Finecare™

BNP (B-type natriuretic) Rapid Quantitative Test

Catalog No. W222

INTENDED USE

The Finecare™ BNP (B-type natriuretic) Rapid Quantitative Test along with Finecare™ FIA Meter is a fluorescence immunoassay for quantitative measurement of Brain Natriuretic Peptides (BNP) in human whole blood or plasma. The test is use as an aid to predict the risk of heart failure.

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

SUMMARY

Brain Natriuretic Peptides (BNP) is a 32-amino acid polypeptide secreted by the ventricles of the heart in response to excessive stretching of heart muscle cells (cardiomyocytes). BNP is secreted along with a 76-amino acid N-terminal fragment (NT-proBNP) that is biologically inactive. BNP binds to and activates the atrial natriuretic factor receptors NPRA, and to a lesser extent NPRB, in a fashion similar to atrial natriuretic peptide (ANP) but with 10-fold lower affinity. The biological half-life of BNP, however, is twice as long as that of ANP, and that of NT-proBNP is even longer, making these peptides better targets than ANP for diagnostic blood testing. The main clinical utility of either BNP or NT-proBNP is that a normal level rules out acute heart failure in the emergency setting. Either BNP or NT-proBNP can also be used for screening and prognosis of heart failure. Both are also typically increased in patients with left ventricular dysfunction, with or without symptoms (BNP accurately reflects current ventricular status, as its half-life is 20 minutes, as opposed to 1–2 hours for NT-proBNP).

PRINCIPLE

The Finecare™ BNP (B-type natriuretic) Rapid Quantitative Test is based on fluorescence immunoassay technology. The Finecare™ BNP Rapid Quantitative Test (Lateral Flow Immunoassay) uses a sandwich immunodetection method, when sample is added to the sample well of the test, the fluorescence-labeled detector BNP antibody on the membrane binds to BNP 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 BNP antigen are captured to BNP antibody that has been immobilized on test strip. Thus the more BNP antigen is in blood specimen, the more complexes are accumulated on test strip. Signal intensity of fluorescence of detector antibody reflects amount of BNP captured and Finecare™ FIA Meter shows BNP concentrations in blood specimen. The default results unit of Finecare™ BNP (B-type natriuretic) Rapid Quantitative Test is displayed as XXX pg/mL from Finecare™ FIA Meter. The assay range and the limit of detection of the BNP test system are 5~5000 pg/mL and 5 pg/mL, respectively.

PRECAUTIONS

1. This kit is for in vitro diagnostic use only. Do not swallow.
2. The desiccant is for storage purposes only, is not used in the test procedures.
3. Do not mix components from different kit lots. Please make sure that the test device, the buffer and the ID Chip are the same lot before use.
4. Do not use test kit beyond the expiration date.
5. Protective measure should be taken when sample collection, handling, storage and mixing.
6. The Finecare™ BNP (B-type natriuretic) Rapid Quantitative Test 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.
7. The test device 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.
8. Disappearance of the blue line on the right of result window of the test will indicate the test device has been used.
9. The Test device and Meter should be used away from vibration and magnetic field. During normal usage, the Test Kit may introduce minute vibration, which should be regarded normal.
10. Do not pull out the ID Chip when test are in procedure.
11. Bring the test device to room temperature before open. Test should be performed in the required environment.
12. Do not insert the test in the meter when the cassette cover is bedewed with blood or other fluid. Or else, the meter may be damaged.

13. Do not use whole blood specimen when hemolysis or blood clot appears.
14. Use separate clean pipette tips and detector buffer vials for different specimens. The pipette tip and detector buffer vial should be used for one specimen only. Discard after single use.
15. Do not smoke, eat, or drink in areas in which specimens or kit reagents are handled.
16. The Finecare™ BNP (B-type natriuretic) Rapid Quantitative Test should not be used as absolute evidence for myocardial infarction or suspected congestive heart failure. The results should be interpreted by the physician along with clinical findings and other laboratory test results.
17. The test will be applied on a routine basis and not in emergency situations.

MATERIAL

Material Provided

1. 25 Individual sealed pouches, each containing:
   - Test Device
   - Desiccant Pouch
2. One Test Device ID Chip
3. Leaflet with instructions for use
4. 25 tubes of buffer

Material Required But Not Provided

1. Finecare™ FIA Meter
2. Transfer Pipette Set
3. Specimen Collection Containers
4. Centrifuge (for plasma only)
5. Timer

STORAGE AND STABILITY

1. Store the test kit at 4~30℃ up to the expiration date.
2. If removed from refrigerator, allow the test for 30 minutes to return to room temperature before testing.
3. Do not remove the device from the pouch until ready to use.The test device should be used within 1 hour once opened.

SPECIMEN COLLECTION AND PREPARATION

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

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. Specimens 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 Plasma:

1. Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube. Use a blood collection tube containing suitable anticoagulant (EDTA recommended).
2. Separate the 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 2 days. For long-term storage, specimens should be kept below -20℃.

Bring specimens to room temperature before testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly. Only clear, non-hemolyzed specimens can be used.

TEST PROCEDURE

Refer to operation manuals of Finecare™ FIA Meter for the complete instructions on use of the test. The test should be in room temperature.

1. Set a Test Device on a dust-free clean place.
2. Check/insert ID Chip onto the instrument. Make sure that the Test Device lot # matches with ID Chip #.
3. Take out one tube of Buffer.
4. Draw 75 µL of whole blood or plasma with a transfer pipette and add it to the buffer tube.
5. Mix well the specimen with Buffer by tapping or inverting the tube.
6. Take 75 µL of sample mixture and load it onto the sample well of the Test Device.
7. Please refer to the Section Ⅴ Operation in user manual for details.
   7.1 For Quick Test mode: If you select the Quick Test mode, start the timer right after adding the sample mixture to the sample well, and leave the Test

Device at room temperature for 15 minutes. Then immediately insert test device onto the holder of the meter and click “Test” . The instrument will automatically start to scan the Test Device immediately(Apply to Finecare™ FIA Meter).

7.2 For Standard Test mode: If you select the Standard Test mode, immediately insert the Test Device onto the Test Device Holder of the meter right after adding the sample mixture to the sample well, and click “Test” (Apply to Finecare™ FIA Meter).

8 . Read the results on the display screen of the Meter.

Traceability: Values of this product are linked to the Triage Meter system for BNP Test based on the respective instrument calibration traceability.

INTERPRETATION OF RESULTS

The Finecare™ FIA Meter calculates BNP test results automatically and displays the exact concentrations of BNP on the screen as form of pg/mL. For further information, refer to the Operation Manual for the Finecare™ FIA Meter. The following BNP concentration values can be used for the reference to predict the risk of developing chronic kidney disease.

Normal Reference Value: 0~100 pg/mL

Note: Recommend that each laboratory formulates its own Reference Range according to actual situation.

QUALITY CONTROL

Each Finecare™ B-type natriuretic (BNP) Rapid Quantitative Test (Lateral Flow Immunoassay) device 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 device 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™ BNP (B-type natriuretic) Rapid Quantitative Test should be evaluated with all clinical and laboratory data available. If BNP 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 human blood from individual to antibodies; and non-specific adhesion of some components in human whole blood that have similar epitopes to capture and detector antibodies.
4. 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 BNP 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.
5. Other factors may interfere with Finecare™ BNP (B-type natriuretic) Rapid Quantitative Test and may cause erroneous results. These include technical or procedural errors, as well as additional substances in blood specimens.

EXPECTED RESULTS

Concentrations	Clinical Reference
0~100 pg/mL	Normal Levels.
>100 pg/mL	To predict the risk of heart failure.

PERFORMANCE CHARACTERISTICS

Accuracy

A comparison study using 105 human plasma samples, demonstrated good correlation with a commercially available kit.

Comparison between the Finecare™ BNP (B-type natriuretic) Rapid Quantitative Test and the Triage BNP Test for the 105 clinical samples, the Correlation Coefficient is 0.968.

AssayRange and Detection Limit

•**Assay Range:** 5~5000 pg/mL
•**Detection Limit (Analytical Sensitivity):** 5 pg/mL

Interference

The following substances do not interfere with the test results at the indicated concentrations.

Bilirubin	≤0.6 mg/mL
Cholesterol	≤60 mg/mL
Triglycerides	≤40 mg/mL

Linearity

A serial concentration of BNP controls from 5 pg/mL~5000 pg/mL were each tested for three times, the Correlation Coefficient (R) is ≥0.9900.

Precision

Intra-Run
Within-run precision has been determined by using two concentration of BNP controls with one batch of test, C.V. is ≤15%.

Inter-Run
Between-run precision has been determined by using two concentration of BNP controls with three batches of tests. C.V. is ≤15%.

BIBLIOGRAPHY OF SUGGESTED READING

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3. Bhalla V, Willis S, Maisel AS (2004). "B-type natriuretic peptide the level and the drug--partners in the diagnosis of heart failure". Congest Heart Fail 10 (1 Suppl 1) 3–27.
4. 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.
5. Bhalla V, Isakson S, Bhalla MA, Lin JP, Clopton P, Gardetto N, Maisel AS (February 2005). "Diagnostic ability of B-type natriuretic peptide and impedance cardiography testing to identify left ventricular dysfunction in hypertensive patients". Am. J. Hypertens. 18 (2 Pt 2) 73S–81S.
6. Castellanos LR, Bhalla V, Isakson S, Daniels LB, Bhalla MA, Lin JP, Clopton P, Gardetto N, Hoshino M, Chiu A, Fitzgerald R, Maisel AS (February 2009). "B-type natriuretic peptide and impedance cardiography at the time of routine echocardiography predict subsequent heart failure events". J. Card. Fail. 15 (1) 41–7.

INDEX OF SYMBOLS

IVD	In Vitro Diagnostic Use		See Instruction for Use		Expiry Date
Σ	Tests per Kit		Manufacturing Date		Keep Dry
LOT	Batch Number	EC REP	Authorized Representative		Keep away from Sunlight
	Manufacturer		Do not reuse	REF	Catalog #
30°C 4°C	Store between 4～30℃				

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EC REP
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