Quality approved by SD BIOSENSOR / For *In vitro* use only

STANDARD F
TnI FIA

REF F-TNI

STANDARD™ F TnI FIA

PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST

STANDARD™

EXPLANATION AND SUMMARY

[Introduction]
The Troponin (Tn), one of the subunits of the troponin regulatory complex, binds to actin and inhibits interactions between actin and myosin. Troponin complex plays an important role in the regulation of skeletal and cardiac muscle contraction. Troponin complex consists of three subunits: Troponin T (TnT), Troponin I (TnI) and Troponin C (TnC). The subunits are held together by non-covalent interactions. TnT is the tropomyosin-binding subunit that regulates interaction between the troponin complex and the thin filament. The TnI subunit is responsible for inhibiting actomyosin formation at low intracellular Ca2+ concentrations. The third subunit, TnC, binds Ca2+ ions during the excitation of the muscle and changes the conformation of troponin complex, thus enabling the formation of actomyosin complex and the subsequent muscle contraction. Cardiac Troponin I (cTnI) has been known as reliable markers of cardiac cell death. It is now widely used for the diagnosis of acute myocardial infarction (AMI), postsurgery myocardium trauma, chemotherapy cardiotoxicity, as well as some other diseases related to cardiac muscle injury. Being expressed cTnI only in cardiac tissue, cardiac TnI have been the preferred biomarkers for myocardial infarction for a long time. STANDARD F TnI FIA, employing immunofluorescent detection system with STANDARD F analyzer, provides significantly fast, easy and accurate system to identify cardiac Troponin I (cTnI) in serum and whole blood as an aid in the diagnosis of myocardial infarction and enables supportive treatment decisions.

[Intended use]
STANDARD F TnI FIA is a fluorescence immunoassay for the quantitative determination of total Troponin I (cTnI) levels in human serum and whole blood using STANDARD F Analyzers, manufactured by SD BIOSENSOR. This test is an *in vitro* diagnostic use and intended for use as an aid in the screening and monitoring of acute myocardiac infarction (MI).

[Test principle]
When a human specimen is applied into the sample well of the test device, the specimen migrates through the membrane from the sample well. If Troponin I (TnI) is present, it will be bound to by detector coupled to europium microparticle that migrates through the membrane. The europium microparticle complex will be captured by capture antibody on the test line where it is detected by STANDARD F analyzer. If is not present, the europium microparticle will not be trapped by the capture antibody nor detected by STANDARD F Analyzer. The intensity of the fluorescence light generated on the membrane is scanned by the STANDARD F Analyzer. STANDARD F Analyzer can analyze the presence of the TnI in the clinical specimen by processing the results using pre-programmed algorithms and display the test result on the screen.

[Kit contents]
① Test device ② Fixed volume droppper (100 µl) ③ Disposable dropper (100 µl) ④ Extraction buffer
⑤ Instructions for use

[Materials required but not provided]
- STANDARD F Analyzer

KIT STORAGE AND STABILITY
Store the kit at 2-30°C / 36-86°F, out of direct sunlight. Kit materials are stable until expiration date printed on the outer box. Do not freeze the kit.

WARNINGS AND PRECAUTIONS
1. STANDARD F TnI FIA is for *in vitro* diagnostics use only.
2. Carefully follow the instructions and procedures described in this instructions before testing.
3. STANDARD F TnI FIA should be used with STANDARD F Analyzer.
4. STANDARD F TnI FIA should remain in its original sealed pouch until ready to use. Do not use the if the pouch is damaged or the seal is broken.
5. STANDARD F TnI FIA is single use only. Do not re-use it.
6. Do not use hemolyzed samples or frozen samples.
7. Do not use any artificial materials.
8. Place the analyzer on a flat surface when in use.
9. Wash your hands in warm, soapy water. Rinse well and dry completely before testing.
10. Discard the used test kit according to the proper method.
11. Silica gel in foil pouch is to absorb moisture and keep humidity from affecting products. If the moisture indicating silica gel beads change from yellow to green, the test device in the pouch should be discarded.
12. Use a fixed volume dropper (100 µl) - [① labeled on the pouch] for sample extraction purpose only. Do not use it as a sample dispenser.
13. Use a disposable dropper (100 µl) - [② labeled on the pouch] for mixing the sample, and for dispensing the sample mixture into the test device.
14. Check the expiration date printed at the pouch or package.
15. Check the volume (100µL) of extraction buffer.
16. Use the STANDARD F TnI FIA at room temperature.
17. All kit components are must be at room temperature 30 minutes before running the assay.
18. Do not write on the bar code or damage the bar code of the test device.

SPECIMEN COLLECTION AND PREPARATION

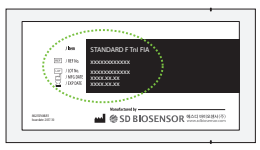
[Whole blood]
- **Venous whole blood**

1. Collect the venous whole blood into the commercially available EDTA tube by venipuncture.
2. It is recommended that collected venous whole blood samples are used immediately. If venous whole blood in an anticoagulant tube is stored in a refrigerator at 2-8°C, the specimen can be used for testing within 8 hours after collection.
3. Do not use hemolyzed blood samples.

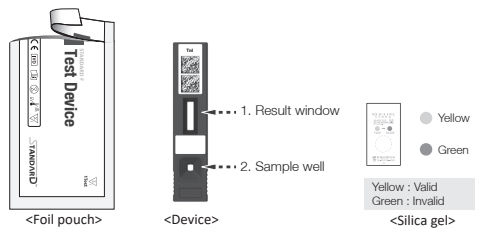
[Serum]
1. Collect the whole blood into the commercially available plain tube, NOT containing anti-coagulants such as heparin, EDTA or sodium citrate by venipuncture and leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant.
2. Serum specimen may be stored at room temperature for up to 1 day or at 2-8°C/36-46°F for up to 3 days prior to testing.
3. For over 3 days storage, specimens may be frozen under -20°C/-4°F for up to 1 month.
4. It should be brought to room temperature prior to use.

TEST PROCEDURE

[Preparation]
1. Allow kit components and collected sample to room temperature at least 30 minutes before staring the test.
2. Carefully read instructions for the STANDARD F TnI FIA.
3. Check the expiry date at the back of the foil pouch. Use another lot if expiry date has passed.

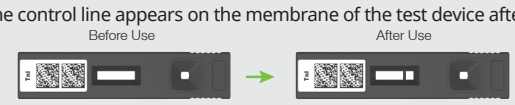


4. Open the foil pouch and check the test device in the foil pouch.



CAUTION

The control line appears on the membrane of the test device after use.



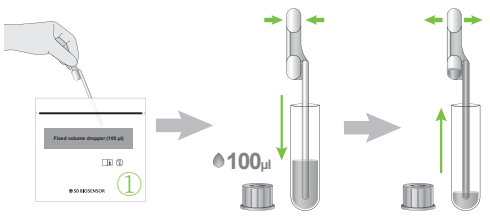
CAUTION

- Do not write on the bar code or damage the bar code of the test device.
- If the color of moisture indicators are changed from yellow to green, please do not use the test device.

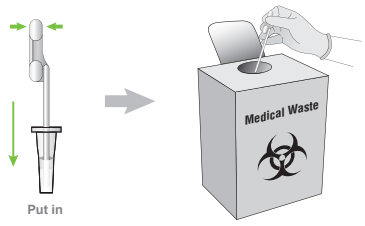
[Analysis of sample]
- **Using a 'STANDARD TEST' mode**
  - **Applied STANDARD F100, F200 and F2400 analyzer**

1. Prepare a STANDARD F Analyzer and select the 'Standard Test' mode according to the analyzer's manual. In case of STANDARD F2400 analyzer, go to the 'Workplace' in the main screen. And select the 'Run Test'
2. In case of STANDARD F200 and F2400 analyzer, input patient ID and/or operator ID on the analyzer.
3. Take the test device out of the foil pouch.
4. Insert the test device to the test slot of the analyzer. When inserting the test device to the analyzer, the analyzer read the barcode data, and check the test device is valid.

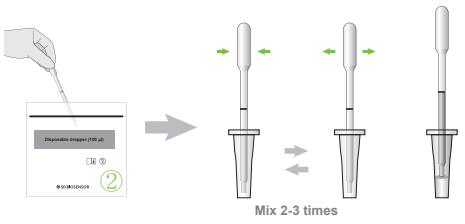
5. Collect 100µl of sample with a fixed volume dropper (100 µl) – [① labeled].



6. Dispense collected sample into the extraction buffer tube. Then, discard the used fixed volume dropper (100 µl).



7. Mix sample and buffer 2-3 times with the disposable dropper (100 µl) - [② labeled]. Then, collect 100 µl of sample mixture.



8. After applying the sample, immediately press the **'TEST START'** button.

9. The analyzer will automatically display the test result within 10 minutes.

CAUTION

- Do not put bubbles in the sample well of the test device.
- Discard the used test kit in proper container, according to your healthcare professional's recommendation.
- If you feel the test result is inaccurate or do not agree your test result, do not change the treatment and contact your healthcare professional.

INTERPRET THE TEST RESULT

STANDARD F TnI FIA reads TnI concentration between 0.05 - 20 ng/mL. If the result is below 0.05ng/mL, it will be reported as "↓0.05ng/mL". If the result is above 20ng/mL, it will be reported as "↑20ng/mL".

CAUTION

- Results should be considered in conjunction with the clinical history and other data available to the physician.
- If an error message appears on the analyzer's screen, refer to the analyzer's manual.

Measuring range	0.05-20 ng/mL
Cut off value for MI	<0.05 ng/mL

NOTE

The Troponin I reference ranges are provided for orientational purpose only. Clinicians should use the test results in conjunction with the patient's other diagnostic findings and clinical signs, and interpret the concrete values in the context of the patient's clinical situation.

QUALITY CONTROL

[STANDARD F Analyzers Calibration Check]

The calibration set test of STANDARD F Analyzers should be conducted according to the analyzers' manual.

- **When to use calibration set**
  1. Before using the analyzer for the first time
  2. When you drop the analyzer
  3. Whenever you do not agree with your result
  4. When you want to check the performance of an analyzer and test device
- **How to use calibration set**

  Calibration set test is a required function that ensures optimal performance by checking the internal analyzer optics and functions.
  1. Select the 'Calibration' menu.
  2. The specific calibration set is included with the analyzer.
  3. Insert the CAL-1 first, and then insert the CAL-2 for UV-LED testing and the CAL-3 for RGB-LED testing in order.
     - The STANDARD F analyzer automatically calibrate and identify the optical performance through measuring the membrane of the test device whenever the test is conducted in 'Standard Test' mode. If 'EEE' message displays on the screen, it means that the analyzer has a problem, so check with test device. Contact the SD BIOSENSOR local distributor if the 'EEE' message still appears.

[External quality control]

Quality control testing should be run to check the performance of STANDARD F TnI FIA and STANDARD F Analyzers. STANDARD F TnI Control manufactured by SD BIOSENSOR should be used for quality control testing. Control test should be conducted in accordance with the instructions of STANDARD F TnI Control.

Control test should be run:

- once for each new lot.
- once for each untrained operator.
- as required by test procedures in instructions for use of STANDARD F TnI Control and in accordance with local, state and federal regulations or accreditation requirements.

BIBLIOGRAPHY

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5. Hamm CW. (2001). "Acute coronary syndromes. The diagnostic role of troponins". Thromb Res. 103 (1): 63–69.

Product Disclaimer

Whilst every precaution has been taken to ensure the diagnostic ability and accuracy of this product, the product is used outside of the control of the SD BIOSENSOR and distributor and the result may accordingly be affected by environmental factors and/or user error. A person who is the subject of the diagnosis should consult a doctor for further confirmation of the result.

Warning

The SD BIOSENSOR and distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect of consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.

CE IVD

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IVD *In vitro* Diagnostics
Consult Instructions for Use
Contains Sufficient for <n> Tests
Caution
To indicate the temperature limitations in which the transport package has to be kept and handled.
Note
Do not re-use.
Use by
LOT Batch code
Manufacturer
Date of manufacture
CE Fulfill the requirements of Directive 98/79/EC on *in vitro* diagnostic medical devices