NT-proBNP Rapid Quantitative Test

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

INTENDED USE

The Anbio NT-proBNP Rapid Test along with Anbio 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.

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.

Note: Individual reference range is suggested to be established for each laboratory.

AND PRINCIPLE OF THE PROCEDURE

The Anbio NT-proBNP Rapid Test is based on fluorescence immunoassay technology. The Anbio NT-proBNP Rapid 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 Anbio FIA Meter shows NT-proBNP concentrations in blood specimen.

STORAGE AND STABILITY

1. Store the detector buffer at 2～30℃. The buffer is stable up to 18 months.
2. Store Anbio NT-proBNP Rapid Quantitative Test Cartridge at 2～30℃, shelf life is up to 18 months.
3. Test Cartridge should be used within 1 hour after opening the pack.

Materials Supplied

- Test Cartridge
- IC Card
- Whole Blood Buffer

MATERIALS REQUIRED BUT NOT PROVIDED

- Transfer Pipette Set (10μL, 100μL size)
- Specimen Collection Containers
- Sterile Lancets (for Fingerstick Whole Blood only)
- Alcohol Pads
- Centrifuge (for Plasma/Serum only)
- Timer

WARNINGS AND PRECAUTIONS

1. This kit is for in vitro diagnostic use only.
2. Do not mix components from different kit lots.
3. Do not use test kit beyond the expiration date.
4. Do not use Test Cartridge if its lot # does not match with IC Card # that is inserted onto the equipment.
5. The Anbio NT-proBNP Rapid Quantitative Test kit is only operational in the Anbio FIA Meter.
6. Do not use the Test Cartridge if the pouch is punctured or not well sealed.
7. The Test Cartridge and Meter should be used away from vibration and magnetic field. During normal usage, the Meter itself may cause vibration, which should be regarded as normal.
8. Use separate clean pipette tips and detector buffer vials for different specimens.
9. Blood specimens, used Test Cartridges, pipette tips and detector buffer vials should be handled and disposed in accordance with standard procedures and relevant regulations of microbiological hazard materials.
10. The results should be interpreted by the physician along with clinical findings and other laboratory test results.

SPECIMEN COLLECTION AND PREPARATION

The test can be performed with serum or plasma or whole blood.The plasma and whole blood samples are recommended to use EDTA, heparin or sodium citrate for anticoagulation. Other body fluids and samples may not get accurate results.

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.
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 storing at 2℃～8℃ for more than 2 days.

For Serum and Plasma:

1. Separate the serum/plasma from blood as soon as possible to avoid hemolysis.
2. 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 Anbio FIA Meter Operation Manual for the complete instructions on use of the Test. The test should be operated in room temperature.

Step1: Preparation

Check/ Swipe the IC Card information to the equipment.

Step2: Loading

Serum / plasma: take 100μL of serum or plasma samples, load it onto the sample well of the Test Cartridge;
Whole blood: take 120μL of whole blood sample, load it onto the sample well of the Test Cartridge, immediately add a drop of whole blood buffer to the sample well;

Step3: Testing

Standard test: Insert the Test Cartridge onto the Test Cartridge Holder and click “timing Test”. 15 minutes later, 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 “Quick Test”. The result will show in the display and print out when click “Print”.

LIMITATIONS OF PROCEDURE

1. This test has been developed for testing human whole blood, serum and plasma specimen.
2. The results of Anbio 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 may come from cross-reactions with some similar antibodies in blood; and similar epitopes from non-specific components in blood capturing fluorescent labeled antibodies.
4. Other factors may interfere with Anbio 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

Detection Limit: 100.0pg/mL;
Linear Range: 100.0～35000.0pg/mL ;
Linear correlation coefficient R ≥ 0.990;
Precision: within batch C.V. is ≤ 15%; between batches C.V. is ≤ 20%;
Accuracy: the relative deviation of the measurement results shall not exceed ± 15% when the accuracy calibrator prepared by NT-proBNP national standard or standardized accuracy calibrator are tested.

Version: 1.1

BIBLIOGRAPHY OF SUGGESTED READING

1.De Lemos JA,McGire DK, Drazner MH. B-type natriuretic peptide in cardiovascular disease . Lancet2003;362;316-22
2.Pfister R ,Scholz M, Wielckens K, Erdmann E, Schneider CA.The value of natriuretic peptides NT-proBNP and BNP for the assessment of left-ventricular volume and function. A prospective study of 150 patients. Deutsche medizische Wochenschrift (1946) 2002 ;127(49);2605.
3.Nousiainen T, Vanninen E, Jantunen E, Puustinen J, Remes J, Rantala A, et al. Natriuretic peptides during the development of doxorubicin-induced left ventricular diastolic dysfunction. Journal of internal medicuine 2002;251(3);228.