ARCHITECT SYSTEM

CE

STAT CK-MB

IVD REF 2K42

840279/R3

STAT CK-MB

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

REF	List Number	LOT	Lot Number
IVD	*In Vitro* Diagnostic Medical Device		Expiration Date
2°C 8°C	Store at 2-8°C	REACTION VESSELS	Reaction Vessels
		SAMPLE CUPS	Sample Cups
	Consult instructions for use	SEPTUM	Septum
SN	Serial Number	REPLACEMENT CAPS	Replacement Caps
EC REP	Authorized Representative	REAGENT LOT	Reagent Lot
		ASSAY CD-ROM	Assay CD-ROM
	Manufacturer	CONTROL NO.	Control Number

See **REAGENTS** section for a full explanation of symbols used in reagent component naming.

ABBOTT
Diagnostics Division

NAME

ARCHITECT *STAT* CK-MB

INTENDED USE

ARCHITECT *STAT* CK-MB is a Chemiluminescent Microparticle Immunoassay (CMIA) 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).[6,7] MI is defined as myocardial cell death due to prolonged 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 CMIA 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.

* *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 *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 2[11] or other appropriate biosafety practices[12,13] 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.

Handling Precautions

- Do not use reagent kits beyond the expiration date.
- **Do not pool reagents within a kit or between reagent kits.**
- Prior to loading the ARCHITECT *STAT* CK-MB 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 Procedure** 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

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The ARCHITECT *STAT* CK-MB 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* CK-MB 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 on-board 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, you must initiate a scan to update the on-board 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 may be invalid and may require retesting. Assay recalibration may be necessary. For troubleshooting information, refer to the ARCHITECT System Operations Manual, Section 10.

INSTRUMENT PROCEDURE

- The ARCHITECT *STAT* CK-MB assay file must be installed on the ARCHITECT *i* System with *STAT* protocol capability from the ARCHITECT *i* Assay CD-ROM Addition B prior to 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* CK-MB 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* CK-MB assay.

	Glass	Plastic
Serum	• No additive (uncoated)	• Serum separator tubes
Plasma	• Lithium heparin • Plasma separator tubes with lithium heparin	• Lithium heparin • Plasma separator tubes with lithium heparin • Sodium heparin

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 *i* 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 *i* 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 *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
- 2K42-01 ARCHITECT *stat* CK-MB Calibrators
- 2K42-10 ARCHITECT *stat* CK-MB 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* 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 *i* 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 *i* 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.

- 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. Calibrators 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) 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 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).[14] 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.[15] The presence of heterophilic antibodies in a patient specimen may cause anomalous values to be observed.[15] Additional information may be required for diagnosis.
- ARCHITECT *STAT* CK-MB is not intended to be used on an ARCHITECT *i* 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 tube type utilized. Since CK-MB is released from damaged myocardium, CK-MB levels in normal individuals are often low or undetectable.[16] A reference range study was conducted based on guidance from National Committee for Clinical Laboratory Standards (NCCLS) Protocol C28-A2.[17] Plasma samples from apparently healthy individuals were evaluated in replicates of one using the ARCHITECT *STAT* CK-MB assay. The observed values are summarized in the following table.*

Population	n	99th Percentile (ng/mL)
Female	153	3.4
Male	157	7.2
TOTAL	310	6.6

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

The concentration of CK-MB in serum rises rapidly subsequent to myocardial infarction.[6,18] It is recommended that serial samples be drawn at intervals subsequent to initial symptoms for most accurate results.[18,19] Correlation with other clinical findings (e.g., ECG, symptoms, etc.) should be sought in evaluating the determined CK-MB levels.[16] 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.[20] CK-MB values which increase rapidly or which show an early time to peak may be indicative of reperfusion.[20-22]

Since low levels of CK-MB are present in other tissues,[3-5] a rise in CK-MB 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[23-26] due to CK-MB present in skeletal muscle.[27] Additionally, patients with acute skeletal muscle trauma,[28] dermatomyositis,[29] polymyositis[30] and muscular dystrophy[31] may exhibit elevated CK-MB and total CK levels. Renal failure,[32] tissue damage following surgery[33,34] and cardiac contusion[35] 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.

$$\text{Relative \% Index} = \frac{\text{ARCHITECT } \textit{STAT} \text{ CK-MB value (ng/mL)}}{\text{Total CK (U/L)}} \times 100$$

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 NCCLS Protocol EP5-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.*

Sample	Instrument	Reagent Lot	n	Mean Conc. (ng/mL)	Within Run SD	Within Run % CV	Total SD	Total % CV
	1	A	80	7.1	0.24	3.3	0.25	3.6
		B	80	7.2	0.29	4.1	0.31	4.3
Low		C	80	7.0	0.25	3.6	0.28	4.0
Control	2	A	80	7.6	0.27	3.5	0.30	4.0
		B	80	7.5	0.28	3.7	0.29	3.9
		C	80	7.3	0.29	3.9	0.32	4.3
	1	A	80	30.3	0.94	3.1	1.09	3.6
		B	80	31.9	1.39	4.4	1.44	4.5
Medium		C	80	30.4	1.12	3.7	1.21	4.0
Control	2	A	80	30.7	1.00	3.3	1.09	3.6
		B	80	30.3	1.21	4.0	1.23	4.1
		C	80	30.9	1.15	3.7	1.30	4.2
	1	A	80	80.1	2.45	3.1	2.69	3.4
		B	80	85.8	2.64	3.1	3.18	3.7
High		C	80	80.6	2.92	3.6	3.51	4.3
Control	2	A	80	80.0	3.24	4.0	3.53	4.4
		B	80	79.8	3.15	3.9	3.41	4.3
		C	80	81.6	2.92	3.6	3.58	4.4
	1	A	80	5.4	0.13	2.5	0.15	2.9
		B	80	5.4	0.16	3.0	0.20	3.6
Panel 1		C	80	5.4	0.19	3.6	0.23	4.2
	2	A	80	5.8	0.20	3.4	0.24	4.1
		B	80	5.8	0.20	3.5	0.21	3.7
		C	80	5.6	0.17	3.0	0.21	3.6
	1	A	80	14.1	0.34	2.4	0.42	3.0
		B	80	15.1	0.46	3.0	0.47	3.1
Panel 2		C	80	14.3	0.33	2.3	0.42	3.0
	2	A	80	14.7	0.40	2.7	0.47	3.2
		B	80	14.8	0.35	2.4	0.43	2.9
		C	80	14.7	0.55	3.7	0.57	3.9

* 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).[38] Fourteen human plasma panels ranging in concentration from 0.5 – 5.5 ng/mL were tested in replicates of 2 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* CK-MB assay value exhibiting a 10% CV is 4.6 ng/mL.

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.*

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

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

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

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

Autodilution Verification

Recovery performance was evaluated for the autodilution method of the ARCHITECT *STAT* 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.*

Sample ID	Mean Undiluted Value (ng/mL)	Mean Observed Value (ng/mL)	% Recovery**
1	128.3	119.4	93
2	169.7	164.0	97
3	260.8	268.1	103
4	273.3	304.6	111
5	278.2	264.2	95

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

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

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 NCCLS Protocol EP7-A[39] 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.*

Cross-reactant	Cross-reactant Concentration (ng/mL)	% Cross-reactivity
CK-BB	10,000	0.01
CK-MM	10,000	0.00

* 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 based on guidance from the NCCLS Protocol EP7-A[39] 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.

Potentially Interfering Substance	Potentially Interfering Substance Concentration
Bilirubin	20 mg/dL
Hemoglobin	500 mg/dL
Total Protein (Low)	4 g/dL
Total Protein (High)	10 g/dL
Triglycerides	1000 mg/dL

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.*

Clinical Condition	Number of Specimens	Mean Absolute % Interference
HAMA Positive	10	5.6
RF Positive	10	3.9

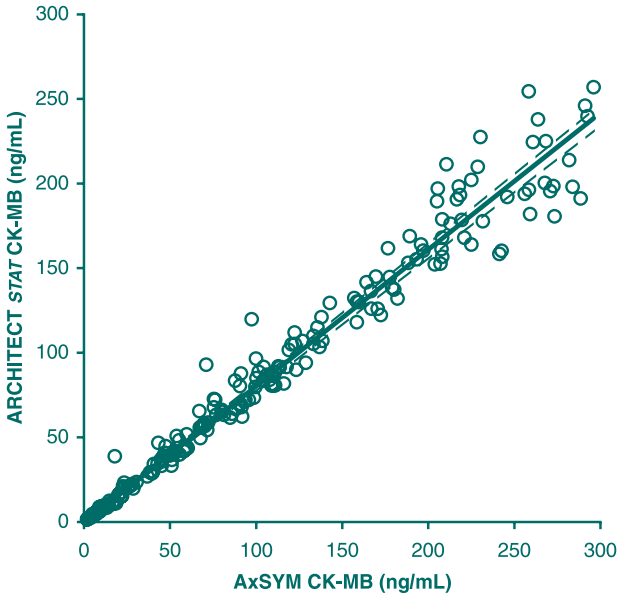
* Representative data; results in individual laboratories may vary from these data.

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 *STAT* CK-MB over a period of three calibration cycles with three reagent lots on three instruments and compared with AxSYM CK-MB. Data from this study were analyzed using the Passing-Bablok[40] regression method and are summarized in the following table and scatter plot.*

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

Regression Method	n	Slope (95% CI)	Intercept (95% CI)	Correlation Coefficient (r)
Passing-Bablok**	201	0.81 (0.79 to 0.82)	-0.51 (-1.16 to 0.14)	0.985



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

Sample Range (AxSYM CK-MB): 1.8-296.0 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.

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Abbott Laboratories
Diagnostics Division
Abbott Park, IL 60064, USA

EC REP
ABBOTT
Max-Planck-Ring 2
65205 Wiesbaden
Germany
+49-6122-580

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Fisher Scientific, 8365 Valley Pike,
Middletown, VA 22645, USA
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