**STANDARD F NT-proBNP FIA**

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**PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST**

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### 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. NT-proBNP 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 immuno-fluorescence technology with STANDARD F Analyzer manufactured by SD BIOSENSORS to measure the NT-proBNP concentration in human serum and whole blood. The specific antibody against human NT-proBNP 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 electrical 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

**[Materials required but not provided]**

- STANDARD F Analyzer

**[Kit STORAGE AND STABILITY]**

Store the kit at 2-30°C. It is not recommended to out direct sunlight. Kit materials are stable until expiration date printed on the outer box.

**No.1. WARNINGS AND PRECAUTIONS**

1. STANDARD F NT-proBNP FIA is for in vitro diagnoses 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 is single use only. Do not re-use.
5. Do not use hemolyzed samples or frozen samples.
6. Do not use any artificial materials.
7. Place the analyzer on a flat surface when in use.
8. Wash your hands in warm, soapy water. Rinse well and dry completely before testing.
9. Do not discard the used test kit according to the proper method.
10. Do not put bubbles in the sample well of the test device.
11. Do not write on the bar code or damage the bar code of the test device.
12. The control line appears on the membrane of the test device after use.

**[Specimen Collection and Preparation]**

**[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 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. NTF not containing anticoagulants 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 before testing.
3. It should be brought to room temperature prior to use.

**[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 F100 and F200 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.

**[Test Procedure]**

**[Preparation]**

1. Allow kit components and collected sample to room temperature (15°C-30°C/59°F-86°F) at least 30 minutes before starting the test.
2. Carefully follow the 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.

**[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".**

- **<75 yrs:**<125 pg/mL
- **75 yrs:**≥125 pg/mL
- **≥75 yrs:**≥450 pg/mL

**[Interpret the test result]**

**[Acute Heart Failure Diagnosis (Patient presenting with acute dyspnea)]**

<table>
<thead>
<tr>
<th>Age-adjusted cut-off</th>
<th>&lt;75 yrs</th>
<th>75 yrs</th>
<th>≥75 yrs</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;50 pg/mL</td>
<td>&lt;125 pg/mL</td>
<td>&gt;125 pg/mL</td>
<td>≥450 pg/mL</td>
</tr>
<tr>
<td>50-75 pg/mL</td>
<td>&gt;125 pg/mL</td>
<td>≥750 pg/mL</td>
<td>≥450 pg/mL</td>
</tr>
<tr>
<td>75-150 pg/mL</td>
<td>&gt;750 pg/mL</td>
<td>≥7,500 pg/mL</td>
<td>≥1,500 pg/mL</td>
</tr>
</tbody>
</table>

**[Symptomatic Chronic Heart Failure Diagnosis]**

<table>
<thead>
<tr>
<th>Heart failure cause</th>
<th>≥75 yrs</th>
<th>&gt;10,000 pg/mL</th>
<th>≥1,800 pg/mL</th>
<th>&gt;125 pg/mL</th>
<th>≥450 pg/mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>LV dysfunction</td>
<td></td>
<td>&lt;50 pg/mL</td>
<td>&lt;125 pg/mL</td>
<td>&gt;125 pg/mL</td>
<td>&gt;25,000 pg/mL</td>
</tr>
<tr>
<td>Right ventricle dysfunction</td>
<td></td>
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</table>

**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.
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
  1. Calibration set test is a required function that ensures optimal performance by checking the internal analyzer optics and functions.
  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]
Qual 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 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 regulators or accreditation requirements.

BIBLIOGRAPHY

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.