHITECT STAT CK-MB method comparison correlation coefficient (r) is ≥ 0.90. A study was performed where lithium heparin plasma specimens were tested in replicates of one using ARCHITECT CK-MB over a period of three calibration cycles with three reagent lots. Data from this study were analyzed using the Passing-Bablok regression method and are summarized in the following table and scatter plot.*

**ARCHITECT STAT CK-MB vs. AxSYM CK-MB**

<table>
<thead>
<tr>
<th>Regression 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**</td>
<td>201</td>
<td>0.81 (-0.79 to 0.82)</td>
<td>-0.51 (-1.16 to 0.14)</td>
<td>0.985</td>
</tr>
</tbody>
</table>

**Sample Range** (ARCHITECT STAT CK-MB): 1.5-256.9 ng/mL

**Sample Range** (AxSYM CK-MB): 1.8-296.0 ng/mL

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

**BIBLIOGRAPHY**


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