QUANTON BIOLIFE SCIENCES
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NT-ProBNP Rapid Test Kit (Serum/Plasma/Whole blood)

QBL/PBNP/RPT_066

The NT-ProBNP Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of NT-ProBNP in human serum/plasma/whole blood specimens.

For *In-Vitro Diagnostic* Use only

ORDER INFORMATION

Pack Size	REF
01 Test	PBNP 01
05 Tests	PBNP 05
10 Tests	PBNP 10
25 Tests	PBNP 25
50 Tests	PBNP 50

CLINICAL SIGNIFICANCE

N-terminal B-type natriuretic peptide precursor is secreted from the le cardiac ventricle in response to volume and pressure overload. It's an inactive N-terminal fragment that split from BNP prohormone. NT-proBNP can be used to evaluate heart contractile, diastolic dysfunction, and ventricular segmental wall motion coordination. Besides, its sensitivity and negative predictive value is well. NT-proBNP is used to find heart failure patient at the early stage, and is used as a marker to determine risk levels, to monitor medical efficiency of HF drug, to evaluate prognosis of HF patient and to distinguish dyspnea that caused by heart failure from other diseases. Furthermore, NT-proBNP is a risk assessment indicator for Acute Coronary Syndrome.

PRINCIPLE

The test uses an anti-human NT-proBNP monoclonal antibody conjugated with Gold nano particle and an anti-human NT-proBNP polyclonal antibody coated on the test line. When the sample (serum, plasma or whole blood) is applied to the test strip, the Gold nano particle-labelled anti-human NT-proBNP monoclonal antibody binds to the NT-proBNP in sample and forms a marked antigen-antibody complex. This complex moves to the test card detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by the anti-human NT-proBNP polyclonal antibody. The intensity of the test line increases in proportion to the NT-proBNP concentration.

KIT COMPONENTS

• Test Cassettes • Droppers • Buffer • Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

• Specimen Collection Containers • Centrifuge (For plasma only)
• Timer

PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Do not use after the expiration date.
2. Wear protective gloves while handling specimens wash thoroughly afterwards.
3. The device is sensitive to humidity as well as heat. Therefore, take out the device from seal pouch before test.
4. Do not mix reagents from different lot.
5. Dispose all the samples and kits properly as per the instruction after test in accordance in GLP.
6. Follow the testing procedure exactly as mention in the insert.

STORAGE AND STABILITY

1. The kit can be stored at room temperature or refrigerated (2-30°C). The test device must remain in the sealed pouch until use. DO NOT FREEZE.
2. Do not use beyond the expiration date.
3. Do not use the test kit, if the pouch is damaged or seal is broken.

SPECIMEN COLLECTION & PREPARATION

The NT-ProBNP Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood, serum and plasma specimen.

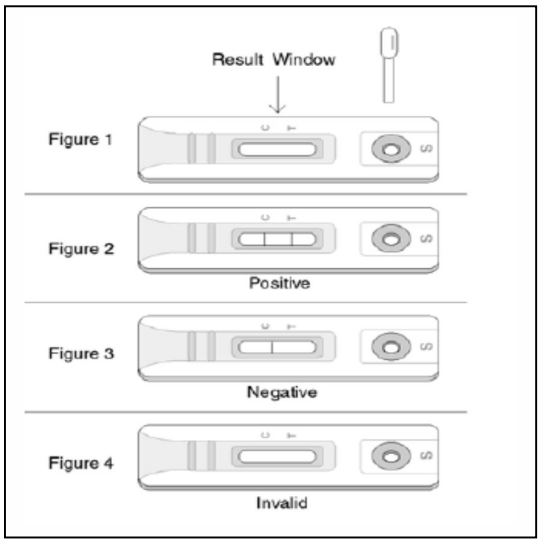
- **Serum (S):** Collect the whole blood into a collection tube (NOT containing anticoagulants such as heparin, EDTA, and sodium citrate) by veinpuncture, leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant.
- **Plasma (P):** Collect the whole blood into a collection tube (containing anticoagulants such as EDTA K2, Heparin sodium, Citrate sodium and Oxalate potassium) by veinpuncture and then centrifuge blood to get plasma specimen.
- **Whole Blood (WB):** Both Fingerstick Whole Blood and Venipuncture Whole Blood can be used.

DIRECTIONS FOR USE

Allow the test device, specimen and/or buffer to equilibrate at room temperature (15-30°C) before testing.

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within 1 hour.
2. Place the cassette on a clean and level surface.
3. **For Serum or Plasma specimen**: Hold the dropper vertically and transfer 1 drops of serum or plasma and add 1 drop of buffer into the specimen well, and start the timer. See illustration below.
   For Venipuncture Whole Blood specimen: Hold the dropper vertically and transfer 1 drops of whole blood to the specimen well, then add 1 drop of buffer, and start the timer. See illustration below.
   For Fingerstick Whole Blood specimen: Take sample using sample dropper and transfer approximately 25 µL of fingerstick whole blood specimen to the specimen well of test cassette, then add 1 drop of buffer and start the timer. See illustration below.
4. Wait for the colored line(s) to appear. Read results at 15 minutes.
   Note: Do not interpret the result after 20 minutes.

INTERPRETATION OF RESULTS



1) Positive
The control line (C) and test line (T) lines are visible on the test device. This is positive for NT-ProBNP Ag. This is indicative of presence of NT-ProBNP Ag.
2) Negative
The control line is the only visible line on the test device. No NT-ProBNP Ag were detected
3) Invalid
The control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the likeliest reasons for control line failure. Repeat the test using a new test device.

Quality Control
Internal procedural controls are included in the test individually. A colored line appearing in control line region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

Limitations of the Test
1. The NT-ProBNP Rapid Test Cassette (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. This test should be used for detection of NT-ProBNP Ag in whole blood, serum or plasma specimens. Neither the quantitative value nor the rate of increase in the concentration of NT-ProBNP Ag can be determined by this qualitative test.
2. A negative result can occur if the level of NT-ProBNP present in the specimen is below the detection limits of the assay or NT-ProBNP that is detected is not present during the stage of AMI in which a sample is collected. However, a negative test result does not preclude the possibility of AMI.
3. AMI progresses rapidly. If symptoms are suspicious or persist while the result from the NTproBNP Rapid Test is negative or non-reactive, it is recommended to test with an alternative test method, such as ECG.
4. As with all diagnostic tests, all results must be considered with other clinical information available to the physician

Detection Limitation
The NT-ProBNP Rapid Test Cassette (Whole Blood/Serum/Plasma) can detect NT-ProBNP antigen as low as 0.45ng/ml.

Sensitivity and Specificity
A total of 305 specimens were collected from susceptible subjects and tested by NT-ProBNP Rapid Test and a commercial NT-ProBNP Rapid test as reference. Comparison for all subjects is showed in the following table.

Method		Other Rapid Test		Total Test
NT-ProBNP Rapid Card Test	Result	Positive	Negative	
	Positive	74	1	75
	Negative	1	229	230
Total Results		75	230	305

NT-proBNP	
Sensitivity	98.66 %
Specificity	99.56 %

Cross-reactivity
The NT-ProBNP Rapid Test Cassette (Serum/Plasma/Whole Blood) has been tested for HBsAg, anti-HIV, anti-HCV, anti-RF, anti-Spyhilis, anti-H.pylori, anti-Toxo IgG positive specimens. The results showed no cross-reactivity.

Interfering Substances
The following compounds have also been tested using the NT-ProBNP Rapid Test Cassette (Whole Blood/Serum/Plasma) and no interference was observed. Caffeine: 20mg/dl, Creatine: 200mg/dl, Acetylsalicylic Acid: 20mg/dl, Gentisic Acid: 20mg/dl, Albumin: 2000mg/dl, Ascorbic Acid: 2g/dl, Hemoglobin: 1000mg/dl, Oxalic acid: 600mg/dl, Bilirubin: 1000mg/dL, Triglycerides: 1600mg/dl & Cholesterol: 800mg/d.l

BIBLIOGRAPHY

1. Daubert, MA, Jeremias, A 2010, 'The utility of troponin measurement to detect myocardial infarction: review of the current findings', Vascular Health and Risk Management, vol. 6, pp. 691-699.
2. 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.
3. 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.

GLOSSARY OF SYMBOL

	Consult Instruction for Use
	Catalog Number
	Store between
	Manufacturer
	Keep away from sunlight

Paramcare Life Sciences Private Limited, G/F-12/13, Evershine-2, Survey No. 307/3/1, Balitha N.H No 48, Vapi, Valsad, Gujarat, 396191.

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