

# N-terminal Prohormone of Brain Natriuretic Peptide (NT-proBNP) Rapid Test Kit

(Fluorescence Immunochromatographic Assay)

Catalog Number: 5194C4X025,5194C4X050

## INTENDED USE

This kit is suitable for in vitro quantitative detection of the concentration of N-terminal Pro-Brain Natriuretic Peptide (NT-proBNP) in human serum, plasma and whole blood. This product is used for testing in medical and health institutions as an aid in the diagnosis of individuals suspected of having congestive heart failure (CHF) and detection of mild forms of cardiac dysfunction.

## PRINCIPLE OF THE PROCEDURE

This test uses highly specific double antibody sandwich method principle and fluorescence immunochromatography analysis technology to quantitatively detect the amount of NT-proBNP in human serum, plasma and whole blood and peripheral blood. This product is pre-embedded with fluorescent microspheres labeled mouse anti-NT-proBNP antibody and rabbit IgG antibody on the binding pad, and coated with mouse anti-NT-proBNP antibody and goat anti-rabbit IgG antibody respectively on the test line and control line of nitrocellulose membrane. When the sample is tested, the NT-proBNP antigen in the sample is combined with the fluorescent microspheres-labeled mouse anti-NT-proBNP antibody embedded on the conjugate pad to form the fluorescent microspheres-labeled mouse anti-NT-proBNP antibody-NT-proBNP immune complex. Under the action of chromatography, the immune complex flows along the nitrocellulose membrane to the end of the absorbent filter paper. On the test line, the immune complex is captured by the mouse anti-NT-proBNP antibody pre-coated, forming the double-antibody sandwich structure of fluorescent microspheres labeled mouse anti-NT-proBNP antibody-NT-proBNP-mouse anti-NT-proBNP antibody and enriching. When the samples pass the control line, the rabbit IgG antibody labeled with fluorescent particles is enriched by combining with the pre-coated goat anti-rabbit IgG antibody. The concentration of NT-proBNP in the sample is positively correlated with the fluorescence intensity of the test line. The

concentration of NT-proBNP in the sample is obtained through the test and analysis by the Immunofluorescence Analyzer.

## COMPONENT

### Materials provided with the test kits

1. The test card for a single copy of the aluminum foil bag packaging, containing the NT-proBNP test card and desiccant, test card main components as follows: the backplane, sample pad, conjugate pad, nitrocellulose membrane, absorbent paper and plastic parts, the test line (T) was coated with anti-NT-proBNP antibody, the quality control line (C) was coated with goat anti-rabbit IgG antibody, and the conjugate pad was embedded with fluorescent microspheres-labeled anti-NT-proBNP antibody and rabbit IgG antibody. The identification code of the test card contains the item name, batch number, ID chip card contains the batch number, calibration curve, concentration unit, reference value, detection time and other information of the kit.
2. The sample diluent is a phosphate buffer.
3. Main components:

Ingredients	Specifications	25 tests/kit	50 tests/kit
Test card with desiccant in a sealed foil pouch		25	50
Sample diluent		25	50
Pipette tip		25	50
ID chip		1	1
Instruction for use		1	1

4. The components in different batches of kits are not interchangeable.

### MATERIALS REQUIRED BUT NOT PROVIDED

- The immunofluorescence analyzer
- Transfer Pipette
- Specimen Collection Containers
- Centrifuge (for serum/plasma specimen only)
- Timer

## STORAGE AND STABILITY

1. Kits should be stored in 2° C~30°C in a cool, dark, dry place preservation, valid for 24 months, frozen or in use after the period of validity of avoid by all means.
2. The test card should be in aluminum foil bag after opening, to the specified environment (temperature 2°C~35°C, humidity 40%~90%) used within 60 minutes.

3. Sample diluent is available on demand.

## APPLICABLE INSTRUMENT

This Test Kit is applicable to the Immunofluorescence Analyzer CHF100, CHF200, CHF300, CHF400, CHF500, CHF600, CHF800, produced by Dongguan Tronho Medical Technology Co., Ltd.

## SAMPLE COLLECTION AND STORAGE

1. Samples may be serum, heparin anticoagulant plasma, sodium citrate anticoagulant plasma, EDTA anticoagulant plasma, and whole blood.
2. Samples should be collected according to routine clinical methods and avoid hemolysis.
3. Serum and plasma samples collection: If serum or plasma specimens are not tested immediately, they should be refrigerated at 2°C~8°C and test within 7 days. For long time storage, they should be -20°C cryopreservation, to avoid repeated freezing and thawing.
4. Collection of whole blood samples: collect venous blood with disposable vacuum blood collection containing anticoagulant without separation and directly as the test sample. Whole blood samples can be in 2°C~8°C kept in refrigerator for 3 days, not cryopreservation.
5. Restore the sample to room temperature before test.
6. Obvious hemolysis, lipohemia and jaundice samples should not be used.

## TEST PROCEDURE

Before the test, the instruction manual of the product and the operation manual of the detector must be read completely, and the reagent should be restored to room temperature before the test. The test operation cannot be carried out under the condition that the room temperature is not restored, so as not to affect the accuracy of the test results.

### Operation process:

1. Instrument preparation: turn on the power of the immunofluorescence analyzer, select the test mode (immediate test, standard test or batch test), read the reagent ID chip, select the sample type and test items. The specific operation of the instrument shall be carried out according to the operating instructions of the corresponding type of instrument.
2. Preparation of reagents: balance the reagent or sample to

room temperature, tear open the aluminum foil bag, take out the test card, and lay it flat on a flat operating table. It is recommended to restore the sample to room temperature before sampling.

3. Sampling: take 30 µL serum or plasma or whole blood samples from the pipette, add the samples to the sample diluents and fully mix them for 60 seconds.
4. Add sample: take out the test card from the package and add 100µL mixed samples from the pipette to the sample well of the test card. Let stand at room temperature for 15mins (please strictly control the time for 15mins).
5. Detection: insert the detection card into the instrument before the end of the 15minutes countdown to the reaction of the detection card. After the end of the 15minutes countdown to the reaction, manually click "test" or the instrument will automatically test the test card according to the detection mode selected by the user, and record, read and print the test results. If the test card fails to be tested in time after the 15minutes countdown, it will be deemed invalid and the sample shall be re-tested with a brand new test card.

## CALIBRATION

Traceability: Calibrator for calibration curve establishment are traceable to internal reference standards. This method has been standardized against the Roche Elecsys proBNP II assay.

The calibration curve of the reagent is embedded in ID chip. The fluorescence analyzer substitutes the test signal of the detection card into the calibration curve to calculate the concentration of NT-proBNP in the sample.

## REFERENCE INTERVAL

The statistical analysis of serum samples of 200 healthy persons aged less than 75 years and over 75 years showed that: NT-proBNP. The upper limit of the normal reference value is the 95th percentile: NT-proBNP(<75 aged):<300pg/mL; NT-proBNP(>75 aged):<450pg/mL.

Due to differences in geography, ethnicity, and age, it is recommended that each laboratory establish a reference interval with relevant clinical significance for the population of the region.

## INTERPRETATION OF TEST RESULTS

1. The concentration of the sample NT-proBNP measured is higher than the reference value range, it is indeed abnormal and should be diagnosed in combination with clinical symptoms.

Item name	Test results	Clinical application recommendations
NT-proBNP	<75aged: <300 pg/mL ≥75aged: <450 pg/mL	Normal level
	<75aged: ≥300 pg/mL ≥75aged: ≥450 pg/mL	It indicates that the patient is at risk of Heart disease (heart failure). Note: the positive rate reached 13.3% at 3 hours, 86.6% at 6 hours, 96.6% at 9 hours and 100% at 12 hours.

2. The measurement results of this method are only suitable for the reference value range established by this method, and are not directly comparable with the results of other methods.
3. Other factors can also cause errors in test results, including technical reasons, operational errors and other sample factors.

## QUALITY CONTROL

This product used in conjunction with immunofluorescence analyzer contains internal control for routine quality control requirements. This internal control is performed each time when a patient sample is tested. This control indicates whether the test cartridge was inserted and read properly by immunofluorescence analyzer. An invalid result from the internal control causes an error message on analyzer indicating that the test should be repeated.

## LIMITATIONS

1. This reagent is suitable for the detection of human serum/plasma/whole blood samples, and the detection results of other samples may be wrong.
2. Please check the integrity and expiry date of the kit package before use, and then open the package. The package can only be opened at room temperature after cryopreservation.
3. Direct use of low temperature will affect test results.
4. Improper operation and other factors may affect the accuracy of the results.
5. Different batches of sample diluents cannot be mixed.
6. Human anti-mouse antibody (HAMA) may be present in patients who have received murine monoclonal

immunotherapy. This kit has been developed to minimize the impact of these antibodies on test results through special methods. However, test results should be carefully evaluated when patients are known to have these antibodies.

7. For samples whose NT-proBNP concentration may be greater than the linear range, it is necessary to measure with normal saline after appropriate dilution, and the maximum dilution ratio of normal saline is 10 times.
8. When the erythrocyte volume (hematocrit) of the sample exceeds the normal range, the whole blood sample cannot be used as the test sample for this reagent. The erythrocyte volume (hematocrit) of the whole blood samples will affect the test results.
9. The test result has been corrected and compensated for whole blood sample. But in order to obtain more accurate results, individual NT-proBNP test results (C0) and hematocrit (P) can be substituted into the following formula for further correction, and the calculated results (C1) can be used as the final test results.

$$C1=0.625*C0/(1-P)$$

Or the corresponding correction coefficients of the test results C0 multiplied by the table below can be used as the final test results.

Hct(%)	0.2	0.25	0.3	0.35	0.4	0.45	0.5
CC(K)	0.78	0.83	0.89	0.96	1.04	1.14	1.25
Hct(%)	0.55	0.6	0.65	0.7	0.75	0.8	
CC(K)	1.39	1.56	1.79	2.08	2.50	3.13	
Result (pg/mL)	C <sub>0</sub>						
Final result (pg/mL)	C <sub>1</sub> =C <sub>0</sub> *K						

10. As with all diagnostic reagents, the final diagnosis should be made by the doctor after the combination of various indicators and clinical symptoms.

## PRODUCT PERFORMANCE INDEX

Internal calibration products were used for evaluation, and the performance indicators of the kit met the standards. The specific performance indicators are as follows:

1. Reportable range: NT-proBNP 100~350000 pg/mL.
2. Linearity: NT-proBNP :100~35000 pg/mL, and the analysis performance meets the following requirements:

a) the deviation of the measurement results shall be within 15%.

b) linear correlation coefficient (r) should  $\geq 0.9900$ .

3. Accuracy: The recovery rate should be in the range of 85% to 115%.

4. Detection limit: NT-proBNP  $\leq 100$ pg/mL.

5. Repeatability: CV  $\leq 10\%$ .

6. Inter-batch variation: CV  $\leq 15\%$ .

7. HOOK effect: When the NT-proBNP concentration reached 40000 pg/mL, no HOOK effect occurred.

8. Interference experiment: the following substances were tested at the concentration shown, and no interference was found.

Bilirubin	$\leq 12$ mg/dL	Hemoglobin	$\leq 6$ mg/mL
Triglyceride	$\leq 15$ mg/mL	Total Cholesterol	$\leq 10$ mg/mL

## PRECAUTIONS

1. This reagent is only used for in vitro diagnosis. It is disposable.
2. The kit should be sealed and kept away from moisture. The strip should be used as soon as possible after it is removed from the package to avoid being in the air for too long and being affected with damp.
3. Do not use samples that have been placed for too long or repeatedly frozen or thawed should not exceed three times.
4. The amount of specimen added should be accurate, or it may cause wrong results.
5. Used reagents and samples should be treated as medical waste with the risk of biological transmission, and pay attention to safe operation. The desiccant in the aluminum foil bag should not be taken internally.
6. Check whether the aluminum foil bag is damaged before test. If it is damaged, the test cannot be used, so as not to affect the judgment of test results.
7. Incorrect operation may affect the accuracy of the results, such as wet display window or insufficient amount.
8. If you have any questions or suggestions in the process of using this product, please contact us.










## BIBLIOGRAPHY

1. China National Clinical Laboratory Procedures (third edition, 2006). Department of Health, Ministry of Health.
2. Ambrose T M. Review of the clinical utility of NT-proBNP in the diagnosis, prognosis, and therapy monitoring of patients

with congestive heart failure[J]. Journal of clinical ligand assay, 2002, 25(2): 160-166.

1. Jingtiao ma etc.the value of NT-proBNP in the diagnosis of heart failure. International journal of laboratory medicine .2001,32(20).
2. Hansen JH,et al.HAMA Interference with Murine Monoclonal Antibody-Based Immunoassays[J].J of Clin Immunoassay,1993,16:294-299.

## KEY TO SYMBOLS USED

<b>COMPONENT</b>	Materials Included	<b>ID CHIP</b>	ID Chip
<b>TEST CARD</b>	Test Card with Desiccant in a Sealed Foil Pouch	<b>TIP</b>	Pipette Tip
<b>DILUENT</b>	Sample Diluent	<b>IFU</b>	Instruction for Use
	Consult Instructions For Use		Date of Manufacturer
	Store at 2°C~30°C		Do Not Reuse
	Expiration Date	<b>REF</b>	Catalogue Number
	Manufacturer		Keep away from Sunlight
<b>LOT</b>	Lot Number		Tests per Kit
<b>EC REP</b>	Authorized Representative		Keep Dry
<b>IVD</b>	In Vitro Diagnostic Medical Device	<b>MAN.ADD.</b>	The address of manufacture factory
<b>FICA</b>	Fluorescence Immunochromatographic Assay		



Guangzhou Decheng Biotechnology Co., LTD  
Room 218, Building 2, No.68, Nanxiang Road, Science City,  
Huangpu District, 510000, Guangzhou P.R.China  
TEL: +86-020-82557192  
service@dochebio.com  
www.dochebio.com



Caretechion GmbH  
Niederrheinstr. 71,  
40474 Duesseldorf, Germany.

