Chuangxingwell

NT-proBNP Rapid Test Test Kit
Package Insert

CE

For in vitro diagnostic use only. For professional use only. IVD

INTENDED USE

The NT-proBNP Rapid Test Test Kit is a fluorescence immunoassay for quantitative measurement of N-terminal prohormone of brain natriuretic peptide (NT-proBNP) in human whole blood, serum or plasma.

-Fluorescence immunoassay
-Diagnosis of suspected congestive heart failure.

SUMMARY

The N-terminal prohormone of brain natriuretic peptide (NT-proBNP) which consists of 76 amino acids, is the N-terminal fragment of the prohormone of brain natriuretic peptide. NT-proBNP level in the blood is used for screening, diagnosis of acute congestive heart failure (CHF) and may be useful to establish prognosis in heart failure, as it is typically higher in patients with worse outcome. NT-proBNP may be a useful screening tool for left ventricular dysfunction in patients with history suggestive of heart disease and be used to assist in forming a pretest probability, which in turn could greatly assist in appropriateness of patient referral and in optimization of drug therapy.

Normal Reference Value:

Concentrations	Clinical Reference
＜75 years old: 0～300 ng/L ≥75 years old: 0～450 ng/L	Preliminarily determined that the patient did not suffer from Congestive Heart Failure
＜75 years old: ＞300 ng/L ≥75 years old: ＞450 ng/L	Indicating risk of congestive heart failure.

PRINCIPLE

The NT-proBNP Rapid Test Test Kit is based on fluorescence immunoassay technology. The Test Kit uses a sandwich immunodetection method, when sample is added to the sample well of the test, the fluorescence-labeled detector anti-NT-proBNP antibody binds to NT-proBNP antigen in blood specimen. As the sample mixture migrates on the nitrocellulose matrix of test strip by capillary action, the complexes of detector antibody and NT-proBNP are captured to anti-NT-proBNP antibody that has been immobilized on test strip. Thus the more NT-proBNP antigen is in blood specimen, the more complexes are accumulated on test strip. Signal intensity of fluorescence of detector antibody reflects amount of NT-proBNP captured and Immunofluorescence Analyzer shows NT-proBNP concentrations in blood specimen. The default results unit of NT-proBNP Rapid Test Test Kit is displayed as ng/L from Immunofluorescence Analyzer. The working range and the detection limit of the NT-proBNP Test system are 18～35000 ng/L and 18 ng/L, respectively.

PRECAUTIONS

1. This kit is for in vitro diagnostic use only. Do not swallow.
2. Do not mix components from different kit lots.
3. Do not use test kit beyond the expiration date.
4. Don't use Test Kit if its lot # does not match with ID Chip # that is inserted onto the instrument.
5. The NT-proBNP Rapid Test Kit is only operational in the corresponding Immunofluorescence Analyzer. And tests should be applied by professionally trained staff working in certified laboratories at some remove from the patient and clinic at which the sample(s) is taken by qualified medical personnel.
6. The test Kit should remain in its original sealed pouch until ready to use. Do not use the test Kit if the pouch is punctured or not well sealed. Discard after single use.
7. The Test Kit and Analyzer should be used away from vibration and magnetic

field. During normal usage, the Test Kit may introduce minute vibration, which should be regarded normal.

8. Use separate clean pipette tips and detector buffer vials for different specimens. The pipette tips and detector buffer vials should be used for one specimen only. Discard after single use.
9. Do not smoke, eat, or drink in areas in which specimens or kit reagents are handled.
10. Blood specimens, used test cartridges, pipette tips and detector buffer vials are potentially infectious. Proper laboratory safety techniques, handing and disposal methods should be followed in accordance with standard procedures and relevant regulations observed by microbiological hazard materials.
11. The NT-proBNP Rapid Test Test Kit should not be used as absolute evidence for congestive heart failure. The results should be interpreted by the physician along with clinical findings and other laboratory test results.
12. The test will be applied on a routine basis and not in emergency situations.

MATERIAL

Material Provided

Test Cassettes	25
Test Cassette ID Chip	1
Detector Buffer	25
Package Insert	1

Material Required But Not Provided

1. Immunofluorescence Analyzer
2. Transfer Pipette Set (100μL size)
3. Specimen Collection Containers
4. Alcohol Pads
5. Centrifuge (for Plasma/Serum only)
6. Timer

STORAGE AND STABILITY

1. Store the detector buffer at 4～30℃. The buffer is stable up to 24 months.
2. Store the Test Cassette at 4～30℃, shelf life is up to 24 months.
3. Test Cassette should be used within 1 hour after opening the pack.

SPECIMEN COLLECTION AND PREPARATION

The test can be performed with serum or plasma or whole blood.

For Whole Blood Collected by Venipuncture:

1. Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube with suitable anticoagulant (EDTA recommended)
2. It is recommended that specimens should be tested immediately. Do not leave the specimens at room temperature for prolonged periods. If the specimens are not tested immediately, they may be stored at 2℃～8℃.
3. It's not suitable to test the whole blood samples which have been stored at 2℃～8℃ for more than 2 days.

For Serum and Plasma:

1. Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube. If collecting plasma use a blood collection tube containing suitable anticoagulant (EDTA recommended).
2. Separate the serum/plasma from blood as soon as possible to avoid hemolysis.
3. Test should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2℃～8℃ for up to 3 days. For long-term storage, specimens should be kept below -20℃.

TEST PROCEDURE

Refer to Immunofluorescence Analyzer Operation Manual for the complete instructions on use of the Test. The test should be operated in room temperature.

Step1: Preparation

Before testing, activate "use" in setting then save it.

Check/insert ID Chip into the equipment.

Step2: Sampling

Draw 75μL of whole blood, serum or plasma with a transfer pipette and add it to the buffer tube.

Step3: Mixing

Mix well the specimen with buffer for 1 minute by tapping or inverting the tube.

Step4: Loading

Take 75μL of sample mixture and load it onto the sample well of the Test Cassette.

Step5: Testing

There are two test modes for Fluorescence Immunoassay Analyzer, Standard Test mode and Quick Test mode. Please refer to the user manual of Fluorescence Immunoassay Analyzer for details.

Standard test: Insert the Test Cassette onto the Test Cassette Holder and click "Test". 15 minutes later, choose the sample type, then the result will show in the display and print out when click "Print".

Quick test: Put the Test Cassette on the operation platform. 15 minutes later, insert the Test Cassette onto the Test Cassette Holder and click "Test". Choose the sample type, then the result will show in the display and print out when click "Print".

INTERPRETATION OF RESULTS

The Fluorescence Immunoassay Analyzer calculates NT-proBNP test results automatically and displays the concentration of NT-proBNP on the screen. For further information, refer to the User Manual for the Fluorescence Immunoassay Analyzer.

Reference range of NT-proBNP:

1. Detection range: 18～35000 ng/L
2. Cut-off : 18 pg/mL

QUALITY CONTROL

Each NT-proBNP Rapid Test Test Kit contains internal control that satisfies routing quality control requirements. This internal control is performed each time a patient sample is tested. This control indicates that the test Cassette was inserted and read properly by Immunofluorescence Analyzer. An invalid result from the internal control causes an error message on Immunofluorescence Analyzer indicating that the test should be repeated.

LIMITATIONS OF PROCEDURE

1. This test has been developed for testing human whole blood, serum, plasma specimen only.
2. The results of NT-proBNP Rapid Test Test Kit should be evaluated with all clinical and laboratory data available. If NT-proBNP test results do not agree with the clinical evaluation, additional tests should be performed.
3. The false positive results include cross-reactions with some components of serum from individual to antibodies; and non-specific adhesion of some components in human blood that have similar epitopes to capture and detector antibodies. In the case of false negative results, the most common factors are: non-responsiveness of antigen to the antibodies by that certain unknown components are masking its epitope, such that antigen cannot be seen by the antibodies; instability of NT-proBNP antigen, resulting in degradation with time and, or temperature, such that they become no longer recognizable by antibodies; and degraded other test components. The effectiveness of the test is highly dependent on storage of kits and sample specimens at optimal conditions.
4. Plasma using anticoagulants (e.g. heparin or citrate) other than EDTA has not been evaluated in NT-proBNP Rapid Test Test Kit and thus should not be used.
5. Other factors may interfere with NT-proBNP Rapid Test Test Kit and may cause erroneous results. These include technical or procedural errors, as well as additional substances in blood specimens.

PERFORMANCE CHARACTERISTICS

Accuracy

A comparison study using 211 human blood samples, demonstrated good correlation with a commercially available kit.

Comparison between the NT-proBNP Rapid Test Test Kit and the Roche Diagnostics GmbH NT-proBNP STAT for the 211 clinical samples, the Correlation Coefficient is 0.974

Assay Range and Detection Limit

- **Assay Range**: 18～35000 ng/L
- **Detection Limit:** 18 ng/L

Linearity

A serial concentration of NT-proBNP controls at 120 ng/L, 450 ng/L 1500 ng/L, 3000 ng/L, 6000 ng/L, 15000 ng/L were each tested for three times, the Correlation Coefficient (R) is ≥0.995.

Precision

Intra-Lot Precision

Within-run precision has been determined by using 10 replicates of specimen of 450 ng/L NT-proBNP. C.V. is ≤15%.

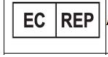
Inter-Lot Precision

Between-run precision has been determined by using 3 replicates for each of three lots using NT-proBNP specimen levels at 450 ng/L. C.V. is ≤15%.

BIBLIOGRAPHY OF SUGGESTED READING

1. Bhalla V, Willis S, Maisel AS (2004). "B-type natriuretic peptide: the level and the drug--partners in the diagnosis of congestive heart failure". Congest Heart Fail 10 (1 Suppl 1): 3–27.
2. Atisha D, Bhalla MA, Morrison LK, Felicio L, Clopton P, Gardetto N, Kazanegra R, Chiu A, Maisel AS (September 2004). "A prospective study in search of an optimal B-natriuretic peptide level to screen patients for cardiac dysfunction". Am. Heart J. 148 (3): 518–23.

Index of Symbols

	Caution		In Vitro Diagnostic Medical Device
	Manufacturer		Date of Manufacture
	CE Marking		Do Not Re-use
	Keep Dry		Keep Away From Sunlight
	Batch Code		Do Not Use if Package is Damaged
	Catalogue Number		Contains Sufficient for <n> Tests
	Use-By Date		Temperature Limit
	Authorized representative in the European Community		

Manufacturer
Jinan Chuangxingwell Biotech Co., Ltd.
Add.: Building 1-2B-402, Liando U Valley, Gangyuan Sixth Road, Jinan Zhangjin Comprehensive Bonded Zone, Gaoxin District, Jinan city, Shandong Province, China
Tel: +86-0531-88894020
Email: s@1stiot.com

EC REP

Riomavix S.L.
Add.: Calle de Almansa 55, 1D, Madrid 28039 Spain
E-mail: leis@riomavix.com
Tel.: +34 658 396 230
(SRN: ES-AR-000001202)