Finecare™ NT-proBNP Rapid Quantitative Test

Catalog No. W202

INTENDED USE

The Finecare™ NT-proBNP Rapid Quantitative Test along with Finecare™ FIA Meter 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.

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

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

PRINCIPLE

The Finecare™ NT-proBNP Rapid Quantitative Test is based on fluorescence immunoassay technology. The Finecare™ NT-proBNP Rapid Quantitative Test 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 Finecare™ FIA Meter shows NT-proBNP concentrations in blood specimen. The default results unit of Finecare™ NT-proBNP Rapid Quantitative Test is displayed as XXX pg/mL from Finecare™ FIA Meter. The working range and the detection limit of the NT-proBNP Test system are 18～35000 pg/mL and 18 pg/mL, 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 Cartridge if its lot # does not match with ID Chip # that is inserted onto the instrument.
5. The Finecare™ NT-proBNP Rapid Quantitative Test kit is only operational in the Finecare™ FIA Meter. 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 cartridge should remain in its original sealed pouch until ready to use. Do not use the test cartridge if the pouch is punctured or not well sealed. Discard after single use.
7. The Test Cartridge and Meter should be used away from vibration and magnetic field. During normal usage, the Test Cartridge 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 Finecare™ NT-proBNP Rapid Quantitative Test 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 Cartridge	25
Test Cartridge ID Chip	1
Detector buffer	25

Leaflet of instruction.

Material Required But Not Provided

1. Finecare™ FIA Meter
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 Finecare™ NT-proBNP Rapid Quantitative Test Cartridge at 4～30℃, shelf life is up to 24 months.
3. Test cartridge 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 Finecare™ FIA Meter 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 Cartridge.

Step5: Testing

1. Finecare™ FIA meter:

Standard test: Insert the Test Cartridge onto the Test Cartridge 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 Cartridge on the operation platform. 15 minutes later, insert the Test Cartridge onto the Test Cartridge Holder and click “Test”. Choose the sample type, then the result will show in the display and print out when click “Print”.

2. Finecare™ multi-channel FIA meter:

Insert the Test Cartridge onto the Test Cartridge Holder. 15 minutes later, choose the sample type, then the result will show in the display and print out when click “Print”.

Please refer to the **Operation** in user manual of Finecare™ FIA Meter for details.

QUALITY CONTROL

Each Finecare™ NT-proBNP Rapid Quantitative Test Cartridge 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 cartridge was inserted and read properly by Finecare™ FIA Meter. An invalid result from the internal control causes an error message on Finecare™ FIA Meter 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 Finecare™ NT-proBNP Rapid Quantitative Test 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 Finecare™ NT-proBNP Rapid Quantitative Test and thus should not be used.
5. Other factors may interfere with Finecare™ NT-proBNP Rapid Quantitative Test 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 Finecare™ NT-proBNP Rapid Quantitative Test 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 pg/mL
- **Detection Limit:** 18 pg/mL

Linearity

A serial concentration of NT-proBNP controls at 120 pg/mL, 450 pg/mL, 1500 pg/mL, 3000 pg/mL, 6000 pg/mL, 15000 pg/mL 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 pg/mL 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 pg/mL. 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.