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

Read Highlighted Changes
Revised November, 2007

Key to symbols used

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>REF</td>
<td>List Number</td>
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<tr>
<td>IVD</td>
<td>In Vitro Diagnostic Medical Device</td>
</tr>
<tr>
<td>2°C/8°C</td>
<td>Store at 2-8°C</td>
</tr>
<tr>
<td>📘</td>
<td>Consult instructions for use</td>
</tr>
<tr>
<td>SN</td>
<td>Serial Number</td>
</tr>
<tr>
<td>EC</td>
<td>REP</td>
</tr>
<tr>
<td>Manufacturer</td>
<td></td>
</tr>
<tr>
<td>LOT</td>
<td>Lot Number</td>
</tr>
<tr>
<td>📅</td>
<td>Expiration Date</td>
</tr>
<tr>
<td>🔊</td>
<td>Reaction Vessels</td>
</tr>
<tr>
<td>🛋️</td>
<td>Sample Cups</td>
</tr>
<tr>
<td>🍼</td>
<td>Septum</td>
</tr>
<tr>
<td>🧼</td>
<td>Replacement Caps</td>
</tr>
<tr>
<td>📜</td>
<td>Reagent Lot</td>
</tr>
<tr>
<td>🔎</td>
<td>Assay CD-ROM</td>
</tr>
<tr>
<td>🔍</td>
<td>Control Number</td>
</tr>
</tbody>
</table>

See REAGENTS section for a full explanation of symbols used in reagent component naming.
NAME
ARCHITECT STAT Myoglobin

INTENDED USE
ARCHITECT STAT Myoglobin is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of myoglobin in human serum and plasma on the ARCHITECT / System with STAT protocol capability. Myoglobin values are used to assist in the diagnosis of myocardial infarction (MI).

SUMMARY AND EXPLANATION OF TEST
Myoglobin is a tightly folded, globular heme-protein located in the cytoplasm of both skeletal and cardiac muscle cells. Its function is to store and supply oxygen to muscle cells. The molecular weight of myoglobin is approximately 17,800 daltons.1,2 The relatively low molecular weight and the location of storage accounts for the rapid release from damaged muscle cells and earlier rises in concentration measured above baseline in blood as compared to other cardiac markers.1,3,4

In ischemic heart disease, such as myocardial infarction (MI), a temporal pattern of increased release of myoglobin into the blood stream is observed. The serum or plasma myoglobin level will start to show an increase between 2-4 hours after an MI has occurred, peaking at approximately 8-10 hours, and returning to baseline after 24 hours. Measurement of myoglobin between 2-12 hours after an MI can be a good adjunct to electrocardiography (ECG) in improving the efficiency of early diagnosis of MI.1,5,6 Monitoring the myoglobin levels can also help in evaluating the success of thrombolytic therapy.6,7

Since myoglobin is present in both cardiac and skeletal muscle, any damage to either of these muscle types results in its release into the blood stream. Elevated serum levels of myoglobin have been observed under the following conditions: skeletal muscle damage, skeletal muscle or neuromuscular disorders, cardiac bypass surgery, renal failure, strenuous exercise.2,5 Therefore, serum myoglobin levels should be used in conjunction with other aspects of the patient assessment to aid in the diagnosis of an MI. Myoglobin may also rise moderately above the reference range in chronic ischemic heart disease (i.e. unstable angina).2

For diagnostic purposes, the ARCHITECT STAT Myoglobin assay results should be used in conjunction with other data; e.g., other clinical testing, ECG, symptoms, clinical observations.

BIOLOGICAL PRINCIPLES OF THE PROCEDURE
The ARCHITECT STAT Myoglobin assay is a two-step immunoassay for the quantitative determination of myoglobin in human serum and plasma using CMIA technology with flexible assay protocols, referred to as Chemiflex.

In the first step, sample and anti-myoglobin coated paramagnetic microparticles are combined and incubated. Myoglobin present in the sample binds to the anti-myoglobin coated microparticles. After washing, anti-myoglobin 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 myoglobin in the sample and the RLUs detected by the ARCHITECT.7

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

* i = immunoassay

REAGENTS
Reagent Kit, 100 Tests/500 Tests
NOTE: Some kit sizes are not available in all countries or for use on all ARCHITECT / Systems. Please contact your local distributor.
ARCHITECT STAT Myoglobin Reagent Kit (2K43)
• MICROPARTICLES 1 or 4 Bottles (6.6 mL/27.0 mL) Anti-myoglobin (mouse, monoclonal) coated microspheres in TRIS buffer with protein (bovine) stabilizer. Preservative: antimicrobial agents.
• CONJUGATE 1 or 4 Bottles (5.9 mL/28.3 mL) Anti-myoglobin (mouse, monoclonal) acridinium-labeled conjugate in MES buffer under the protein (bovine) stabilizer. Preservative: ProClin 300.
• SPECIMEN DILUENT 1 or 4 Bottles (10.0 mL/50.9 mL) Myoglobin Specimen Diluent containing protein (bovine) stabilizer in TRIS buffer. Preservative: sodium azide.

Other Reagents
ARCHITECT / Pre-Trigger Solution
• PRE-TRIGGER SOLUTION Pre-Trigger Solution containing 1.32% (w/v) hydrogen peroxide.
ARCHITECT / Trigger Solution
• TRIGGER SOLUTION Trigger Solution containing 0.35 N sodium hydrosulfite.
ARCHITECT / 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.8 Biosafety Level 29 or other appropriate biosafety practices10,11 should be used for materials that contain or are suspected of containing infectious agents.
• The ARCHITECT STAT Myoglobin Conjugate contains 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 is classified per applicable European Community (EC) Directives as: Irritant (Xi). The following are the appropriate Risk (R) and Safety (S) phrases:

<table>
<thead>
<tr>
<th>R</th>
<th>S</th>
</tr>
</thead>
<tbody>
<tr>
<td>R43</td>
<td>May cause sensitization by skin contact.</td>
</tr>
<tr>
<td>S24</td>
<td>Avoid contact with skin.</td>
</tr>
<tr>
<td>S35</td>
<td>This material and its container must be disposed of in a safe way.</td>
</tr>
<tr>
<td>S37</td>
<td>Wear suitable gloves.</td>
</tr>
<tr>
<td>S46</td>
<td>If swallowed, seek medical advice immediately and show this container or label.</td>
</tr>
</tbody>
</table>

• 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.
• For information on the safe disposal of sodium azide and a detailed discussion of safety precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 8.

Handling Precautions
• Do not use reagent kits beyond the expiration date.
• Do not pool reagents within a kit or between reagent kits.

Before loading the ARCHITECT STAT Myoglobin Reagent Kit on the system for the first time, the microparticle bottle requires mixing to resuspend microparticles that have settled during shipment. For microparticle mixing instructions, refer to the PROCEDURE, Assay Protocol section of this package insert.

• Septums MUST be used to prevent reagent evaporation and contamination and to ensure reagent integrity. Reliability of assay results cannot be guaranteed if septums are not used according to the instructions in this package insert.

• To avoid contamination, wear clean gloves when placing a septum on an uncapped reagent bottle.
• Prior to placing the septum on an uncapped reagent bottle, squeeze the septum in half to confirm that the slits are open. If the slits appear sealed, continue to gently squeeze the septum to open the slits.
• Once a septum has been placed on an open reagent bottle, do not invert the bottle as this will result in reagent leakage and may compromise assay results.

• 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

- **2°C - 8°C**: The ARCHITECT STAT Myoglobin 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.
- When stored and handled as directed, reagents are stable until the expiration date.
- The ARCHITECT STAT Myoglobin Reagent Kit may be stored on board the ARCHITECT i System with **STAT protocol capability** for a maximum of 30 days. After 30 days, the reagent kit must be discarded.
- For information on tracking onboard time, refer to the ARCHITECT System Operations Manual, Section 5.
- Reagents may be stored on or off the ARCHITECT i System. If reagents are removed from the system, store them at 2-8°C (with septums and replacement caps) in an upright position. For reagents stored off the system, it is recommended that they be stored in their original trays and boxes to ensure they remain upright. If the microparticle bottle does not remain upright (with a septum installed) while in refrigerated storage off the system, the reagent kit must be discarded. After reagents are removed from the system, initiate a reagent scan to update the onboard stability timer.

Indications of Reagent Deterioration
When a control value is out of the specified range, it may indicate deterioration of the reagents or errors in technique. Associated test results are invalid and must be retested. Assay recalibration may be necessary. For troubleshooting information, refer to the ARCHITECT System Operations Manual, Section 10.

**INSTRUMENT PROCEDURE**
- The ARCHITECT STAT Myoglobin assay file must be installed on the ARCHITECT i System with **STAT protocol capability** from the ARCHITECT i Assay CD-ROM Addition B before performing the assay. For detailed information on assay file installation and on viewing and editing assay parameters, refer to the ARCHITECT System Operations Manual, Section 2.
- For information on printing assay parameters, refer to the ARCHITECT System Operations Manual, Section 5.
- For a detailed description of system procedures, refer to the ARCHITECT System Operations Manual.
- The default result unit for the ARCHITECT STAT Myoglobin assay is ng/mL. An alternate result unit, μg/L, may be selected for reporting results by editing assay parameter "Result concentration units" to μg/L. The conversion factor used by the system is 1.0.

**SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS**
- The following specimen collection tubes may be used in the ARCHITECT STAT Myoglobin assay:

<table>
<thead>
<tr>
<th>Specimen Types</th>
<th>Glass</th>
<th>Plastic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum</td>
<td>No Additive (uncoated)</td>
<td>Serum separator tubes</td>
</tr>
<tr>
<td>Plasma</td>
<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>
<td>Sodium Heparin</td>
</tr>
</tbody>
</table>

Other anticoagulants have not been validated for use with the ARCHITECT STAT Myoglobin assay.
- When serial specimens are being evaluated, the same type of specimen should be used throughout the study.
- The ARCHITECT i System does not provide the capability to verify the correct specimen types are used in the ARCHITECT STAT Myoglobin assay.
- 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 into a sample cup or secondary tube.

**Preparation for Analysis**
- Follow the manufacturer’s processing instructions for plasma or serum collection tubes.
- Specimens must be mixed THOROUGHLY after thawing by LOW speed vortexing or by gently inverting, 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.

**Storage**
- If testing will be delayed for more than 8 hours, remove plasma or serum from the serum or plasma separator, red blood cells or clot. Specimens removed from the separator gel, cells or clot 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.
- 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 onboard sample storage constraints.

**Shipping**
- Before shipping specimens, it is recommended that specimens be removed from the serum or plasma separator, red blood cells or clot. 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).
- Do not exceed the storage time limitations identified in the section of the package insert.

**PROCEDURE**

**Materials Provided**
- 2K43 ARCHITECT STAT Myoglobin Reagent Kit

**Materials Required but not Provided**
- ARCHITECT i System with **STAT protocol capability**
- 3K51 ARCHITECT i ASSAY CD-ROM - US - Addition B
- 3K53 ARCHITECT i ASSAY CD-ROM - WW (excluding US) - Addition B
- 2K43-01 ARCHITECT STAT Myoglobin Calibrators
- 2K43-10 ARCHITECT STAT Myoglobin Controls
- ARCHITECT i PRE-TRIGGER SOLUTION
- ARCHITECT i TRIGGER SOLUTION
- ARCHITECT i WASH BUFFER
- ARCHITECT i REACTION VESSELS
- ARCHITECT i SAMPLE CUPS
- ARCHITECT i SEPTUM
- ARCHITECT i 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 Myoglobin 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 inverting the bottle until the microparticles have been completely resuspended.
- If the microparticles do not resuspend, DO NOT USE. Contact your local Abbott 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 Myoglobin 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 cup 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: 80 μL for the first ARCHITECT STAT Myoglobin test plus 30 μL for each additional ARCHITECT STAT Myoglobin test from the same sample cup.
  - ≤ 3 hours on board: 150 μL for the first ARCHITECT STAT Myoglobin test plus 30 μL for each additional ARCHITECT STAT Myoglobin 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 Myoglobin Calibrators and Controls should be prepared according to their respective package inserts.
  - To obtain the recommended volume requirements for the ARCHITECT STAT Myoglobin 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.
    - Adds pre-trigger and trigger solutions.
    - Measures chemiluminescent emission to determine the quantity of myoglobin 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 myoglobin value exceeding 1200.0 ng/mL will be flagged as “>1200.0” 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 1:10 dilution of the specimen and automatically calculates the concentration of the specimen before dilution and reports the result.
- Specimens with a myoglobin value exceeding 12000.0 ng/mL are flagged with the code “>12000.0” when run using the Automated Dilution Protocol. These specimens may be diluted by following the Manual Dilution Procedure.

**Manual Dilution Procedure**

- Manual dilutions should be performed as follows:
  - The suggested dilution for a myoglobin test is 1:20.
  - Prior to diluting the specimen, dispense approximately 10 drops of ARCHITECT STAT Myoglobin Calibrator A into a clean test tube for use in the next step.
  - Transfer 190 μL of ARCHITECT STAT Myoglobin Calibrator A from the test tube prepared in the prior step into another clean test tube and add 10 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 40.0 ng/mL.
  - For detailed information on ordering dilutions, refer to the ARCHITECT System Operations Manual, Section 5.

**Calibration**

- To perform an ARCHITECT STAT Myoglobin calibration, test the Calibrators A, B, C, D, E, and F in duplicate. A single sample of each ARCHITECT STAT Myoglobin 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: 0.0 – 1200.0 ng/mL.
- Once an ARCHITECT STAT Myoglobin 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 Myoglobin assay is that a single sample of each control level be tested once every 24 hours each day of use. If laboratory quality control procedures require more frequent use of controls to verify test results, follow those procedures.

The ARCHITECT STAT Myoglobin 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 Myoglobin assay belongs to method group 1. Use ARCHITECT STAT Myoglobin Calibrators in place of MasterCheck as described in the ARCHITECT System Operations Manual, Appendix B.
**RESULTS**
Calculation
The ARCHITECT STAT Myoglobin 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 Myoglobin 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) × (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**
- For diagnostic purposes, the ARCHITECT STAT Myoglobin assay results should be used in conjunction with other data; e.g., other clinical testing, ECG, symptoms, clinical observations, 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 Myoglobin 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 Myoglobin 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, dietary, or environmental factors. Serial sampling may be required to detect elevated levels. Any condition resulting in skeletal or cardiac muscle damage can potentially increase myoglobin levels above the expected value. A reference range study was conducted based on guidance from the National Committee for Clinical Laboratory Standards (NCCLS) Protocol C28-A2. Human plasma specimens from apparently healthy individuals were evaluated in replicates of one.

**SPECIFIC PERFORMANCE CHARACTERISTICS**

**Precision**
The ARCHITECT STAT Myoglobin assay precision is ≤ 10% total CV for samples ≥ 40.0 ng/mL. A study was performed for the ARCHITECT STAT Myoglobin assay with guidance from the NCCLS Protocol EP5-A. ARCHITECT STAT Myoglobin 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</th>
<th>Mean % CV</th>
<th>Run SD</th>
<th>Total Run SD</th>
<th>% CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>A</td>
<td>80</td>
<td>1</td>
<td>56.9</td>
<td>2.0</td>
<td>3.6</td>
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<tr>
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<td>80</td>
<td></td>
<td>1</td>
<td>56.7</td>
<td>1.9</td>
<td>3.4</td>
<td>2.0</td>
<td>3.5</td>
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<tr>
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<td>Control</td>
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<td>A</td>
<td>62.3</td>
<td>2.2</td>
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<td>60.8</td>
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<td>3.4</td>
<td>2.3</td>
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<tr>
<td>C</td>
<td>80</td>
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<td>60.1</td>
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<td>3.8</td>
<td>2.4</td>
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<td>Medium Control</td>
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<td>324.9</td>
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<td>15.1</td>
<td>16.6</td>
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<td>80</td>
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<td>1</td>
<td>329.6</td>
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<td>12.0</td>
<td>3.6</td>
<td></td>
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<td>353.0</td>
<td>11.0</td>
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<td>12.8</td>
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<tr>
<td>Low MCC</td>
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<td>80</td>
<td>354.9</td>
<td>10.3</td>
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<tr>
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<td>337.2</td>
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<td>11.3</td>
<td>3.4</td>
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<td>C</td>
<td>80</td>
<td></td>
<td>1</td>
<td>337.6</td>
<td>12.0</td>
<td>3.6</td>
<td>12.7</td>
<td>3.8</td>
<td></td>
</tr>
</tbody>
</table>

**Population N 99 th Percentile (ng/mL)**

| Control | Female | 160 | 106.0 |
|         | Male   | 159 | 154.9 |
|         | Total  | 319 | 140.1 |

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

**Precision Profile**
Precision profile testing was performed with guidance from the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC). Human plasma panels ranging in concentration from 0.3 – 28.8 ng/mL were tested in replicates of two over 10 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 fitted curve. The lowest ARCHITECT STAT Myoglobin assay value exhibiting a 10% CV is 1.6 ng/mL.
Dilution Linearity

The ARCHITECT STAT Myoglobin assay recovers diluted specimens within 20% of the expected result. A dilution linearity study was performed evaluating ARCHITECT STAT Myoglobin using specimens with undiluted values that ranged between 300.1 and 1100.7 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 Expected Value (ng/mL)</th>
<th>% Recovery***</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>undiluted</td>
<td>300.1</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>1:2</td>
<td>162.2</td>
<td>10.3</td>
<td>160.3</td>
</tr>
<tr>
<td></td>
<td>1:10</td>
<td>46.5</td>
<td>18.5</td>
<td>48.5</td>
</tr>
<tr>
<td></td>
<td>1:50</td>
<td>25.8</td>
<td>20.2</td>
<td>26.2</td>
</tr>
<tr>
<td>2</td>
<td>undiluted</td>
<td>796.4</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>1:2</td>
<td>404.3</td>
<td>21.4</td>
<td>419.6</td>
</tr>
<tr>
<td></td>
<td>1:10</td>
<td>110.8</td>
<td>38.5</td>
<td>118.1</td>
</tr>
<tr>
<td></td>
<td>1:50</td>
<td>54.5</td>
<td>41.9</td>
<td>57.8</td>
</tr>
<tr>
<td>3</td>
<td>undiluted</td>
<td>1100.7</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>1:2</td>
<td>566.0</td>
<td>10.3</td>
<td>560.6</td>
</tr>
<tr>
<td></td>
<td>1:10</td>
<td>128.6</td>
<td>18.5</td>
<td>128.6</td>
</tr>
<tr>
<td></td>
<td>1:50</td>
<td>42.0</td>
<td>20.2</td>
<td>42.2</td>
</tr>
</tbody>
</table>

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

** Mean Expected Value includes endogenous myoglobin (ng/mL) found in the normal human plasma.

*** % Recovery = \( \frac{\text{Mean Observed Value (ng/mL)}}{\text{Mean Expected Value (ng/mL)}} \times 100 \)

Autodilution Verification

Recovery performance was evaluated for the autodilution method of the ARCHITECT STAT Myoglobin assay by testing specimens with undiluted values that ranged between 980.3 and 1170.3 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>1170.3</td>
<td>1148.8</td>
<td>98.2</td>
</tr>
<tr>
<td>2</td>
<td>980.3</td>
<td>928.9</td>
<td>94.8</td>
</tr>
<tr>
<td>3</td>
<td>1036.6</td>
<td>1010.8</td>
<td>97.5</td>
</tr>
<tr>
<td>4</td>
<td>1023.7</td>
<td>945.2</td>
<td>92.3</td>
</tr>
<tr>
<td>5</td>
<td>1063.1</td>
<td>998.6</td>
<td>93.9</td>
</tr>
</tbody>
</table>

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

** % Recovery = \( \frac{\text{Mean Observed Value (ng/mL)}}{\text{Mean Undiluted Value (ng/mL)}} \times 100 \)

Analytical Sensitivity

The ARCHITECT STAT Myoglobin analytical sensitivity is ≤ 1.0 ng/mL 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 ARCHITECT STAT Myoglobin Calibrator A (0.0 ng/mL) grand mean and represents the lowest concentration of myoglobin that can be distinguished from zero.

Analytical Specificity

The ARCHITECT STAT Myoglobin assay analytical specificity is ≤ 0.0001% cross-reactivity with hemoglobin. A study based on guidance from NCCLS Protocol EP7-A18 was performed using the ARCHITECT STAT Myoglobin assay. Specificity of the assay was determined by studying the cross-reactivity of hemoglobin in normal human plasma.*

Interference

Potential interference from elevated levels of bilirubin, hemoglobin, triglycerides, and total protein in the ARCHITECT STAT Myoglobin assay is ≤ 15% at the levels indicated in the following table. A study based on guidance from the NCCLS Protocol EP7-A18 was performed for the ARCHITECT STAT Myoglobin assay. Specimens with myoglobin levels between 50.3 and 167.5 ng/mL were supplemented with the following potentially interfering compounds.

<table>
<thead>
<tr>
<th>Substance</th>
<th>Potentially Interfering Substance 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 Other Potential Interferents

Potential interference from HAMA and rheumatoid factor (RF) in the ARCHITECT STAT Myoglobin assay is ≤ 15%. The ARCHITECT STAT Myoglobin assay was evaluated by testing specimens with HAMA and RF to further assess the clinical specificity. Specimens positive for HAMA and specimens positive for RF were evaluated for % interference with myoglobin levels spiked between 107.5 and 174.5 ng/mL. Mean absolute % interference is summarized in the following table.*

<table>
<thead>
<tr>
<th>Other Potential Interferents</th>
<th>Number of Specimens</th>
<th>Mean Absolute Interference</th>
</tr>
</thead>
<tbody>
<tr>
<td>HAMA Positive</td>
<td>10</td>
<td>7.7</td>
</tr>
<tr>
<td>RF Positive</td>
<td>10</td>
<td>12.6</td>
</tr>
</tbody>
</table>

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

Method Comparison

The ARCHITECT STAT Myoglobin method comparison correlation coefficient (r) is ≥ 0.90 when compared with AxSYM Myoglobin. The method comparison slope is 1.0 ± 0.15. A study was performed where lithium heparin plasma specimens were tested in replicates of one using ARCHITECT STAT Myoglobin over a period of three calibration cycles with three reagent lots on two instruments and compared with AxSYM Myoglobin. Data from this study were analyzed using the Passing-Bablok regression method and are summarized in the following table and scatter plot.*

ARCHITECT STAT Myoglobin vs. AxSYM Myoglobin

<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>234</td>
<td>0.987</td>
<td>2.738</td>
<td>0.989</td>
</tr>
</tbody>
</table>

| Sample Range (ARCHITECT STAT Myoglobin): 7.6 - 1188.7 ng/mL |
| Sample Range (AxSYM Myoglobin): 7.6 - 990.9 ng/mL |

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

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