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

<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>LOT</td>
<td>Lot Number</td>
</tr>
<tr>
<td>-10°C</td>
<td>Store at ≤ -10°C</td>
</tr>
<tr>
<td>2°C</td>
<td>Store at 2-8°C</td>
</tr>
<tr>
<td>15°C</td>
<td>Store at 15-30°C</td>
</tr>
<tr>
<td>Manufacturer</td>
<td></td>
</tr>
<tr>
<td>STANDARD CAL</td>
<td>Standard Calibrator (A-F)</td>
</tr>
<tr>
<td>L</td>
<td>Control Low, Medium, High (L, M, H)</td>
</tr>
<tr>
<td>CONTROL</td>
<td>Reagent Pack</td>
</tr>
<tr>
<td>PACK</td>
<td>Reaction Vessels</td>
</tr>
<tr>
<td>REAGENT</td>
<td>Matrix Cells</td>
</tr>
<tr>
<td>VESSELS</td>
<td>Sample Cups</td>
</tr>
<tr>
<td>MATRIX</td>
<td>Contains Sodium Azide. Contact with acids liberates very toxic gas.</td>
</tr>
<tr>
<td>CELLS</td>
<td>Consult instructions for use</td>
</tr>
</tbody>
</table>

See REAGENTS section for a full explanation of symbols used in reagent component naming.
SUMMARY AND EXPLANATION OF THE TEST

CK-MB is an 84,000 molecular weight enzyme that represents a significant fraction of the creatine kinase present in myocardial tissue. CK-MB is also present in a variety of other tissues, albeit at much lower levels. The appearance of CK-MB in serum, in the absence of major muscle trauma, may be indicative of cardiac damage and thus, myocardial infarction. Furthermore, the temporal pattern of CK-MB release following an infarction is important. Thus, a CK-MB value which shows no significant change over time is not confirmatory of myocardial infarction. Assessment of CK-MB following an acute coronary thrombosis has been reported to be useful in determining the efficacy of reperfusion therapy.

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

AxSYM CK-MB is based on Microparticle Enzyme Immunoassay (MEIA) technology. The AxSYM CK-MB Reagents and sample are pipetted in the following sequence:

Sampling Center
- Sample and all AxSYM CK-MB reagents required for one test are pipetted by the Sampling Probe into various wells of a Reaction Vessel (RV).
- Sample is pipetted into one well of the RV and the conjugate into another well.
- Microparticles and Assay Diluent are pipetted and mixed with the sample.
- An additional aliquot of Assay Diluent is pipetted into another well. The RV is immediately transferred into the Processing Center.
- Further pipetting is done in the Processing Center with the Processing Probe.

Processing Center
- The CK-MB binds to the Anti-CK-MB Coated Microparticles forming an antibody-antigen complex.
- An aliquot of Assay Diluent is transferred to the matrix cell followed by an aliquot of the reaction mixture containing the antibody-antigen complex bound to the microparticles. The microparticles bind irreversibly to the glass fiber matrix.
- The matrix cell is washed to remove unbound materials.
- The Anti-CK-MM (Goat): Alkaline Phosphatase Conjugate is dispensed onto the matrix cell and binds to the antibody-antigen 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 CK-MB Reagent Pack (7K47-20)*
- 1 Bottle (7.9 mL) Anti-CK-MM (Mouse, Monoclonal) Coated Microplates in TRIS buffer. Preservative: Sodium Azide. (Reagent Bottle 1)
- 1 Bottle (13.2 mL) Anti-CK-MM (Goat): Alkaline Phosphatase Conjugate in TRIS buffer with protein stabilizers. Minimum concentration: 0.5 µg/mL. Preservative: Sodium Azide. (Reagent Bottle 2)

AxSYM CK-MB — the MB isoenzyme of creatine kinase

INTENDED USE

AxSYM CK-MB is a Microparticle Enzyme Immunoassay (MEIA) for the quantitative measurement of the MB isoenzyme of creatine kinase (CK-MB) in human serum or plasma. The assay is used to assist in the diagnosis of acute myocardial infarction (AMI).

NAME

AxSYM CK-MB is intended for use in the diagnosis of acute myocardial infarction (AMI).

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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 Pathogens14. Biosafety Level 215 or other appropriate biosafety practices16,17 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 information on the safe disposal of sodium azide and a detailed discussion of safety precautions during system operation, refer to the AxSYM System Operations Manual, Section 7 and 8.

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

• If AxSYM CK-MB Reagents are used within 72 hours of receipt or have been dropped or jarringed, they should be inspected for bubbles. If bubbles are present, 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 Reagent Packs beyond the expiration date or a maximum of 336 cumulative hours on board the AxSYM System.

• Do not mix reagents from different reagent packs.

STORAGE INSTRUCTIONS

• The AxSYM CK-MB Reagent Pack must be stored at 2-8°C (do not freeze), in an upright position and may be used immediately after removal from 2-8°C storage. The AxSYM CK-MB Reagent Pack should be returned to 2-8°C storage immediately after use.

The AxSYM CK-MB Reagent Pack may be on board the AxSYM System for a maximum of 336 cumulative hours; for example, 42 eight hour shifts. Recalibration may be required to obtain maximum onboard reagent stability. More frequent use of controls may be required to monitor reagent performance consistently. Refer to the AxSYM System Operations Manual, Appendices, for further information on tracking onboard time.

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

The AxSYM CK-MB Standard Calibrators, AxSYM CK-MB Controls and AxSYM CK-MB Specimen Diluent must be stored at ≤-10°C. The AxSYM CK-MB Standard Calibrators, AxSYM CK-MB Controls and AxSYM CK-MB Specimen Diluent should be thawed completely at room temperature (15-30°C) for 45-60 minutes. Prior to use, mix THOROUGHLY by inversion 5-10 times. After each use, immediately return the thawed Standard Calibrators, Controls and Specimen Diluent to refrigerated storage (2-8°C) for up to 90 days after thawing; until expiry.

NOTE: AxSYM CK-MB Standard Calibrators, AxSYM CK-MB Controls and AxSYM CK-MB Specimen Diluent are shipped on dry ice and should be stored at ≤-10°C after receipt.

INSTRUMENT PROCEDURE

Assay File Installation

The AxSYM CK-MB Assay File must be installed on the AxSYM System from one of the following software disks prior to performing CK-MB assays:

• 03D52-02
• 07G53-01, or higher

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

NOTE: AxSYM CK-MB Version 1.00.4 or higher must only be run with AxSYM System(s) Software Version 3.00 or higher.

AxSYM CK-MB Assay Parameters

The default values for the visible assay parameters used for the AxSYM CK-MB assay are listed below. Assay parameters that can be edited contain a (> ) symbol. These parameters can be displayed and edited according to the procedure in the AxSYM System Operations Manual, Section 2. However, some parameters that contain a (> ) symbol may not be editable if there are no additional options. In order to obtain values for the parameters with an asterisk (*), review the specific Assay Parameter screen. Press PRINT to print the assay parameters.

<table>
<thead>
<tr>
<th>Assay Parameters</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Long Assay Name (English): CK-MB</td>
</tr>
<tr>
<td>6 Abbrev Assay Name (English): CK-MB</td>
</tr>
<tr>
<td>11 Assay Number: 362</td>
</tr>
<tr>
<td>12 Assay Version: *</td>
</tr>
<tr>
<td>13 Calibration Version: *</td>
</tr>
<tr>
<td>14 Assay File Revision: *</td>
</tr>
<tr>
<td>15 Assay Enabled &gt; ON</td>
</tr>
<tr>
<td>17 Assay Type: MEIA</td>
</tr>
<tr>
<td>18 Standard Cal Reps &gt; 2</td>
</tr>
<tr>
<td>21 Cal A Concentration: 0.0</td>
</tr>
<tr>
<td>22 Cal B Concentration: 3.0</td>
</tr>
<tr>
<td>23 Cal C Concentration: 10.0</td>
</tr>
<tr>
<td>24 Cal D Concentration: 30.0</td>
</tr>
<tr>
<td>25 Cal E Concentration: 100.0</td>
</tr>
<tr>
<td>26 Cal F Concentration: 300.0</td>
</tr>
<tr>
<td>43 Default Dilution Protocol &gt; UNDILUTED</td>
</tr>
<tr>
<td>44 Default Calibration Method &gt; Standard Cal</td>
</tr>
<tr>
<td>45 Selected Result Concentration Units &gt; ng/mL</td>
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<tr>
<td>46 Selected Result Decimal Places &gt; 1</td>
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<td>64 Max Intercept-Max MUP intercept: 9000.0000</td>
</tr>
<tr>
<td>65 Min Intercept-Min MUP intercept: 1100.0000</td>
</tr>
<tr>
<td>66 Upper limit for NRMSE for low rates: 9999.9900</td>
</tr>
<tr>
<td>67 Upper limit for NRMSE for high rates: 0.7500</td>
</tr>
<tr>
<td>68 Max Rate-Max rate used to check Min MUP intercept: 1800.0000</td>
</tr>
<tr>
<td>69 Min Rate-Rate cutoff for NRMSE and Corr. Coef.: 10.0000</td>
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<tr>
<td>70 Min correlation coefficient for low rates: 0.8500</td>
</tr>
<tr>
<td>71 Min correlation coefficient for high rates: 0.9500</td>
</tr>
<tr>
<td>72 MUP T Delay-Time delay following MUP: 3.4000</td>
</tr>
<tr>
<td>73 Low Limit-Normal/Therapeutic Range lower limit &gt; 0.0</td>
</tr>
<tr>
<td>74 High Limit-Normal/Therapeutic Range upper limit &gt; 0.0</td>
</tr>
<tr>
<td>75 Low Extreme Value &gt; 0.0</td>
</tr>
<tr>
<td>76 High Extreme Value &gt; 0.0</td>
</tr>
<tr>
<td>91 Low Range Undiluted: 0.0</td>
</tr>
<tr>
<td>92 High Range Undiluted: 300.0</td>
</tr>
</tbody>
</table>

NOTE: Parameter 45 in CKMB assay file 1.00.3 (03D52-02) cannot be edited. Parameter 45 in CKMB assay file 1.00.4 (07G53-01 or higher) can be edited to the alternate result unit, μg/L.

Refer to the AxSYM System Operations Manual for a detailed description of Instrument Procedures.
SAMPLE COLLECTION AND PREPARATION FOR ANALYSIS

- Serum (including serum collected in separator tubes) or plasma (collected in sodium heparin or tripotassium EDTA) may be used in the AxSYM CK-MB Assay. Follow the manufacturer’s processing instructions for serum or plasma collection tubes.
- The AxSYM System does not provide the capability to verify sample type. It is the responsibility of the operator to verify the correct sample type(s) are used in the AxSYM CK-MB assay.
- Ensure that complete clot formation has taken place prior to centrifugation. Some samples, especially those from patients receiving anticoagulant or thrombolytic therapy may exhibit increased clotting time. For these patients, plasma specimens may be preferable to decrease processing time and minimize particulate matter. If a serum sample is centrifuged before a complete clot forms, the presence of fibrin may cause erroneous results.
- For optimal results, samples should be free of fibrin, red blood cells or other particulate matter.
- Patient samples should be mixed and centrifuged after any freeze-thaw cycle or to remove red cells or particulate matter.
- Multiple freeze-thaw cycles should be avoided. Samples must be mixed thoroughly after thawing, by LOW speed vortexing or by gently inverting, and centrifuged prior to use to remove particulate matter and to ensure consistency in the results.
- Samples may be stored for up to 24 hours at 2-8°C prior to being tested. If testing will be delayed more than 24 hours, serum or plasma should be separated from the clot or red blood cells and stored frozen at -20°C or colder. Samples stored frozen at -20°C or colder for 12 months showed no performance difference.
- To minimize the effects of evaporation, all samples (patient samples, controls and calibrators) should be tested within 3 hours of being placed on board the AxSYM System. Refer to the AxSYM System Operations Manual, Section 5, for a more detailed discussion of onboard sample storage constraints.
- Inspect all samples for bubbles. Remove bubbles prior to analysis.
- When shipped, samples must be packaged and labeled in compliance with applicable federal and international regulations covering the transport of clinical samples and etiologic agents.

Sample Volume

The sample volume required to perform a single undiluted CK-MB test on the AxSYM System varies depending on the type of sample container used. For sample cups, both ROUTINE and STAT tests require 154 µL. For each additional CK-MB test performed (ROUTINE or STAT) from the same container, an additional 104 µL of sample is required.

The sample cup minimum volume for both STAT and ROUTINE tests are calculated by the AxSYM System. They are displayed on the Order screen. The sample volume required to perform a single undiluted CK-MB test on the AxSYM System varies depending on the type of sample container used. For sample cups, both ROUTINE and STAT tests require 154 µL. For each additional CK-MB test performed (ROUTINE or STAT) from the same container, an additional 104 µL of sample is required.

To obtain the recommended volume requirements for the AxSYM CK-MB Calibrators and Controls, hold the bottles vertically and dispense 5 drops of each Calibrator or 4 drops of each Control into each respective sample cup. Refer to the AxSYM System Operations Manual, Section 5, for sample volume requirements in primary or aliquot tubes and calibrator/control requirements for multiple reagent lots.

AxSYM CK-MB PROCEDURE

Materials Provided

- 7K47-20 AxSYM CK-MB Reagent Kit, containing:
  - AxSYM CK-MB (REAGENT PACK)
  - 100 REACTION VESSELS
  - 100 MATRIX CELLS

Materials Required But Not Provided

- AxSYM System
- 7K47-10 AxSYM CK-MB Controls
- 7K47-01 AxSYM CK-MB Standard Calibrators
- 7K47-50 AxSYM CK-MB Specimen Diluent
- 8A47-04 SOLUTION 1 [MUP]
- 8A81-04 SOLUTION 2 [MATRIX CELL WASH]
- 8A46 SOLUTION 3 [LINE DILUENT]
- 9A35-05 AxSYM PROBE CLEANING SOLUTION
- 8A76-01 SAMPLE CUPS

Automated Dilution Protocol

Manual Dilution Protocol

Patient samples with a CK-MB value exceeding 300 ng/mL are flagged with the code “>300”. These samples may be diluted manually with the AxSYM CK-MB Specimen Diluent (7K47-50) or AxSYM CK-MB Standard Calibrator A (0 ng/mL) before pipetting the sample into the sample cup. A 1:4 dilution (e.g., 100 µL sample + 300 µL Specimen Diluent or Standard Calibrator A) is adequate for most samples. The dilution should be performed so that the diluted test results read greater than the sensitivity of the assay (0.7 ng/mL). To determine the concentration of CK-MB in the specimen, multiply the concentration of the diluted sample by the dilution factor.

Final Sample Concentration = Concentration x Factor

Manual Dilution Factor = (Volume of Sample + Manual Dilution Volume of Dilution Reagent) / Volume of Sample

QUALITY CONTROL PROCEDURES

Calibration

The AxSYM CK-MB Assay must be calibrated using a Standard Calibration (6-point) procedure. Standard Calibration

To perform an AxSYM CK-MB Standard Calibration, test Standard Calibrators A, B, C, D, E, and F in duplicate. A single sample of all levels of AxSYM CK-MB Controls must be tested as a means of evaluating the assay calibration.

Once the AxSYM CK-MB 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.

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 recommended control requirement for an AxSYM CK-MB Assay is a single sample of all CK-MB control levels tested once every 24 hours each day of use. Controls may be placed in any position in the Sample Carousel.

If the quality control procedures in your laboratory require more frequent use of controls to verify test results, follow those procedures.

To achieve maximum onboard reagent stability, more frequent use of controls may be required to monitor reagent performance within the same lot.

Ensure that assay control values are within the concentration ranges specified in the package insert. Refer to the REAGENTS, Controls section of this package insert for AxSYM CK-MB Control ranges.

**Indications of Instability or Deterioration of Reagents**

When a control value is out of the specified 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, Subsection: Observed Problems, for further troubleshooting information.

The AxSYM System has a capability to generate a Levey-Jennings plot of each assay’s quality control performance. Refer to the AxSYM System Operations Manual, Section 5. At the discretion of the laboratory, selected quality control rules may be applied to the quality control data.

**Fluorescence Background Acceptance Criteria**

Quality Control with regards to the MUP substrate blank is automatically determined by the instrument and checked under Assay Parameter 64 Max Intercept-Max MUP intercept each time a test result is calculated. 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.

**RESULTS**

AxSYM CK-MB utilizes a four parameter logistic curve (4 PLC) X-weighted data reduction method to generate a calibration curve.

**Alternate Result Unit**

The default result unit for AxSYM CK-MB is ng/mL. When selecting the alternate result unit, µg/L, the conversion factor used by the AxSYM System is 1.0. The conversion formula to change to the alternate result unit is 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, Section 2.

**LIMITATIONS OF THE PROCEDURE**

- For diagnostic purposes, the AxSYM CK-MB results should be used in conjunction with other clinical data; e.g., EKG, 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 which employ mouse monoclonal antibodies. These specimens should not be assayed with the AxSYM CK-MB assay.

Refer to the SAMPLE COLLECTION AND PREPARATION FOR ANALYSIS section in this package insert.

**EXPECTED VALUES**

Since CK-MB is released from damaged myocardium, CK-MB levels in normal individuals are often low or undetectable. The expected values for normal and hospitalized non-AMI populations are summarized in the following table.

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>Entire Range (ng/mL)</th>
<th>95% Quantile (ng/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>580</td>
<td>0 - 10.4</td>
<td>≤ 3.8</td>
</tr>
<tr>
<td>Hospitalized Non-AMI</td>
<td>294</td>
<td>0 - 49.4</td>
<td>≤ 9.3</td>
</tr>
</tbody>
</table>

Due to the demographic population differences, the normal range must be established at each laboratory.

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., EKG, 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, a rise in CK-MB and total CK is not always indicative of AMI 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 and total CK levels. 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 AMI from non-AMI specimens. The relative percent index of CK-MB is calculated by the following equation.

\[ \text{Relative % Index} = \frac{\text{AxSYM CK-MB value (ng/mL)}}{\text{Total CK (U/L)}} \times 100 \]

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 in all samples.

**SPECIFIC PERFORMANCE CHARACTERISTICS**

**Precision**

Precision was determined as described in Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS) protocol EP5-T. A three member human serum based panel was assayed in replicates of 2 at two separate times per day for twenty days. Data from this study are summarized as follows.

**Panel Member 1**

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Mean Conc. Value (ng/mL)</th>
<th>Within Run SD CV (%)</th>
<th>Between Run SD CV (%)</th>
<th>Between Day SD CV (%)</th>
<th>Total Run SD CV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5.20</td>
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<td>4.61</td>
<td>0.09</td>
<td>1.76</td>
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<td>0.19</td>
<td>4.03</td>
<td>0.00</td>
<td>0.00</td>
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<td>0.24</td>
<td>4.87</td>
<td>0.22</td>
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<td>0.21</td>
<td>4.38</td>
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</table>

**Panel Member 2**

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<th>Instrument</th>
<th>Mean Conc. Value (ng/mL)</th>
<th>Within Run SD CV (%)</th>
<th>Between Run SD CV (%)</th>
<th>Between Day SD CV (%)</th>
<th>Total Run SD CV (%)</th>
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</thead>
<tbody>
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<td>0.67</td>
<td>3.49</td>
<td>0.41</td>
<td>1.23</td>
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</table>
Recovery

Known concentrations of CK-MB were added to 3 human serum samples. The concentration of CK-MB was determined using the AxSYM CK-MB assay and the resulting percent recovery was calculated.

**Known Recovery:**

- 0.0035% cross-reactivity. Cross-reactivity with 5000 ng/mL CK-MM was 0.0035%.
- Specificity shows the lowest measurable concentration of CK-MB that can be distinguished from zero.
- **Sensitivity:** The sensitivity of the AxSYM CK-MB assay was calculated to be better than or equal to 0.7 ng/mL (n = 48 runs in replicates of 10). This sensitivity is defined as the concentration at 2 standard deviations from the AxSYM CK-MB Standard Calibrator A (0 ng/mL) and represents the lowest measurable concentration of CK-MB that can be distinguished from zero.

### Specificity

- The specificity of the AxSYM CK-MB assay was determined by studying the cross-reactivity with CK-BB and CK-MM. Serum specimens, which were negative for CK-MB, were supplemented with 10,000 ng/mL CK-BB and shown to have 0.0035% cross-reactivity. Cross-reactivity with 5000 ng/mL CK-MM was 0.0035%.

### Interference

- The AxSYM CK-MB assay demonstrated the stated interference in the presence of the following:
  - Bilirubin: <10% interference at 50 mg/dL
  - Hemoglobin: <10% interference at 1000 mg/dL
  - Triglycerides: <10% interference at 1000 mg/dL

### Accuracy by Correlation

- The AxSYM CK-MB assay was compared to a commercially available diagnostic kit. The results of the specimen testing are shown in the following table.

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Number of Observations</th>
<th>Intercept</th>
<th>Slope</th>
<th>Correlation Coefficient</th>
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<tbody>
<tr>
<td>Abbott AxSYM CK-MB vs. Abbott IMx STAT CK-MB</td>
<td>1138</td>
<td>0.80</td>
<td>1.02</td>
<td>0.989</td>
</tr>
</tbody>
</table>

In this evaluation, serum samples tested ranged from 0.7 to 294.7 ng/mL by AxSYM CK-MB.

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