SCREEN®

SCREEN IFA TEST TROPONINA (Whole Blood/Serum/Plasma) Package Insert

REF: SC-1590-20	English

A rapid test for the diagnosis of myocardial infarction (MI) to detect cardiac Troponin I (cTnI) in whole blood, serum or plasma with the use of SCREEN® Fluorescence Immunoassay Analyzer. For professional in vitro diagnostic use only.

INTENDED USE

The Cardiac Troponin I Test Cassette (Whole Blood/Serum/Plasma) is intended for in vitro quantitative determination of human cardiac Troponin I in 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 remains 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 Cardiac Troponin I Test Cassette (Whole Blood/Serum/Plasma) is a simple test that utilizes a combination of anti-cTnI antibody coated particles and capture reagent to detect cTnI in whole blood, serum or plasma.

PRINCIPLE

The Cardiac Troponin I Test Cassette (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 SCREEN® Reader to show cTnI concentration in specimen.

REAGENTS

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

PRECAUTIONS

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. 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. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. Do not interchange or mix reagents from different lots.
6. Humidity and temperature can adversely affect results.
7. Used testing materials should be discarded in accordance with local regulations.
8. Read the entire procedure carefully prior to any testing.
9. The SCREEN® cTnI Test Cassette should only be used with the SCREEN® Analyzer by approved 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

Preparation
1. Before performing the test, please make sure that all components are brought to room temperature(15-30 ℃). Cold buffer solution or moisture condensation on the membrane can lead to invalid test results.
2. Take a tube with buffer solution out of the kit. Document patients name or ID on it.

Sample Handling
1. Collect the specimen according to standard procedures.
2. 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 stick should be tested immediately.
3. 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.
4. EDTA K2, Heparin sodium, Citrate sodium and Oxalate potassium can be used as the anticoagulant tube for collecting the blood specimen.

Sample Dilution
1. The specimen (**75 uL of serum/plasma/ whole blood**) can be added directly with the micro pipette into the buffer.
2. Close the tube and shake the sample by hand for approximately **10 seconds** so sample and dilution buffer mix well.
3. Let the diluted sample homogenize for approximately **1 minute.**
4. It is best to place the diluted sample on an ice pack and leave the sample at room temperature for no more than 2 hours.

MATERIALS

Materials Provided
- Test Cassettes
- Specimen Collection Tubes with Buffer
- ID Card
- Package Insert

Materials Required But Not Provided
- Timer
- Centrifuge
- SCREEN® Fluorescence Immunoassay Analyzer
- Pipette

DIRECTIONS FOR USE

Refer to SCREEN® Fluorescence Immunoassay Analyzer Operation Manual for the complete instructions on use of the Test. The test should be conducted at room temperature. **Allow the test, specimen, buffer and/or controls to reach room temperature (15-30 °C) prior to testing.**
1. Turn on the Analyzer power. Then according to the need, select "standard test" or "Quick test" mode.
2. Take out the ID card and insert it into the Analyzer port.
3. **Serum/plasma:** Transfer **75 µL serum/plasma** into the buffer tube, mix the specimen and the buffer well.
   Whole blood: Transfer **75 µL whole blood** into the buffer tube with pipette; mix the specimen and the buffer well.
4. **Add diluted specimen with a Pipette:** Pipette **85 µL diluted specimen** into the sample well. Start the timer at the same time.
5. There are two test modes for SCREEN® Fluorescence Immunoassay Analyzer, Standard Test mode and Quick Test mode. Please refer to the user manual of SCREEN® Fluorescence Immunoassay Analyzer for details.
   "Quick test" mode: Insert the test cassette into the Analyzer at **15 minutes** after sample application and click **"New test "**, the Analyzer will automatically give the test result after a few seconds.
   "Standard test" mode: Insert the test cassette into the Analyzer immediately after sample application, click "**New test**" at the same time, the Analyzer will automatically count down **15 minutes**. After the countdown, the Analyzer will give the result at once.

RESULTS INTERPRETATION

Results read by SCREEN® Fluorescence Immunoassay Analyzer.
The result of tests for cTnI is calculated by SCREEN® Fluorescence Immunoassay Analyzer and display the result on the screen. For additional information, please refer to the user manual of SCREEN® Fluorescence Immunoassay Analyzer.
Linearity range of SCREEN® cTnI Test is 0.1-40 ng/mL

QUALITY CONTROL

Each SCREEN® cTnI Test Cassette contains internal control that satisfies routine quality control requirements. This internal control is performed each time a patient sample is tested. This control indicates that the test device was inserted and read properly by SCREEN® Fluorescence Immunoassay Analyzer. An invalid result from the internal control causes an error message on SCREEN® Fluorescence Immunoassay Analyzer indicating that the test should be repeated. An invalid result from the internal control causes an "N/A" message on SCREEN® Fluorescence Immunoassay Analyzer. 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 Cardiac Troponin I Test Cassette (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 Cardiac Troponin I Test Cassette (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.
3. Like 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 40ng/mL of Cardiac Troponin I.
5. The hematocrit of the whole blood should be between 25% and 65%.
6. The results of SCREEN® cTnI Rapid Tests are based on measuring the levels of cTnI in a specimen. It should not be used as the sole criterion for treatment decisions. If the result is positive, other clinical findings and alternative test methods are recommended to reach proper medical treatments.

EXTENDED VALUES

Concentrations	Clinical Reference
< 0.5 ng/mL	Not indicative of Acute Myocardial Infarction
> 0.5 ng/mL	Indicative of Acute Myocardial Infarction

【PERFORMANCE CHARACTERISTICS】

1. Accuracy
The test deviation is ≤±15%.
2. Sensitivity
The Cardiac Troponin I Test Cassette (Whole Blood/Serum/Plasma) can detect levels of Cardiac Troponin I as low as 0.1ng/mL whole blood, serum or plasma.
3. Detection range
0.1~40 ng/mL
4. Linearity range
0.1~40 ng/mL , R≥0.990
5. Precision
CV≤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 cTnI negative and positive specimens.

Acetaminophen: 20 mg/dl	Caffeine: 20 mg/dL
Acetylsalicylic Acid: 20 mg/dL	Gentisic Acid: 20 mg/dL
Ascorbic Acid: 20mg/mL	Albumin: 10,500mg/dL
Creatin: 200 mg/dL	Hemoglobin 1,000 mg/dL
Bilirubin: 1,000mg/dL	Oxalic Acid: 600mg/dL

Cholesterol: 800mg/dL Triglycerides: 1,600mg/dL
None of the substances at the concenntration tested interfered in the assay.

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		Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
4°C 30°C	Store between 4-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged		Manufacturer		

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