# TruQuick™ H-FABP 10T

**A rapid test for the diagnosis of acute myocardial infarction (AMI) to detect Heart Type Fatty Acid-Binding Protein (H-FABP) qualitatively in whole blood, serum or plasma.**

REF **TQ3610** IVD **Rx Only**

## INTENDED USE
TruQuick H-FABP is a rapid chromatographic immunoassay for the qualitative detection of human H-FABP in whole blood, serum or plasma as an aid in the diagnosis of acute myocardial infarction (AMI).

## SUMMARY AND EXPLANATION OF THE TEST
FABP is a newly introduced plasma marker of acute myocardial infarction (AMI). The plasma kinetics of FABP (15 kD) closely resemble those of myoglobin in that elevated plasma concentrations are found within two hours after AMI and return to normal generally within 18 to 24 hours. But the concentration of FABP in the skeletal muscle is 20 times lower than in cardiac tissue (for myoglobin the same content for cardiac and skeletal tissue), that makes FABP to be more cardiac specific than myoglobin. This makes FABP a useful biochemical marker for the early assessment or exclusion of AMI. FABP also appears to be a useful plasma marker for the estimation of myocardial infarct size. FABP is suitable for use as a standard in immunoassay for early detection of acute myocardial infarction, immunogen for antisera production, mass FABP standard, FABP biochemical and immunochemical studies, tracer for iodination.

## BIOLOGICAL PRINCIPLES
TruQuick H-FABP is a qualitative, membrane based immunoassay for the detection of Heart-type Fatty Acid-Binding Protein (H-FABP) in whole blood, serum or plasma. In this test procedure, capture reagent is immobilized in the test line region of the test. After specimen is added to the specimen area of the cassette, it reacts with anti-H-FABP antibody coated colloid gold particles in the test. This mixture migrates chromatographically along the length of the test and interacts with the immobilized capture reagent. The test format can detect H-FABP in specimens. If the specimen contains Heart-type Fatty Acid-Binding Protein (H-FABP), a colored line will appear in the test line region, indicating a positive result. If the specimen does not contain Heart-type Fatty Acid-Binding Protein (H-FABP), a colored line will not appear in this region, indicating 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-H-FABP antibody-coated colloid gold particles and capture reagent coated on the membrane.
- Buffer: A buffered solution containing Proclin 300 as a preservative. The Buffer is supplied in ready to use dropper vials.
- 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 H-FABP 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.

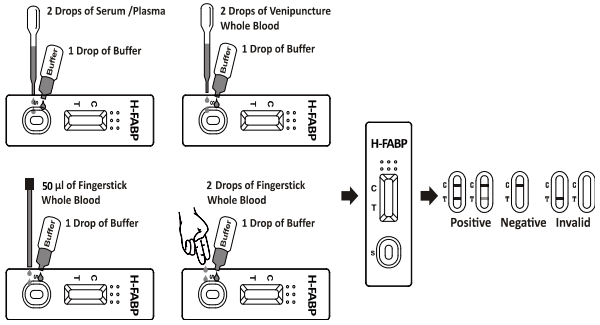
   Add the Fingerstick Whole Blood specimen to the test by using **a capillary tube**:
   - Touch the end of the capillary tube to the blood until filled to approximately 50 µL. Avoid air bubbles.
   - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood 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.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear nonhemolyzed specimens.
- 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 one day of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- 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.
- 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 **2 drops of whole blood** (approximately **50 µL**) to the specimen area, then **add 1 drop 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 50 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 **2 hanging drops of fingerstick whole blood** specimen (approximately 50 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: *Two lines appear.** One colored line should be in the control line region (C) and another colored line should be in the test line region (T).
***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of Fatty Acid-Binding Protein (H-FABP) present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.
**NEGATIVE: One colored line appears in the control line region (C).** No line appears in the test line region (T).
**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
***This test should be performed per applicable local, state, or federal regulations or accrediting agencies.***
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 H-FABP has been compared with a leading commercial H-FABP EIA test, demonstrating an overall correlation of 90.7%.

## LIMITATIONS OF THE PROCEDURE
1. TruQuick H-FABP is for in vitro diagnostic use only. This test should be used for the detection of Fatty Acid-Binding Protein (H-FABP) in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in H-FABP can be determined by this qualitative test.
2. TruQuick H-FABP will only indicate presence/absence of H-FABP above a particular level in the specimen and should not be used as the sole criteria for the diagnosis of acute myocardial infarction.
3. TruQuick H-FABP cannot detect H-FABP at a concentration less than 8 ng/mL in specimens. A negative result at any time does not preclude the possibility of acute 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 levels 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 one day 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 H-FABP was evaluated with a leading commercial H-FABP EIA test using clinical specimens. The results show that the sensitivity of TruQuick H-FABP is 89.9% and the specificity is 91.0% relative to the leading EIA test.

| Method | | EIA | | Total Result |
|---|---|---|---|---|
| TruQuick H-FABP (Whole Blood/Serum/Plasma) | Results | Positive | Negative | |
| | Positive | 62 | 19 | 81 |
| | Negative | 7 | 193 | 200 |
| Total Result | | 69 | 212 | 281 |

Sensitivity: 62/69 = 89.9% (95% CI*: 80.2%~95.8%);
Specificity: 193/212 = 91.0% (95% CI*: 86.4%~94.5%);
Correlation: (62+193)/(62+7+19+193) = 90.7%(95% CI*: 86.7%~93.9%). *Confidence Intervals

## REPRODUCIBILITY
**Intra-Assay Precision**
Within-run precision was determined by using 15 replicates of five specimens: H-FABP negative, H-FABP 8 ng/mL, H-FABP 10 ng/mL, H-FABP 20 ng/mL and H-FABP 50 ng/mL. The samples were correctly identified > 99% of the time.
**Inter-Assay Precision**
Between-run precision was determined by 15 independent assays on the same five specimens: H-FABP negative, H-FABP 8 ng/mL, H-FABP 10 ng/mL, H-FABP 20 ng/mL and H-FABP 50 ng/mL . Three different lots of TruQuick H-FABP were tested. The samples were correctly identified > 99% of the time.

## CROSSREACTIVITY
TruQuick H-FABP was tested with specimens containing 10,000 ng/mL Skeletal Troponin I, 2,000 ng/mL Troponin T, 20,000 ng/mL Cardiac Myosin, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, Syphilis, anti-HIV, anti-*H. pylori*, Mononucleosis, anti-CMV, anti-Rubella and anti-Toxoplasmosis. The samples showed no crossreactivity.

## TESTS FOR INTERFERING SUBSTANCES
The following potentially interfering substances were added to H-FABP negative and positive serum and plasma pools.

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

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

**REFERENCES**


1. Oktay B, et al. Evaluation of the relationship between heart type fatty acid binding protein levels and the risk of cardiac damage in patients with obstructive sleep apnea syndrome. Sleep Breath 2008;12(3), 223-228.
2. Lescuyer P, et al. Heart-fatty acid-binding protein as a marker for early detection of acute myocardial infarction and stroke. Mol Diagn. 2005;9(1),1-7.
3. Akbal E, et al. Serum heart type fatty acid binding protein levels in metabolic syndrome. Endocrine 2009;36(3), 433-437.
4. Petzold T, et al. Heart-type fatty acid binding protein (hFABP) in the diagnosis of myocardial damage in coronary artery bypass grafting. Eur J Cardiothorac Surg. 2001;19(6), 859-864.
5. Storch J, Thumser AE. The fatty acid transport function of fatty acid-binding proteins. Biochim Biophys Acta. 2000;1486, 28–44.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**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.