TruQuick™ CK-MB 10T

A rapid test for the diagnosis of myocardial infarction (MI) to detect CK-MB qualitatively in whole blood, serum or plasma.

REF **TQ3010** IVD **Rx Only**

INTENDED USE
TruQuick CK-MB is a rapid chromatographic immunoassay for the qualitative detection of human CK-MB in whole blood, serum or plasma as an aid in the diagnosis of myocardial infarction (MI).

SUMMARY AND EXPLANATION OF THE TEST
Creatine Kinase MB (CK-MB) is an enzyme present in the cardiac muscle with a molecular weight of 87.0 kDa.[1] Creatine Kinase is a dimeric molecule formed from two subunits designated as "M" and "B" which combine to form three different isoenzymes, CK-MM, CK-BB, and CK-MB. CK-MB is the isoenzyme of Creatine Kinase most involved in the metabolism of cardiac muscle tissue.[2]

The release of CK-MB into the blood following MI can be detected within three to eight hours after the onset of symptoms. It peaks within nine to 30 hours, and returns to baseline levels within 48 to 72 hours.[3] CK-MB is one of the most important cardiac markers and is widely recognized as the traditional marker for the diagnosis of MI.

TruQuick CK-MB is a simple test that utilizes a combination of antibody coated particles and capture reagents to qualitatively detect CK-MB in whole blood, serum or plasma. The minimum detection level is 5 ng/mL CK-MB.

BIOLOGICAL PRINCIPLES
TruQuick CK-MB is a qualitative, membrane based immunoassay for the detection of CK-MB in whole blood, serum or plasma. The membrane is precoated with specific capture antibodies in each of the test line regions of the test. During testing, the whole blood, serum or plasma specimen reacts with the particle coated with specific antibodies. The mixture migrates upward on the membrane chromatographically by capillary action to react with specific capture reagents on the membrane and generate a colored line. The presence of this colored line in the specific test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS/MATERIALS PROVIDED
The maximum number of tests obtained from this test kit is listed on the outer box.
- Test Cassettes: The test contains anti-CK-MB antibody-conjugated colloid gold particles and capture reagents coated on the membrane.
- Buffer: A buffered solution containing Proclin 300 as a preservative. The Buffer is supplied in a dropper vial ready for use.
- Droppers
- Package insert

MATERIALS NOT PROVIDED
- Specimen collection Containers
- Centrifuge
- Timer

For fingerstick whole blood
- Lancets
- Heparinized capillary tubes and dispensing bulb

PRECAUTIONS
1. For in vitro diagnostic use only. Do not use after expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Do not use test if pouch is damaged.
4. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
6. The used test should be discarded according to local regulations.
7. Humidity and temperature can adversely affect results.

HAZARD and PRECAUTIONARY STATEMENTS
Refer to the SDS, available at www.meridianbioscience.com for Hazard and Precautionary Statements.

SHELF LIFE AND STORAGE
Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30 C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use after the expiration date.

SPECIMEN COLLECTION AND PREPARATION
1. TruQuick CK-MB can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
2. To collect **Fingerstick Whole Blood specimens**:
   - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
   - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
   - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
   - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.

   Add the Fingerstick Whole Blood specimen to the test by using **a capillary tube**:
   - Touch the end of the capillary tube to the blood until filled to approximately 75 µL. Avoid air bubbles.
   - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen area of the test cassette.

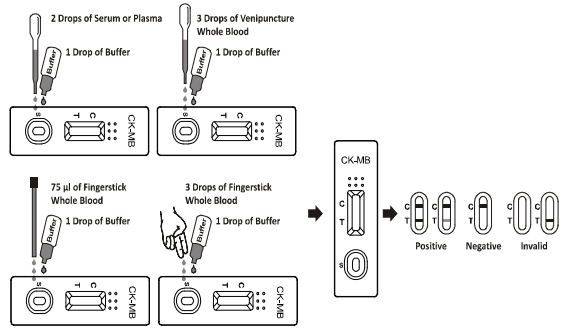
   Add the Fingerstick Whole Blood specimen to the test by using **hanging drops**:
   - Position the patient's finger so that the drop of blood is just above the specimen area of the test cassette.
   - Allow three hanging drops of fingerstick whole blood to fall into the center of the specimen area on the test cassette, or move the patient's finger so that the hanging drop touches the center of the specimen area. Avoid touching the finger directly to the specimen area.
3. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clearnon-hemolyzed specimens.
4. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8 C for up to three days. For long term storage, specimens should be kept below -20 C. Whole blood collected by venipuncture should be stored at 2-8 C if the test is to be run within two days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
5. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
6. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

TEST PROCEDURE
Allow the test, specimen, Buffer and/or controls to reach room temperature (15-30 C) prior to testing.
1. Bring the pouch to room temperature before opening it. Remove the Test Cassette from the sealed pouch and use it within one hour.
2. Place the cassette on a clean and level surface.

   For **Serum or Plasma** specimen:
   - Hold the dropper vertically and transfer **2 drops of serum or plasma (approximately 50 µL)** to the specimen area, then **add 1 drops of Buffer** (approximately **40 µL**), and start the timer. See illustration below.

   For **Venipuncture Whole Blood** specimen:
   - Hold the dropper vertically and transfer **3 drops of whole blood** (approximately **75 µL**) to the specimen area, then **add 1 drops of Buffer** (approximately **40 µL**), and start the timer. See illustration below.

   For **Fingerstick Whole Blood** specimen:
   - To use a capillary tube: Fill the capillary tube **and transfer approximately 75 µL of fingerstick whole blood specimen** to the specimen area of Test Cassette, then **add 1 drop of Buffer** (approximately 40 µL) and start the timer. See illustration below.
   - To use hanging drops: Allow **3 hanging drops of fingerstick whole blood specimen** (approximately 75 µL) to fall into the specimen area of Test Cassette, then **add 1 drop of Buffer** (approximately 40 µL) and start the timer. See illustration below.
3. Wait for the colored line(s) to appear. Read results at 10 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS
(Please refer to the illustration above.)
POSITIVE: *A colored line in the control line region (C) and the presence of one or more colored lines in the test line regions indicates a positive result. This indicates that the concentration of CK-MB is above the minimum detection level.
***NOTE:** The intensity of the color in the test line region(s) will vary depending on the concentration of CK-MB present in the specimen. Therefore, any shade of color in the test line regions should be considered positive.
NEGATIVE: One colored line appears in the control line region (C). No line appears in the test line region (T). This indicates that the concentration of CK-MB are below the minimum detection levels.
INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL
This test should be performed per applicable local, state, or federal regulations or accrediting agencies.
A procedural control is included in the test. A colored line appearing in the control line region(C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

External controls are not supplied with this kit; however, it is recommended that positive and negative external controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

If the expected control reactions are not observed, repeat the control tests as the first step in determining the root cause of the failure. If control failures are repeated please contact Meridian's Technical Services Department at 1-800-343-3858 (US) or your local distributor.

EXPECTED VALUES
TruQuick CK-MB has been compared with a leading commercial Myoglobin/CK-MB/cTnI EIA test, demonstrating an overall correlation of 99.4% with CK-MB.

LIMITATIONS OF THE PROCEDURE
1. TruQuick CK-MB is for in vitro diagnostic use only. This test should be used for the detection of CK-MB in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in CK-MB can be determined by this qualitative test.
2. TruQuick CK-MB will only indicate the qualitative level of CK-MB in the specimen and should not be used as the sole criteria for the diagnosis of myocardial infarction.
3. TruQuick CK-MB cannot detect less than 5 ng/mL CK-MB in specimens. A negative result at any time does not preclude the possibility of myocardial infarction.
4. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
5. Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor (RF) may affect expected results. Even if the test results are positive, further clinical evaluation should be considered with other clinical information available to the physician.
6. There is a slight possibility that some whole blood specimens with very high viscosity or which have been stored for more than two days may not run properly on the Test Cassette. Repeat the test with a serum or plasma specimen from the same patient using a new Test Cassette.

SPECIFIC PERFORMANCE CHARACTERISTICS
Sensitivity and Specificity
TruQuick CK-MB was evaluated with a leading commercial CK-MB ELISA test using clinical specimens. The results show that relative to leading ELISA tests, TruQuick CK-MB shows > 99.9% sensitivity and 99.4% specificity for CK-MB.

TruQuick CK-MB vs ELISA

Method		ELISA		Total Result
TruQuick CK-MB	Results	Positive	Negative	
	Positive	62	3	65
	Negative	0	468	468
Total Result		62	471	533

Sensitivity: 62/62 = > 99.9% (95% CI*: 95.3%~100.0%);
Specificity: 468/471 = 99.4% (95% CI*: 98.1%~99.9%);
Correlation: (62+468)/(62+3+468) = 99.4% (95% CI*: 98.4%~99.9%).
*Confidence Intervals

REPRODUCIBILITY
Intra-Assay Precision
Within-run precision was determined by using 15 replicates of below five specimens: CK-MB specimen levels at 0 ng/mL, 5 ng/mL, 10 ng/mL, 20 ng/mL and 40 ng/mL. The specimens were correctly identified > 99% of the time.
Inter-Assay Precision
Between-run precision was determined by three independent assays on the same five specimens: 0 ng/mL, 5 ng/mL, 10 ng/mL, 20 ng/mL, and 40 ng/mL of CK-MB. Three different lots of TruQuick CK-MB were tested using these specimens. The specimens were correctly identified > 99% of the time.

CROSSREACTIVITY
TruQuick CK-MB was tested by 3,200 ng/mL CK-MM, 1,700 ng/mL CK-BB, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, syphilis, anti-HIV, anti-*H. pylori*, MONO, anti-CMV, anti-Rubella and anti-Toxoplasmosis positive specimens. The results showed no crossreactivity.

TESTS FOR INTERFERING SUBSTANCES
The following potentially interfering substances were added to CK-MB negative and positive specimens respectively.

Acetaminophen 20 mg/dL	Caffeine 20 mg/dL	Bilirubin 1,000 mg/dL
Acetylsalicylic Acid 20 mg/dL	Creatin 200 mg/dL	Oxalic Acid 600 mg/dL
Gentisic Acid 20 mg/dL	Ascorbic Acid 20 mg/dL	Cholesterol 800 mg/dL
Hemoglobin 1,000 mg/dL	Albumin 10,500 mg/dL	Triglycerides 1,600 mg/dL

None of the substances interfered in the assay at the concentration tested.

REFERENCES

1. Apple FS, Preese LM. Creatine kinase-MB: detection of myocardial infarction and monitoring reperfusion. J Clin Immunoassay. 1994;17:24-9.
2. Lee TH, Goldman L. Serum enzyme assays in the diagnosis of acute myocardial infarction. Ann Intern Med. 1986;105:221-233.
3. Kallner A, Sylven C, Brodin U, et al. Early diagnosis of acute myocardial infarction; a comparison between chemical predictors. Scand J Clin Lab Invest. 1989;49:633-9.

Manufactured By

Meridian Bioscience, Inc.
USA/Corporate Office
3471 River Hills Drive
Cincinnati, Ohio 45244
Telephone: 513.271.3700
Orders/Customer Service:
800.543.1980
Technical Support Center:
800.343.3858
Information Fax: 513.272.5432
Ordering Fax: 513.271.0124

EC REP
Authorized Representative

Meridian Bioscience Europe S. r. L
Via dell' Industria, 7
20020 Villa Cortese, Milano
ITALY
Tel: +39 0331 43 36 36
Fax: +39 0331 43 36 16
Email: info@meridianbioscience.eu
WEB: www.meridianbioscience.eu

SYMBOL USAGE
You may see one or more of these symbols on the labeling/packaging of this product:
Key guide to symbols

	Use By	CONTROL +	Positive control
LOT	Batch Code	CONTROL −	Negative control
IVD	In vitro diagnostic medical device	EC REP	Authorized Representative in the European Community
CE	This product fulfills the requirements of Directive 98/79/EC on in vitro diagnostic medical devices	SMP PREP DIL SPE	Sample Preparation Apparatus containing Sample Diluent
REF	Catalogue number		Do not freeze
	Consult Instructions for Use	BUF RXN	Reaction Buffer
	Manufacturer		For IVD Performance Evaluation Only
Σ	Contains sufficient for <n> tests	SOLN STOP	Stopping Solution
	Temperature limitation	CONJ ENZ	Enzyme Conjugate
SN	Serial number	CONTROL	Assay Control
TEST	Test Device	REAG	Reagent
	Date of manufacture	BUF WASH	Wash Buffer
BUF	Buffer		Warning
CONJ	Conjugate	DIL SPE	Specimen Diluent (or Sample Diluent)
SUBS	Substrate	BUF WASH 20X	Wash Buffer Concentration: 20X
RUO	Research Use Only	DET REAG	Detection Reagent
IUO	Investigational Use Only	Rx Only	Prescription Use Only
	Do not use if package is damaged		

For technical assistance, call Technical Support Services at 800-343-3858 between the hours of 8AM and 6PM, USA Eastern Standard Time. To place an order, call Customer Service Department at 800-543-1980.