

## Instruction for N-terminal Pro-brain Natriuretic Peptide (NT-proBNP) Test Kit (Immunofluorescence)

### 1. Product Name

Generic name: N-terminal Pro-brain Natriuretic Peptide (NT-proBNP) Test Kit (Immunofluorescence)

Trade name: NT-proBNP

### 2. Package

Specification 1: 25T/kit REF: 52026001

Specification 2: 50T/kit REF: 52027001

### 3. Intended Use & Indication

For in vitro quantitative determination of N-terminal Pro-brain Natriuretic Peptide (NT-proBNP) content in human serum, plasma or whole blood

It is mainly used in clinical auxiliary diagnosis of heart failure.

Products for Professional Use Only.

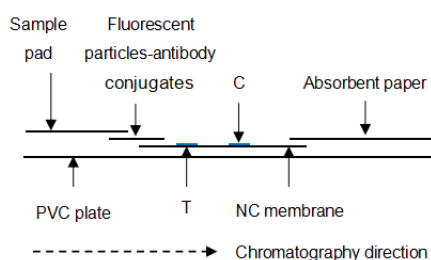
### 4. Test Principle

When the test sample is added to the sample port on the test card, NT-proBNP in the sample combines with mouse anti-NT-proBNP monoclonal antibody which is coupled to fluorescent particles to form fluorescent particles - antibody - antigen complexes. This immune complex reaches to the test area (T) along the nitrocellulose membrane and combines with the pre-coated mouse anti-NT-proBNP monoclonal antibody, its fluorescence intensity is proportional to the NT-proBNP content in the sample, the remaining fluorescent antibody reaches to the quality control area (C) and combines with pre-coated goat anti-mouse IgG. If the sample does not contain NT-proBNP, the test area (T) will not appear fluorescence.

### 5. Main Components & Additional required equipment

The test kit consists of test card, magcard, whole blood buffer and the instruction.

(1) The test card consists of the card housing and test strip. Test strip contains a sample pad, glass fiber (coated with fluorescent particles-NT-proBNP antibody conjugates), nitrocellulose (NC) membrane (test area (T) is coated with NT-proBNP monoclonal antibody, quality control area (C) is coated with goat anti-mouse IgG), absorbent paper and PVC plate. Diagram is as follows:



Schematic diagram of test strip

(2) Magcard: load calibration curve information for reagents with this batch

(3) Whole blood buffer: the main component is phosphate buffer (PBS)

(4) Equipment: Applicable to FA50/FA120 Quantitative Immunoassay Analyzer manufactured by Genrui Biotech Inc.

### 6. Accessories Required But Not Provided

(1) Pipettes and pipette tips: 100  $\mu$ L. (2) Timer

### 7. Special storage & Transport conditions

(1) The test kit can be stored at 2-30

months, once opened, it is valid for 1 hour.

(2) Transport at 2-30  $^{\circ}$ C.

### 8. Sample Requirements

(1) The optimal sample is fresh non-hemolyzed serum, plasma or whole blood. Recommended to use venous blood, results of other body fluids and samples may not be accurate.

(2) Complete the sample test within 24h at room temperature after the sample is collected. Keep serum and plasma refrigerated at 2-8  $^{\circ}$ C for not more than 7 days. Frozen samples need to be frozen below -18  $^{\circ}$ C for not more than 7 days.

(3) Bring the samples to room temperature before the test. Frozen samples need to be melted completely, re-warmed and mixed before use, avoid repeated freezing and thawing.

(4) Human serum or plasma is recommended to be used for testing. EDTA is recommended to be used as the coagulant.

### 9. Test procedure

Carefully read the reagent instruction before using the test kit and strictly operate according to the instruction to ensure reliable results. Bring all reagents to room temperature (18-25  $^{\circ}$ C) before use.

(1) Startup: Click "STD Mode" in the main menu to enter the measurement interface, click "Item" to select the desired test item and click "Type" to select the sample type.

(2) Click "Lot No." to enter the card swiping interface, place magcard of the corresponding item to the magnetic induction zone, when hearing a "di" sound, the magcard is swiped successfully, check whether the magcard and the test card are of the same batch. (Note: reagents are precalibrated and specific calibration curve parameters for each batch of reagents have been stored in the magcard).

(3) Sampling:

a) Serum/Plasma: Take 100 $\mu$ L serum or plasma, drop vertically to the sample port on the test card directly and start timing.

b) Whole blood: Take 100 $\mu$ L whole blood, drop vertically to the sample port on the test card directly, then add one drop of whole blood buffer to the sample port and start timing.

(4) Insert it into the analyzer's test slot (the sample port end toward the inside). Click "Measure", the instrument will automatically detect and print out the results after 15 minutes (If using "Fast Mode", Keep it for 15 minutes and quickly Insert it into the analyzer's test slot).

### 10. Reference interval

Reference range: < 300 pg/mL (< 75 years old)

< 450 pg/mL ( $\geq$  75 years old)

### 11. Explanation for Test Results

(1) When the control area (C) appears fluorescent strips, the analyzer will automatically detect the fluorescence and analyze the test card, and then provide quantitative results.

(2) When the control area (C) does not appear fluorescent strips, the analyzer cannot

detect the fluorescence and alarm automatically, indicating that the operation is

incorrect or the test card is damaged, in this case, carefully read the instructions again and re-test with a new test card, if the problem still exists, immediately stop using products of this batch and contact your supplier.

(3) When the sample test results are greater than 35000pg/mL, the instrument displays > 35000pg/mL, when the test results are less than 18pg/mL, the instrument displays < 18pg/mL. The former can be diluted with saline water by an integer multiple before testing, multiply the result by the dilution ratio.

(4) This test kit does not produce Hook effect within 55000pg/mL.

**12. Detection limit**

(1) This test kit is for in vitro diagnostic use only.  
 (3) Diagnosis and treatment can not only rely on this test result, taking into account the clinical history and other laboratory test results. Each laboratory is recommended to establish its own reference range based on the detected patient population.

**13. Interfering substance**

(1) Hemoglobin, bilirubin, cholesterol, triglycerides, HAMA antibody and rheumatoid factor in samples can interfere with the test results, the maximum allowable concentrations of hemoglobin is 5 g/L, bilirubin is 2 mg/mL, cholesterol is 15 mg/mL, triglycerides is 30 mg/mL, HAMA antibody is 40 ng/ mL, rheumatoid factor is 525 IU/ mL

**14. Product Performance Indicators**

(1) Analysis sensitivity:  $\leq 18\text{pg/mL}$ .  
 (2) Linearity range: 18-35000pg/mL  
 (Linear correlation coefficient:  $r \geq 0.990$ ).  
 (3) Measurement precision: Repeatability:  $CV \leq 15\%$ , relative deviation of test kit's inter batches (R)  $\leq 15\%$ .  
 (4) Accuracy:  $-15\% \leq \text{Bias}\% \leq +15\%$ .  
 (5) The Interference test result:  $-15\% \leq \text{Bias}\% \leq +15\%$ .

**15. Precautions**

(1) Once opened, use the test cards as soon as possible, which may cause moisture. Do not re-use the test cards.  
 (2) Components in test kit of different batches can not be used interchangeably.  
 (3) For substances containing sources of infection or suspected of containing sources of infection, there should be proper bio-safety assurance procedures. Pay attention to the following matters:  
 a) Wear gloves when handling sample or reagent for disinfection.  
 b) Disinfect spilled sample or reagent with disinfectant.  
 c) Disinfect or handle potential contamination sources of all samples or reagents in accordance with local regulations.

**16. Explanation of graphic symbol**

	Consult Instructions for use		Temperature Limitation
	Lot No.		Expiry Date
	In Vitro Diagnostic Reagent		CONFORMITE

			EUROPEENNE
	Production Date		Biohazard
	Manufacturer		Volume
	Contains sufficient for < n>tests		Keep away from sunlight
	Do not re-use		Dark dry preservation
	Authorized representative in the European community		Catalogue number

**17. Reference**

(1) Cowie MR, Mosterd A, Wood DA, et al. The epidemiology of heart failure J. 1997;18:208-225.  
 (2) Mueller C, Scholer A, Laule-Kilian K, et al. Use of B-type natriuretic peptide in the evaluation and management of acute dyspnea. N Eng J Med. 2004;350:647-654.  
 (3) Moeckel, M, Mueller, R, Vollert JO, et al. Role of N-terminal pro-B-type natriuretic peptide in risk stratification in patients presenting in the emergency room. Clin Chem. 2005;51:1624-1631.

**18. Metrological traceability**

The kit was traced to the N-terminal Pro-brain Natriuretic Peptide (NT-proBNP) Test Kit, Produced by Roche Diagnostic GmbH.

**19. Help Information**

If you need help please contact after sales.

**20. Manufacturer**

Genrui Biotech Inc.  
 Address: 4-10F, Building 3, Geya Technology Park, Guangming District, 518106, Shenzhen, China.  
 Web: www.genrui-bio.com

**21. Instruments & Applications**

Genrui's Immunofluorescence products, designed to work in automated lab environment, which are compatible with the FA50/FA120 Quantitative Immunoassay Analyzer. There may or may not be an application developed for you particular instrument, please visit the instrument section of our website.

