

**NT-pro BNP FAST TEST KIT**

**1 X 25 Units  
14410003**

**Intended Use**

NT-proBNP Fast Test Kit (Immunofluorescence Assay) applies fluorescence immunochromatography to detect N-terminal B-type natriuretic peptide precursor (NT-proBNP) in serum, plasma or whole blood samples. This test is used as an aid in the clinical diagnosis, prognosis and evaluation of Heart Failure (HF).

**Clinical Significance**

N-terminal B-type natriuretic peptide precursor is secreted from the left cardiac ventricle in response to volume and pressure overload. It's an inactive N-terminal fragment that split from BNP prohormone. NT-proBNP can be used to evaluate heart contractile, diastolic dysfunction, and ventricular segmental wall motion coordination. Besides, its sensitivity and negative predictive value is well. NT-proBNP is used to find heart failure patient at the early stage, and is used as a marker to determine risk levels, to monitor medical efficiency of HF drug, to evaluate prognosis of HF patient and to distinguish dyspnea that caused by heart failure from other diseases. Furthermore, NT-proBNP is a risk assessment indicator for Acute Coronary Syndrome.

**Principle**

The test uses an anti-human NT-proBNP monoclonal antibody conjugated with fluorescence latex and an anti-human NT-proBNP polyclonal antibody coated on the test line. After the sample (serum, plasma or whole blood) is applied to the test strip, the fluorescence latex-labelled anti-human NT-proBNP monoclonal antibody binds to the NT-proBNP in sample and forms a marked antigen-antibody complex. This complex moves to the test card detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by the anti-human NT-proBNP polyclonal antibody. The fluorescence intensity of the test line increases in proportion to the NT-proBNP concentration.

When inserting test card into the MISPA REVO Immunofluorescence Quantitative Analyzer (hereafter referred to as MISPA REVO), the concentrations of NT-proBNP in samples will be determined and displayed on the screen. The values will be stored in MISPA REVO and available for downloading on demand. The result can be easily transmitted to the laboratory or hospital information system, if the system is connected to MISPA REVO

**Kit Components**

A kit contains:

- 1. Foil bag, which contains one test card and one desiccant .....25
- 2. Manual ..... 1
- 3. SD card ..... 1
- 4. Blood sample diluent..... 1

A test card consists of:

A plastic shell and a reagent strip which is composed of a sample pad, a fluorescence pad (coated with a fluorescence latex-labelled anti-human NT-proBNP monoclonal antibody), nitrocellulose membrane (the test line is coated with another anti-human NT-proBNP polyclonal antibody, and the control line is coated with a rabbit anti-mouse IgG antibody), absorbent paper and liner.

Blood sample diluent:

Phosphate buffered saline, proteins, detergent, preservative, stabilizer.

**Note: Components from different batches cannot be exchanged.**

**Matching Equipment**

MISPA REVO Immunofluorescence Quantitative Analyzer

**Risk & Safety**

Safety sheets (MSDS/SDS) will be provided on request

**Storage & Stability**

Store the test card at 4~30°C with a valid period of 24 months.

Use the test card within 1 hour once the foil bag is opened.

Store the blood sample diluent at 0~30 °C with a valid period of 24 months.

Suggest storing the blood sample diluent at 2~8°C for a better use.

**Precautions**

- 1. For *In-Vitro* diagnostic use.
- 2. For use by healthcare professionals.
- 3. Do not use the kit beyond the expiry date printed on the outside of the box.

- 4. Keep the test card in the sealed pouch until ready to use. Do not reuse the used cards.
- 5. One pipette tip should not be used for multiple samples. Discard it after single use.
- 6. Patient samples, used test cards and pipette tips may be potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
- 7. Carefully follow the instructions and procedures described in this manual.

**Waste Management**

Reagents must be disposed off in accordance with local regulations

**Specimen collection & storage**

- 1. A serum, plasma or whole blood sample is required for testing with this product. Serum or plasma is a better option for test accuracy. Samples should be free of hemolysis.
- 2. Heparin needs to be used as anticoagulant.
- 3. Serum or plasma can be directly used as test samples. If choose whole blood as a test sample, it should be used together with blood sample diluent.
- 4. If testing cannot be completed immediately, the serum and plasma sample should be stored up to 1 day at 2~8°C or stored at- 20°C for 3 months (whole blood sample should be stored up to 3 days at 2~8°C) until it can be tested.
- 5. Samples must be recovered to room temperature before testing. Frozen samples are required to be completely thawed and mixed thoroughly prior to testing. Minimize repeat freeze-thaw cycles to less than 3 times for tested samples to acquire accurate data.
- 6. Avoid heating the samples, which can cause hemolysis and protein denaturation.
- 7. SAMPLE VOLUME: 100 µl serum plasma or whole blood

**Interferences**

Interfering Substance	Concentration (Max)
Hemoglobin	5 g/L
Triglyceride	10 g/L
Bilirubin	0.2 g/L

**Materials required but not provided**

- 1. Pipettes & Tips
- 2. Test tubes/Racks

**Test Procedure**

- 1. Restore samples, sealed test-card foil bags and blood sample diluent to room temperature before using. Open the foil bag, label cards with numbers and use the test cards immediately.
- 2. Confirm SD card lot No. in accord with test kit lot No. Perform "SD Card Calib" operation (Details refer to chapter 8.5.2 of MISPA REVO User's Manual)when necessary.
- 3. On the main interface of MISPA REVO, press "ENT" button to enter testing interface.
- 4. Take 100 µl sample , and drop it vertically to the sample port on the test card (when testing whole blood samples, one drop blood sample diluent should be added after loading 100 µl whole blood on the card). Wait for 10 min, insert the card immediately into MISPA REVO and press "OK"button, the test card can be detected and the result will be printed automatically.

**Calibration**

- 1. It is required to perform SD card calibration operation when using a new batch of kits; Only one SD card calibration is required for the same batch.
- 2. Assure card side towards MISPA REVO is correct and insert the card completely.

**Limitations**

The result of the test should be evaluated in the context of all the clinical and laboratory data available. In those instances where the laboratory results do not agree with the clinical evaluation, additional tests should be performed accordingly.

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**Test Results**

MISPA REVO can measure the test card automatically and display the results on the screen. User can print the test result according to the procedure in user manual of MISPA REVO

For additional information, refer to the user manual of MISPA REVO

**Expected value**

NT-proBNP concentration is determined using samples obtained from 2,500 apparently healthy individuals. The 95th percentile of the concentration for NT-proBNP is 185 pg/ml and the 97.5th percentile of the concentration for NT-proBNP is 300 pg/ml. Because of the apparent difference of the concentration of NT-proBNP among different age groups, the reference values of the NT-proBNP are reported in groups. Details refer to Table 1.

Table 1 NTproBNP reference value

Age Percentile	Age					Statistic analysis
	≤44	45-54	55-64	65-74	≥75	
95	98.5	130	215	290	530	185
97.5	116	170	270	350	740	300

Clinical diagnosis value: refer to Roche criterion, details see Table 2.

Table 2 Standard of excluding/diagnosing HF by NT-proBNP

Age	<50	50-75	≥75	Diagnosis of HF
NT-proBNP (pg/ml)	≥ 450	≥900	≥1800	High probability of HF
	300-450	300-900	300-1800	Low probability of HF, need to combine with other clinical evaluation
	<300	<300	<300	Exclude HF

**Reference Range**

Measuring Range : 100~35000 pg/ml.

Lower Detection Limit : ≤100pg/ml.

Within-Run Precision : ≤10%

Between-Run Precision : ≤15%

**Bibliography**

1. de Lemos JA, McGuire DK, Drazner MH. Btype natriuretic peptide in cardiovascular disease. Lancet 2003; 362: 316~322.
2. Pfister R, Scholz M, Wielckens K, Erdmann E, Schneider CA. The value of natriuretic peptides NT-pro-BNP and BNP for the assessment of leftventricular volume and function. A prospective study of 150 patients. Deutsche medizinische Wochenschrift (1946) 2002; 127(49):2605.

SYMBOLS USED ON THE LABELS: IN VITRO DIAGNOSTIC USE SEE PACKAGE INSERT FOR PROCEDURE LOT NUMBER MANUFACTURER'S ADDRESS MANUFACTURING DATE EXPIRY DATE TEMPERATURE LIMIT



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