CE IVD

NT-proBNP/cTnI

Fast Test Kit

(Immunofluorescence Assay)

User Manual

REF IF1004 for Getein1100
IF2004 for Getein1600

INTENDED USE

NT-proBNP/cTnI Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of N-terminal B-type natriuretic peptide precursor/cardiac Troponin I (NT-proBNP/cTnI) 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), Acute Myocardial Infarction (AMI) and Acute Coronary Syndrome (ACS).

SUMMARY

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 resulted by heart failure from other diseases. Furthermore, NT-proBNP is a risk assessment indicator for Acute Coronary Syndrome.

Troponin, a molecule complex that is bound to the thin filament (actin) of muscle fibers, acts with intracellular calcium to control the interaction of the thin filament with the thick filament (myosin), thus regulating muscle contraction. Troponin consists of three regulatory proteins: T, which connects the Troponin complex and tropomyosin (another cardiac muscle regulatory protein); I, which prevents muscle contraction in the absence of calcium; and C, which binds calcium. Cardiac Troponin I (MW 22.5 kDa) and the two skeletal muscle isoforms of Troponin I have considerable amino acid sequence homology, but cTnI contains an additional N-terminal sequence and is highly specific for myocardium.

Clinical studies have demonstrated the release of cTnI into the blood stream within hours following acute myocardial infarctions (AMI) or ischemic damage. Elevated levels of cTnI are detectable in blood within 4 to 6 hours after the onset of chest pain, reaching peak concentrations in approximately 8 to 28 hours, and remain elevated for 3 to 10 days following AMI. Due to the high myocardial specificity and the long duration of elevation, cTnI has become an important marker in the diagnosis and evaluation of patients suspected of having an AMI.

PRINCIPLE

Mixed monoclonal antibodies against human NT-proBNP and cTnI were conjugated with fluorescence latex and another set of an anti-human NT-proBNP polyclonal antibody and an anti-human cTnI monoclonal antibody were coated on different test lines respectively. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human NT-proBNP or cTnI monoclonal antibodies will bind with the NT-proBNP and cTnI in sample respectively and form marked antigen-antibody complexes. These complexes move to the test card detection zone by capillary action. Then marked antigen-antibody complexes will be captured on different test lines by another set of anti-human NT-proBNP polyclonal antibody or anti-human cTnI monoclonal antibody. The fluorescence intensity of each test line increases in proportion to the amount of NT-proBNP or cTnI in sample.

Then insert test card into Getein1100 Immunofluorescence Quantitative Analyzer (hereinafter referred to as Getein1100), the concentration of NT-proBNP and cTnI in sample will be determined and displayed on the screen. The value will be stored in Getein1100 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

1. A kit for Getein1100 contains:
Package specifications: 25 tests/kit, 10 tests/kit
1) NT-proBNP/cTnI test card in a sealed pouch with desiccant
2) Disposable pipet
3) User manual: 1 piece/kit
4) SD card: 1 piece/kit
5) Whole blood buffer: 1 bottle/kit

2. A kit for Getein1600 contains:
Package specifications: 2×24 tests/kit, 2×48 tests/kit
1) Sealed cartridge with 24/48 Getein NT-proBNP/cTnI test cards
2) User manual: 1 piece/kit

Materials required for Getein1600:
1) Sample diluent: 1 bottle/kit
2) Box with pipette tips: 96 tips/kit
3) Mixing plate: 1 piece/kit

3. Sample diluent/Whole blood buffer composition:
Phosphate buffered saline, proteins, detergent, preservative, stabilizer.

4. A test card consists of:
A plastic shell and a reagent strip which is composed of a sample pad, fluorescence latex pad, nitrocellulose membrane (one end of the membrane is coated with a fluorescence latex-labelled anti-human NT-proBNP and cTnI monoclonal antibodies, these two test lines are coated with another anti-human NT-proBNP polyclonal antibody and another anti-human cTnI monoclonal antibody, respectively. and the control line C is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

Note: Do not mix or interchange different batches of kits.

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test kit at 4~30℃ with a valid period of 24 months.
Use the test card for Getein1100 within 1 hour once the foil pouch is opened.
For test card of Getein1600: if the cartridge is opened, it could be stable within 24 hours once exposed to air. If the test cards can't be used up at a time, please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.

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.
8. Carefully read and follow the manual to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for ***serum, plasma and whole blood samples. Heparin 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. Serum or plasma can be used directly. For whole blood sample, one drop of whole blood buffer must be added before testing.
4. If testing is delayed, serum and plasma samples may be stored up to 7 days at 2~8℃ or stored at -20℃ for 6 months before testing (whole blood sample may be stored up to 3 days at 2~8℃).
5. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
6. Do not use heat-inactivated samples.
7. SAMPLE VOLUME: ***100 μL***.

TEST PROCEDURE

1. Collect specimens according to manual.
2. Test card, sample and reagent should be brought to room temperature before testing.
3. Confirm SD card lot No. in accordance with test kit lot No.. Perform “SD card” calibration when necessary.
4. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
5. Put the test card on a clean table, horizontally placed.
6. Using sample transfer pipette, deliver ***100 μL*** of sample into the sample well on the test card (for whole blood sample, one drop of whole blood buffer must be added after loading 100 μL sample on the test card).
7. ***Reaction time: 10 minutes.*** Insert the test card into Getein1100 and press "ENT" button or click on “Start” icon (for Android Getein 1100) after reaction time is elapsed. The result will be shown on the screen and printed automatically.

Notes:

1. It is required to perform “SD card” calibration when using a new batch of kits for Getein1100.
2. It is suggested to calibrate once for one batch of kits for Getein1100.
3. Make sure the test card and the sample insertion is correct and complete.

TEST RESULTS

Getein1100 can scan the test card automatically and display the result on the screen. Please follow the procedure in user manual of Getein1100 for result printing. For additional information, please refer to the user manual of Getein1100.

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

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 see below:

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

The expected normal value for cTnI was determined by testing samples from 500 apparently healthy individuals. The 99th percentile of the concentration for cTnI is 0.10 ng/ml. (The probability that value of a normal person below 0.10 ng/ml is 99%.)
It is recommended that each laboratory establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

	NT-proBNP	cTnI
Measuring Range	100~15000 pg/ml	0.10~50.00 ng/ml
Lower Detection Limit	≤ 100 pg/ml	≤ 0.10 ng/ml
Within-Run Precision	≤10%	
Between-Run 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. Mauro Pantaghini; Undefined International Federation of Clinical Chemistry and Laboratory Medicine (IFCC). Scientific Division Committee on Standardization of Markers of Cardiac Damage. Clin Chem Lab Med, 1998, 36:887~893.
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 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/ cTnI 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 purchasing NT-proBNP/cTnI Fast Test Kit (Immunofluorescence Assay). Please read this user manual carefully before operating to ensure proper use.

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