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

STANDARD F

NT-proBNP FIA

REF F-NTP-01

STANDARD™ F NT-proBNP FIA

PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST

STANDARD™

EXPLANATION AND SUMMARY

[Introduction]

B-type natriuretic peptide (BNP) and N-terminal pro b-type natriuretic peptide (NT-proBNP) are substances that are produced in the heart and released when the heart is stretched and working hard to pump blood. Tests for BNP and NT-proBNP measure their levels in the blood in order to detect and evaluate heart failure.
BNP was initially called brain natriuretic peptide because it was first found in brain tissue (and to distinguish it from a similar protein made in the atria, or upper chambers, of the heart, termed ANP). BNP is actually produced primarily by the left ventricle of the heart (the heart's main pumping chamber). It is associated with blood volume and pressure and with the work that the heart must do in pumping blood throughout the body. Small amounts of a precursor protein, pro-BNP, are continuously produced by the heart. Pro-BNP is then cleaved by the enzyme called corin to release the active hormone BNP and an inactive fragment, NT-proBNP, into the blood.

When the left ventricle of the heart is stretched, the concentrations of BNP and NT-proBNP produced can increase markedly. This situation indicates that the heart is working harder and having more trouble meeting the body's demands. This may occur with heart failure as well as with other diseases that affect the heart and circulatory system. Heart failure is a somewhat misleading term. It does not mean that the heart has stopped working; it just means that it is not pumping blood as effectively as it should be. The increase in circulating BNP or NT-proBNP will reflect this diminished capacity.

[Intended use]

STANDARD F NT-proBNP FIA is an *in vitro* diagnostic use to measure the N-terminal pro b-type natriuretic peptide (NT-proBNP) in serum and whole blood. The quantitative measurement of the NT-proBNP is useful in the diagnosis of acute and chronic heart failure.

[Test principle]

STANDARD F NT-proBNP FIA is based on the immunofluorescence technology with STANDARD F Analyzer manufactured by SD BIOSENSOR to measure the NT-proBNP concentration in human serum and whole blood. The specimen from human should be processed for the preparation using the components of the STANDARD F NT-proBNP FIA. After applying the sample mixture to the test device, the complex will be formed on the membrane as the result of the antigen-antibody reaction. The intensity of the fluorescence light is scanned and converted into an electric signal which is proportional to the intensity of fluorescence light produced on the membrane. STANDARD F Analyzers can analyze the NT-proBNP concentration of the clinical specimen based on a pre-programmed algorithms and display the test result on the screen.

[Kit contents]

① Test device ② Disposable dropper (100 µl) ③ Extraction buffer ④ 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 NT-proBNP FIA is for *in vitro* diagnostics use only.
2. Carefully follow the instructions and procedures described in this instructions before testing.
3. STANDARD F NT-proBNP FIA should be used with STANDARD F Analyzer.
4. STANDARD F NT-proBNP 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 NT-proBNP 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. Check the expiration date printed at the pouch or package.
13. Check the volume (100µL) of extraction buffer.
14. Use the STANDARD F NT-proBNP FIA at 15-32°C / 59-90°F.
15. All kit components are must be at room temperature 30 minutes before running the assay.
16. 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 at room temperature or at 2-8°C/36-46°F or 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.

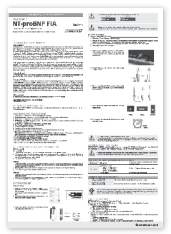
[Serum]

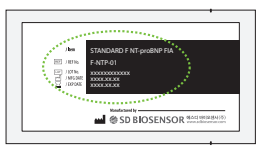
1. Collect the whole blood into the commercially available plain tube, NOT containing anti-coagulants such as heparin, EDTA or sodium citrate by venipuncture and leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant.
2. Serum specimen may be stored at room temperature or at 2-8°C/36-46°F for up to 24 hours prior to testing.
3. It should be brought to room temperature prior to use.

TEST PROCEDURE

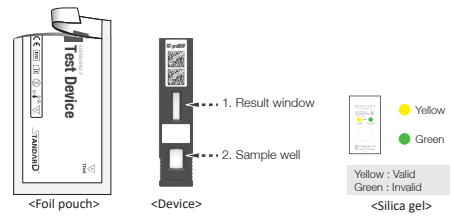
[Preparation]

1. Allow kit components and collected sample to room temperature (15-30°C/59-86°F) at least 30 minutes before staring the test.
2. Carefully read instructions for the STANDARD F NT-proBNP 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 and the silica gel pack inside the foil pouch.



CAUTION

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

CAUTION

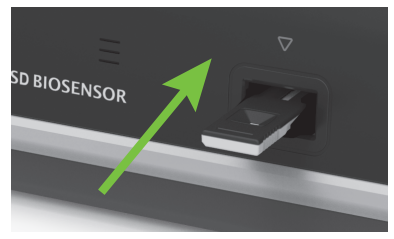
- Do not write on the bar code or damage the bar code of the test device.
- If the color of moisture indicators are changed from yellow to green, please do not use the test device.

[Analysis of sample]

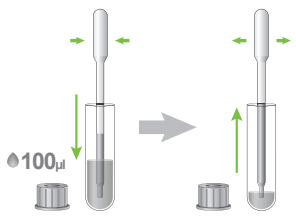
- **Using a 'STANDARD TEST' mode**
  - **STANDARD F100, F200 and F2400 analyzer**

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.

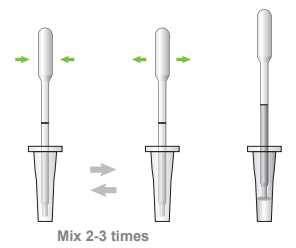
4. Insert the test device to the test slot of the analyzer. When inserting the test device to the analyzer, the analyzer will read the barcode data, and check the test device is valid. Select the sample type on the sample selection screen.



5. Collect 100 µl of sample to the black line of a Disposable dropper (100 µl).



6. Mix the sample and extraction buffer 2-3 times with the disposable dropper (100 µl). Then, collect 100 µl of the sample mixture to the black line.



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

8. The analyzer will automatically display the test result in 15 minutes for serum sample and in 20 minutes for whole blood sample.

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 NT-proBNP FIA reads NT-proBNP concentration between 50 - 25,000 pg/mL. If the result is below 50 pg/mL, it will be reported as "↓50 pg/mL". If the result is above 25,000 pg/mL it will be reported as "↑25,000 pg/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.

Acute Heart Failure Diagnosis (Patient presenting with acute dyspnea)		
HF Rule-out	<300 pg/mL	HF unlikely – Further evaluation of non-cardiac cause of dyspnea
HF Rule-in	Age-adjusted cut-off • <50yrs : > 450 pg/mL • 50-75 yrs : > 900 pg/mL • 75 yrs : > 1,800 pg/mL	HF likely – Triage and treat as appropriate
	> 10,000 pg/mL	HF very likely and likely severe

Symptomatic Chronic Heart Failure Diagnosis	
• <75 yrs : <125 pg/mL • ≥ 75 yrs : <450 pg/mL	HF unlikely – Further evaluation of non-cardiac causes
• <75 yrs : ≥125 pg/mL • ≥ 75 yrs : ≥450 pg/mL	Left ventricular dysfunction possible – Further investigation needed

NOTE

The NT-proBNP 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.

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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.

[External quality control]

Quality control testing should be run to check the performance of STANDARD F NT-proBNP FIA and STANDARD F Analyzers. STANDARD F NT-proBNP 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 NT-proBNP 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 NT-proBNP Control and in accordance with local, state and federal regulations or accreditation requirements.

BIBLIOGRAPHY

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5. (March 27, 2014) National Heart, Lung, Blood Institute. Who is at Risk of Heart Failure? Available online at http://www.nhlbi.nih.gov/health/health-topics/topics/hf/atrisk through http://www.nhlbi.nih.gov. Accessed May 2019

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