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NT-proBNP
Fast Test Kit
(Immunofluorescence Assay)

IF1002 for Getein 1100
IF5002 for Getein 1160
IF3002 for Getein 1180

Instructions for use REF

INTENDED USE

NT-proBNP Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of N-terminal B-type natriuretic peptide precursor (NT-proBNP) in human serum, plasma or whole blood samples. This test is used as an aid in the clinical diagnosis, prognosis and evaluation of Heart Failure (HF). For professional and laboratory use only.

SUMMARY

N-terminal B-type natriuretic peptide precursor (NT-proBNP) 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, it has high sensitivity and negative predictive value (>97%). As a gold standard recommended by the European Society of Cardiology, American Heart Association, and American College of Cardiology for the diagnosis and prognosis of heart failure, NT-proBNP is used to indicate heart failure patients at the early stage, determine HF risk levels, monitor medical efficiency of HF drugs, evaluate prognosis of HF patients and to distinguish dyspnea that caused by HF from other diseases. Furthermore, NT-proBNP is a risk assessment indicator for Acute Coronary Syndrome.

PRINCIPLE

NT-proBNP Fast Test Kit (Immunofluorescence Assay) is a lateral flow immunoassay in a sandwich design. After the sample has been applied to the test strip, the fluorescence labelled NT-proBNP monoclonal antibody binds with 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 NT-proBNP monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of NT-proBNP in sample. Fluorescent signals intensity can be analyzed by applicable device thus the NT-proBNP in sample be detected quantitatively.

CONTENTS

Materials provided	Getein 1100/Getein 1160/Getein 1180	
	10 T/kit	25 T/kit
NT-proBNP test card*	10 pcs	25 pcs
Disposable pipet	10 pcs	25 pcs
Sample diluent**	10 tube	25 tube
Instructions for use	1 pc	1 pc
SD card	1 pc	1 pc

* NT-proBNP test card

A test card main consists of: Fluorescence labelled NT-proBNP monoclonal antibody, NT-proBNP monoclonal antibody and polyclonal IgG antibody.

** Sample diluent

Sample diluent main consists of : phosphate buffer (20 mmol/L), NaN_3 (<0.1%)

Note:

1. The standard curve data can be written to RFID card in the kit. According to the function of RFID card, we define it as "Standard Curve Data Card", short for "SD Card".
2. Do not mix or interchange different batches of kits.

APPLICABLE DEVICE

Getein 1100 Immunofluorescence Quantitative Analyzer
Getein 1160 Immunofluorescence Quantitative Analyzer
Getein 1180 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the kit at 4~30°C with a valid period of 24 months. The test kits are stable until the expiry date printed on the labels.
Use the test card for Getein 1100/Getein 1160/Getein 1180 within 1 hour once the foil pouch is opened.

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Do not use the kit beyond the expiration date.
3. Do not use the test card if the foil pouch is damaged.
4. Do not open pouches until ready to perform the test.
5. Do not reuse the test card.
6. Do not reuse the pipet.
7. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for **serum, plasma and whole blood samples. Heparin, sodium citrate and EDTA** should be used as the anticoagulant for plasma and whole blood. Samples should be free of hemolysis.
2. Suggest using serum or plasma for better results.
3. It is recommended to test the sample within 4 hours after collection. Stable in plasma for 3 days when stored at 2~8°C and 3 month when stored at -20°C. Stable in whole blood for 3 days when stored at 2~8°C.
4. Refrigerated or frozen sample should reach room temperature before testing. Avoid multiple freeze-thaw cycles.
5. SAMPLE VOLUME (**for Getein 1100/Getein 1160/Getein 1180**): 100μL.

TEST PROCEDURE

1. User must carefully read and operate in strict accordance with the instructions for use before testing, otherwise reliable results cannot be guaranteed.
2. Test kit and sample should be brought to room temperature before testing.

For Getein 1100:

(1) Confirm SD card lot No. in accordance with test kit lot No. It is required to perform "SD card" calibration when using a new batch of kits.
(2) Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
(3) Remove the test card from the sealed pouch before use. Horizontally place the test card.
(4) Deliver 100 μL of sample into one tube of sample diluent using disposable pipet or pipette, mix gently and thoroughly. Then drop 100 μL of sample mixture into the sample well on the test card.
(5) ***Reaction time: 10 minutes***. After reaction time is elapsed, insert the test card into Getein 1100 and press "ENT" button (click on "Start" icon for Android Getein 1100). The result will be shown on the screen and printed automatically.

For Getein 1160/Getein 1180:

(1) Confirm SD card lot No. in accordance with test kit lot No. It is required to perform "SD card" calibration when using a new batch of kits.
(2) Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
(3) Remove the test card from the sealed pouch before use. Horizontally place the test card.
(4) Deliver 100 μL of sample into one tube of sample diluent using disposable pipet or pipette, mix gently and thoroughly. Then drop 100 μL of sample mixture into the sample well on the test card.
(5) Insert the test card into Getein 1160/Getein 1180 **immediately** after sample loading. The analyzer will count down the reaction time (10 minutes) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and printed automatically.

TEST RESULTS

Getein 1100/Getein 1160/Getein 1180 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein 1100/Getein 1160/Getein 1180.

EXPECTED VALUE

The expected normal value for NT-proBNP was determined by testing samples 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. Clinical diagnosis value: refer to Roche criterion, details see Table 2.

Table 1 NT-proBNP reference value

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

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

Each laboratory should verify the transferability of the expected values to its own population, and if necessary, determine its own expected values according to good laboratory practice.

PERFORMANCE CHARACTERISTICS

Measuring Range	100~35000 pg/ml
Limit of Detection	≤100 pg/ml
Within-Run Precision	≤10%
Between-Lot Precision	≤15%

LIMITATIONS

1. As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.
2. Interferents in samples may influence the results. The table below listed the maximum allowance of these potential interferents.

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

REFERENCES

1. de Lemos JA, McGuire DK, Drazner MH. B-type 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-proBNP and BNP for the assessment of left-ventricular volume and function. A prospective study of 150 patients. Deutsche medizinische Wochenschrift (1946)2002;127(49):2605.
3. EN ISO 18113-1:2011 In vitro diagnostic medical devices -Information supplied by the manufacturer (labelling)-Part 1: Terms, definitions and general requirements.
4. EN ISO 18113-2:2011 In vitro diagnostic medical devices -Information supplied by the manufacturer (labelling)-Part 2: In vitro diagnostic reagents for professional use.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on NT-proBNP Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult *instructions for use* or consult electronic *instructions for use*	LOT	Batch code
	Temperature limit	IVD	*In vitro* diagnostic medical device
	Contains sufficient for <n> tests	EC REP	Authorized representative in the European Community/European Union
CE	CE mark		Do not use if package is damaged and consult *instructions for use*
REF	Catalogue number		

Thank you for using NT-proBNP Fast Test Kit (Immunofluorescence Assay). Please read this Instructions for use carefully before operating to ensure proper use.

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Getein Biotech, Inc.
Add: No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel: +86-25-68568508
Fax: +86-25-68568500
E-mail: tech@getein.com.cn
overseas@getein.com.cn
Website: www.getein.com

EC REP CMC Medical Devices & Drugs S.L.
Add: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain
Tel: +34951214054