TruQuick™ MYO/CK/cTnI Combo 10T

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

REF **TQ3710** IVD **Rx Only**

INTENDED USE

TruQuick MYO/CK/cTnI Combo is a rapid chromatographic immunoassay for the qualitative detection of human Myoglobin, CK-MB and cardiac Troponin I (cTnI) in whole blood, serum or plasma as an aid in the diagnosis of myocardial infarction (MI).

SUMMARY AND EXPLANATION OF THE TEST

Myoglobin (MYO), Creatine Kinase MB (CK-MB) and cardiac Troponin I (cTnI) are proteins released into the bloodstream after cardiac injury. Myoglobin is a heme-protein normally found in skeletal and cardiac muscle with a molecular weight of 17.8 kDa.[1] When muscle cells are damaged, Myoglobin is released into the blood rapidly due to its relatively small size. The level of Myoglobin increases measurably above baseline within two to four hours post-infarct, peaking at nine to 12 hours, and returning to baseline within 24-36 hours.[2, 3] CK-MB is an enzyme also present in the cardiac muscle, with a molecular weight of 87.0 kDa.[4] 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.[5] The release of CK-MB into the blood following an 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.[6] Cardiac Troponin I is a protein found in cardiac muscle, with a molecular weight of 22.5 kDa.[7] Troponin I is part of a three subunit complex comprised of Troponin T and Troponin C. Along with tropomyosin, this structural complex forms the main component that regulates the calcium sensitive ATPase activity of actomyosin in striated skeletal and cardiac muscle.[8] After cardiac injury occurs, Troponin I is released into the blood four to six hours after the onset of pain. The release pattern of Troponin I is similar to CK-MB, but while CK-MB levels return to normal after 72 hours, Troponin I remains elevated for six to 10 days, thus providing for a longer window of detection for cardiac injury.

TruQuick MYO/CK/cTnI Combo is a simple test that utilizes a combination of antibody-coated particles and capture reagents to qualitatively detect Myoglobin, CK-MB and cardiac Troponin I (cTnI) in whole blood, serum or plasma. The minimum detection level is 50 ng/mL Myoglobin, 5 ng/mL CK-MB and 0.5 ng/mL Troponin I.

BIOLOGICAL PRINCIPLES

TruQuick MYO/CK/cTnI Combo is a qualitative, membrane based immunoassay for the detection of Myoglobin, CK-MB and cardiac Troponin I (cTnI) 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-Myoglobin antibody conjugated colloid gold particles, anti-CK-MB antibody conjugated colloid gold particles, anti-Troponin I antibody conjugated colloid gold particles, and capture reagents coated on the membrane. Each cassette is packaged in a foil pouch.
- 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.

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 MYO/CK/cTnI Combo 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.

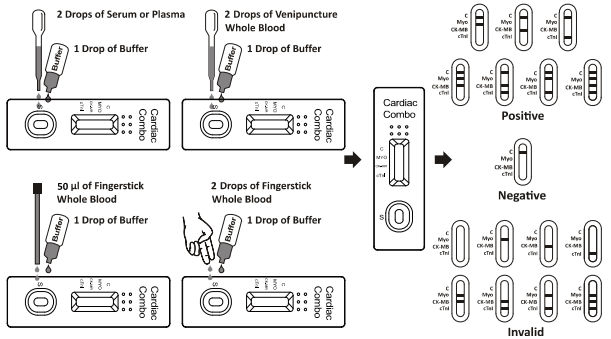
   Add the Fingerstick Whole Blood specimen to the test by using **a capillary tube**:
   - Touch the end of the capillary tube to the blood until filled to approximately 50 µL. Avoid air bubbles.
   - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood 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 two 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 clear non-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 two 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. Remove the Test Cassette from the sealed pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the Test 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 and **add 1 drop of Buffer** (approximately 40 µL) then start the timer. See illustration below.
   For **Venipuncture Whole Blood** specimen:
   Hold the dropper vertically and **transfer 2 drops of whole blood** (approximately 50 µL) to the specimen well (S) of the Test Cassette, then **add 1 drops of Buffer** (approximately **40 µL**) then start the timer. See illustration below.
   For **Fingerstick Whole Blood** specimen:
   To use a capillary tube: Fill the capillary tube and **transfer approximately 50 µL of fingerstick whole blood specimen** to the specimen well (S) of the Test Cassette and **add 1 drop of Buffer** (approximately 40 µL) then start the timer. See illustration below.
3. The results should be read 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 Myoglobin, CK-MB and/or cardiac Troponin I 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 Myoglobin, CK-MB and/or cardiac Troponin I 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 Myoglobin, CK-MB and cardiac Troponin I 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 Meridian's Technical Services Department at 800-343-3858 or your local distributor.

QUALITY CONTROL

Internal procedural controls are 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 MYO/CK/cTnI Combo was compared with a leading commercial Myoglobin ELISA, CK-MB ELISA, cTnI ELISA test, demonstrating an overall accuracy of 97.5% with Myoglobin, 99.1% with cardiac Troponin I (cTnI), 99.4% with CK-MB.

LIMITATIONS OF THE PROCEDURE

1. TruQuick MYO/CK/cTnI Combo is for in vitro diagnostic use only. This test should be used for the detection of Myoglobin, CK-MB, and cardiac Troponin I (cTnI) in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in Myoglobin, CK-MB and cardiac Troponin I can be determined by this qualitative test.
2. TruQuick MYO/CK/cTnI Combo will only indicate the qualitative level of Myoglobin, CK-MB and Troponin I in the specimen and should not be used as the sole criteria for the diagnosis of myocardial infarction.
3. TruQuick MYO/CK/cTnI Combo cannot detect less than 50 ng/mL Myoglobin, 5 ng/mL CK-MB and 0.5 ng/mL cardiac Troponin I (cTnI) 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 MYO/CK/cTnI Combo was evaluated with a leading commercial Myoglobin/CK-MB/cTnI EIA test using clinical specimens. The results show that relative to leading EIA tests, TruQuick MYO/CK/cTnI Combo shows 99.9% sensitivity and 97.2% specificity for Myoglobin, 99.4% sensitivity and 99.0% specificity for cardiac Troponin I (cTnI), and 99.9% sensitivity and 99.4% specificity for CK-MB.

Myoglobin Rapid Test vs. EIA

Method		EIA		Total Result
	Results	Positive	Negative	
Myoglobin	Positive	54	11	65
	Negative	0	379	379
Total Result		54	390	444

Sensitivity: 99.9% (95% CI*: 94.6%~100.0%);
Specificity: 97.2% (95% CI*: 95.0%~98.6%);
Correlation: 97.5% (95% CI*: 95.6%~98.8%). *Confidence Intervals

TruQuick MYO/CK/cTnI Combo vs. EIA

Method		EIA		Total Result
	Results	Positive	Negative	
TruQuick MYO/CK/cTnI Combo	Positive	62	3	65
	Negative	0	468	468
Total Result		62	471	533

Sensitivity: 99.9% (95% CI*: 95.3%~100.0%);
Specificity: 99.4% (95% CI*: 98.1%~99.9%);
Correlation: 99.4% (95% CI*: 98.4%~99.9%). *Confidence Intervals

Cardiac Troponin I Rapid Test vs. EIA

Method		EIA		Total Result
	Results	Positive	Negative	
Cardiac Troponin I	Positive	172	5	177
	Negative	1	472	473
Total Result		173	477	650

Sensitivity: 99.4% (95% CI*: 96.8%~99.9%);
Specificity: 99.0% (95% CI*: 97.6%~99.7%);
Correlation: 99.1% (95% CI*: 98.0%~99.7%) *Confidence Intervals

REPRODUCIBILITY

Intra-Assay Precision

Within-run precision was determined by using 15 replicates of below 15 specimens: Myoglobin specimen levels at 0 ng/mL, 50 ng/mL, 100 ng/mL, 200 ng/mL and 400 ng/mL, CK-MB specimen levels at 0 ng/mL, 5 ng/mL, 10 ng/mL, 20 ng/mL and 40 ng/mL and cardiac Troponin I (cTnI) specimen levels at 0 ng/mL, 1.0 ng/mL, 5.0 ng/mL, 10 ng/mL and 40 ng/mL. The specimens were correctly identified > 99% of the time.

Inter-Assay Precision

Between-run precision was determined by 3 independent assays on the same 15 specimens: 0 ng/mL, 50 ng/mL, 100 ng/mL, 200 ng/mL and 400 ng/mL of Myoglobin, 0 ng/mL, 5 ng/mL, 10 ng/mL, 20 ng/mL, and 40 ng/mL of CK-MB and 0 ng/mL, 1.0 ng/mL, 5 ng/mL, 10 ng/mL and 40 ng/mL of cardiac Troponin I (cTnI). Three different lots of TruQuick MYO/CK/cTnI Combo were tested using these specimens. The specimens were correctly identified > 99% of the time.

CROSSREACTIVITY

TruQuick MYO/CK/cTnI Combo were tested by Skeletal Troponin I, Troponin T, Cardiac Myosin, CK-MM, CK-BB, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, syphilis, anti-HIV, anti-*H. pylori*, Mononucleosis, 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 Myoglobin, CK-MB and/or cardiac Troponin I (cTnI) negative and positive specimens, respectively.

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

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

REFERENCES

1. Wong SS. Strategic utilization of cardiac markers for diagnosis of acute myocardial infarction. Ann Clin Lab Sci. 1996;26:301-12.
2. Kagen LJ. Myoglobin methods and diagnostic uses. CRC Crit. Rev. Clin. Lab. Sci. 1978;2:273.
3. Chapelle JP. et al. Serum myoglobin determinations in the assessment of acute myocardial infarction. Eur. Heart Journal. 1982;3:122.
4. Apple FS, Preese LM. Creatine kinase-MB: detection of myocardial infarction and monitoring reperfusion. J Clin Immunoassay. 1994;17:24-9.
5. Lee TH, Goldman L. Serum enzyme assays in the diagnosis of acute myocardial infarction. Ann Intern Med. 1986;105:221-233.
6. 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.
7. Adams JE, et al. Biochemical markers of myocardial injury. Is MB creatine kinase the choice for the 1990s? Immunoassay Circulation. AMA. 1993;88:750-763.
8. Mehegan JP, Tobacman LS. Cooperative interaction between troponin molecules bound to the cardiac thin filament. J.Biol.Chem. 1991;266:966.

CE

SNTQ3710 **REV. 05/17**

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	R_x 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.