RAPID BIOTEC™

CE IVD

High-Sensitivity Cardiac Troponin I Test Device (Whole Blood/Serum/Plasma)

CATALOGUE NUMBER
D-FIhsCTID10/D-FIhsCTID25

A Fluorescence Immunoassay for the quantitative detection of cardiac Troponin I (cTnI) in human whole blood, serum or plasma with the use of the Fluorescence Immunoassay Analyzer. For professional in vitro diagnostic use only.

INTENDED USE

The High-Sensitivity Cardiac Troponin I Test Device (Whole Blood/Serum/Plasma) is intended for the *in vitro* quantitative detection of human cardiac Troponin I (cTnI) in human whole blood, serum or plasma as an aid in the diagnosis of Myocardial Infarction (MI).

SUMMARY

Cardiac Troponin I (cTnI) is a protein found in cardiac muscle with a molecular weight of 22.5 kDa.[1] Troponin I is part of a three subunit complex comprising 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.[2] After cardiac injury occurs, Troponin I is released into the blood 4-6 hours after the onset of pain. The release pattern of cTnI is similar to CK-MB, but while CK-MB levels return to normal after 72 hours, Troponin I remain elevated for 6-10 days, thus providing for a longer window of detection for cardiac injury. The high specificity of cTnI measurements for the identification of myocardial damage has been demonstrated in conditions such as the perioperative period, after marathon runs, and blunt chest trauma.[3] cTnI release has also been documented in cardiac conditions other than acute myocardial infarction (AMI) such as unstable angina, congestive heart failure, and ischemic damage due to coronary artery bypass surgery.[4] Because of its high specificity and sensitivity in the myocardial tissue, Troponin I has recently become the most preferred biomarker for myocardial infarction.[5]

The High-Sensitivity Cardiac Troponin I Test Device (Whole Blood/Serum/Plasma) is a test that utilizes a combination of anti-cTnI antibody coated particles and capture reagent to detect cTnI in human whole blood, serum or plasma.

PRINCIPLE

The High-Sensitivity Cardiac Troponin I Test Device (Whole Blood/Serum/Plasma) detects cardiac Troponin I (cTnI) based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. If the specimen contains cTnI, it attaches to the fluorescent microspheres-conjugated anti-cTnI antibodies. Then the complex will be captured by the capture antibodies coated on the nitrocellulose membrane (Test line). The concentration of cTnI in the sample correlates with the fluorescence signal intensity captured on the T line. According to the fluorescence intensity of the test and product standard curve, the concentration of cTnI in the sample can be calculated by the analyzer to show cTnI concentration in specimen.

REAGENTS

The test includes anti-cTnI antibody coated fluorophores and anti-cTnI antibody coated on the membrane.

PRECAUTIONS

Please read all the information in this package insert before performing the test.

1. For professional *in vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse.
3. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
4. Do not eat, drink or smoke in the area where the specimens and tests are handled.
5. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens.
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7. Do not interchange or mix reagents from different lots.
8. Humidity and temperature can adversely affect results.
9. Used testing materials should be discarded in accordance with local regulations.
10. Read the entire procedure carefully prior to any testing.
11. The High-Sensitivity cTnI Test Device should only be used with the analyzer by medical professionals.

STORAGE AND STABILITY

1. The test should be stored at 4-30 °C until the expiry date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.
3. **Do not freeze.**
4. Care should be taken to protect the components of the kit from contamination.
5. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND PREPARATION

1. Collect the specimen according to standard procedures.
2. To collect finger prick blood specimens:
   - •Wash the hand with soap and warm water or clean with an alcohol pad. 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 finger prick blood specimen to the buffer tube by using a pipette.
3. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.
4. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8 °C for up to 1 day, 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 used within 1 day of collection. Do not freeze whole blood specimens. Whole blood collected by finger prick 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. Avoid repeated freezing and thawing of specimens.
6. EDTA K2, Heparin sodium, Citrate sodium and Oxalate potassium can be used as the anticoagulant tube for collecting the blood specimen.

MATERIALS

Materials Provided

- Test Devices
- ID Card
- Specimen Collection Tubes with Buffer
- Package Insert

Materials Required But Not Provided

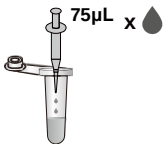
- Timer
- Centrifuge
- Fluorescence Immunoassay Analyzer
- Pipette

DIRECTIONS FOR USE

Refer to the Fluorescence Immunoassay Analyzer User Manual for the complete instructions for the use of the analyzer.

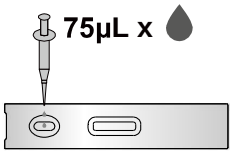
Allow the test, specimen and buffer to reach room temperature (15-30 °C) prior to testing.

1. Turn on the Analyzer power.
2. Import the test information into the analyzer with the ID Card provided in the kit. Choose test mode and/or sample type according to needs.
3. Remove the test device from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
4. Adding sample:



Pipette **75µL of whole blood/serum/plasma** into the buffer tube.

Mix the specimen and the buffer well.



Pipette **75 µL of diluted specimen** into the sample well of the test device.

5. Test results should be interpreted at **15 minutes** with the use of the Fluorescence Immunoassay Analyzer.

Caution: Operator must consult the Fluorescence Immunoassay Analyzer User Manual prior to use and become familiar with the processes and quality control procedures.

INTERPRETATION OF RESULTS

Results read by the Fluorescence Immunoassay Analyzer.

The result of cTnI test is calculated by the analyzer and is displayed on the screen. For additional information, please refer to the user manual of the Fluorescence Immunoassay Analyzer.

Linearity range of cTnI Test is 0.02-20 ng/mL.

QUALITY CONTROL

Each High-Sensitivity cTnI Test Device contains internal control that satisfies routine quality control requirements. This internal control is performed each time a sample is tested. This control indicates that the test device was inserted and read properly by the analyzer. An invalid result from the internal control causes an error message on the analyzer indicating that the test should be repeated. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control 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.

LIMITATIONS

1. The High-Sensitivity Cardiac Troponin I Test Device (Whole Blood/Serum/Plasma) is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of Cardiac Troponin I.
2. The High-Sensitivity Cardiac Troponin I Test Device (Whole Blood/Serum/Plasma) will only indicate the presence of Cardiac Troponin I antigen in the specimen and should not be used as the sole criteria for evaluating Myocardial Infarction. If the result is positive, other clinical findings and alternative test methods are recommended to reach proper medical treatments.
3. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
4. High concentrations of Cardiac Troponin I may produce a dose hook effect, resulting in incorrect interpretation of Cardiac Troponin I levels. High dose hook effect has not been observed with this test up to 20 ng/mL of Cardiac Troponin I.
5. The hematocrit of the whole blood should be between 25% and 65%.

EXPECTED VALUES

Concentrations	Clinical Reference
<0.3 ng/mL	Not indicative of Acute Myocardial Infarction
≥0.3 ng/mL	Indicative of Acute Myocardial Infarction

PERFORMANCE CHARACTERISTICS

1. Accuracy

The test deviation is ≤ ±15%.

2. Sensitivity

The High-Sensitivity Cardiac Troponin I Test Device (Whole Blood/Serum/Plasma) can detect levels of Cardiac Troponin I as low as 0.02 ng/mL in human whole blood, serum or plasma.

3. Detection range

0.02-20 ng/mL

4. Linearity range

0.02-20 ng/mL, R≥0.990

5. Precision

Intra-lot precision

Within-run precision has been determined by using 10 replicates of 2 specimens containing 0.5 ng/mL and 5 ng/mL of cTnI. C.V. is ≤15%.

Inter-lot precision

Between-run precision has been determined by using 10 replicates for each of three lots using 2

specimens containing 0.5 ng/mL and 5 ng/mL of cTnI. C.V. is ≤15%.

6. Cross-reactivity

Cross-reactivity studies were carried out with following analytes.

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*, MONO, anti-CMV, anti-Rubella and anti-Toxoplasmosis positive specimens.

The results showed no cross-reactivity.

7. Interfering Substances

The following potentially interfering substances were added to 2 specimens containing 0.5 ng/mL and 5 ng/mL of cTnI.

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
Creatin: 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 at the concentration tested interfered in the assay.

8. Method comparison

The High-Sensitivity cTnI Test Device was compared with the results obtained with Abbott for 113 samples. The correlation coefficient(r) is 0.989.

LITERATURE REFERENCES

1. Adams,et al. Biochemical markers of myocardial injury, Immunoassay Circulation 88:750-763,1993.
2. Mehegan JP,Tobacman LS.Cooperative interaction between troponin molecules bound to the cardiac thin filament. J.Biol.Chem. 266:966, 1991.
3. Adams, et al. Diagnosis of Perioperative myocardial infarction with measurements of cardiac troponin I. N.Eng.J.Med 330:670, 1994.
4. Hossein-Nia M, et al. Cardiac troponin I release in heart transplantation.Ann.Thorac. Surg. 61:227, 1996.
5. Alpert JS, et al. Myocardial Infarction Redefined, Joint European Society of Cardiology American College of Cardiology: J. Am. Coll.Cardio.,36(3):959,2000.

Index of Symbols

	Consult instructions for use or consult electronic instructions for use		Contains sufficient for <n> tests		Temperature limit
IVD	*In vitro* diagnostic medical device	LOT	Batch code	REF	Catalogue number
EU REP	European Authorized Representative		Use-by date		Do not re-use
	Do not use if package is damaged and consult instructions for use		Manufacturer		Date of manufacture

EU REP **VidaQuick Biotech S.L.**
No.132, Rosello Street, Barcelona,
Barcelona Province, 08036, Spain
E-mail: info@vidaquick.com

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