ImmunoScience INDIA

ImmunoQuick

NT- proBNP

Rapid Test for NT- proBNP– Device

"A rapid test for semi-quantitative determination of NT- proBNP in serum/plasma/whole blood"

For Self - Testing & In-Vitro Diagnostic Use Only **Store at 2°C to 30°C**

OVERVIEW

NT-proBNP (N-terminal pro-B-type natriuretic peptide) is a protein that's released by the heart when it's under stress, primarily when the heart muscle has to work harder than normal to pump blood. It's a biomarker used to help diagnose and assess the severity of heart failure, and can also be used to monitor the effectiveness of treatment

INTENDED USE

Rapid Test for NT- proBNP- Device is a rapid chromatographic immunoassay for the semi quantitative determination of NT- proBNP in whole blood, serum or plasma as a marker in the diagnosis of heart failure.
This test is for healthcare professional use as well as for home use.

PRINCIPLE

The membrane is pre-coated with Anti-NTPBNP mAb on the test line region of the test. During testing, the whole blood, serum or plasma specimen reacts with the nanoparticle coated with anti-NTPBNP antibodies. The mixture migrates upward on the membrane chromatographically by capillary action to react with capture Ab on the membrane and generate a colored line. The presence of this colored line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

CONTENTS OF KIT

1. Test Device with desiccant
2. Dropper.
3. Assay Buffer.
4. Package Insert.

OPTIONAL MATERIAL REQUIRED

1. Stopwatch

PRECAUTIONS/KIT STORAGE AND STABILITY

1. Please read all the information in this package insert before performing the test. Pay particular attention to the position of the Control and Test lines.
2. Do not use after the expiration date printed on the foil pouch.
3. Store in the sealed pouch in a dry place in between temperature 2°C to 30°C.Do not freeze.
4. Do not use if pouch is torn or damaged.
5. Do not open the foil pouch until you are ready to start the test.
6. Keep out of the reach of children.

WARNINGS

1. Do not reuse the test.
2. Follow the instruction to get accurate results.
3. Use appropriate personal protective equipment.
4. Dispose hygienically in domestic waste.
5. Do not touch the membrane.
6. Treat the samples and used test as potentially infectious. Avoid contact with skin.
7. For in vitro diagnostic use. Not to be taken internally.
8. Do not eat the desiccant in the package.
9. Do not mix the specimen sample or interchange the different specimen.
10. The manufacturer and distributor of this product shall not be liable for any loses, liability, claims, costs or damages whether director cons sequential rising out for related to an incorrect diagnosis.

SPECIMEN COLLECTION

Fresh anti-coagulated whole blood should be used as a test sample. EDTA or Heparin can be used as suitable anticoagulants. Fresh serum or plasma can also be used as a test sample. The specimen should be collected in a clean glass or plastic container. If immediate testing is not possible then store the specimen at 2°C to 8°C for up to 24 hours before testing. Clotted, contaminated or hemolyzed blood samples should not be used for performing the test.
Fresh finger pricked blood samples can also be used as a sample for testing

TEST PROCEDURE

1. Bring the kit components to room temperature before testing.
2. Open the pouch and retrieve the test and desiccant pouch. Check the color of the desiccant. It should be blue, if it has turned colorless or pink, discard the test and use another test. Once opened, the test must be used immediately.
3. Label the test with patient's identity. Tighten the vial cap of the assay buffer provided with the kit in the clockwise direction to pierce the dropper bottle nozzle.
4. Keep the device on plain surface & add one drop (Approx.30 µl) serum/plasma or two drops (Approx.60 µl) whole blood sample in sample 'S' well by using dropper.
5. Add 1 drop of assay buffer in sample well "S".
6. Start the timer.
7. Read the result at 10 to 15 minutes. Result reading after 15th minute shall be considered invalid.

INTERPRETATION OF RESULTS

Negative: If colored line appears at control region 'C' & no colored band appears at test region T, then sample is negative (NT- proBNP is absent or less than 0.40 ng/ml).

Positive (more than 0.45 ng/ml): A distinct clearly visible colored line appears at control region 'C' and at the test region 'T', then specimen contains NT- proBNP.

Note:

1. Use the color chart provided with the kit to interpret the range of NT proBNP in the sample. Compare the color intensity of test line with the intensities in color chart and determine the range in positive sample.
2. The NT proBNP is highly unstable protein hence, the concentration may vary with the time of collection and testing, storage and transportation of sample.

Invalid: Test should be considered invalid and repeat the test using fresh test if

a. No line appears at control side 'C' and line appears only at test side 'T'.

b. No line appears at control side 'C' and test side 'T'.

PERFORMANCE CHARACTERISTICS

INTERNAL EVALUATION

Total 185 samples were evaluated for specificity & sensitivity. sensitivity was found to be 100% (60/60) and relative specificity was found 100% (125/125).

The Positive predictive value (PPV) and Negative Predictive value (NPV) for the test was 100 %.

No cross reactivity found with High T3, T4, TSH, Pregnancy, High Bilirubin, Troponin I, High Cholesterol positive samples.

Sample	NT- proBNP Test		Reference		Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
	Positive	Negative	Positive	Negative				
Positive	60	0	60	0	100	-	100	-
Negative	0	100	0	100	-	100	-	100
Cross reactivity	0	25	0	25	No cross reactivity observed			
Total	60	125	60	125	-			

EXTERNAL EVALUATION

The product is evaluated by NABL approved laboratory. 100 % sensitivity and 100 % specificity were found in external evaluation.

Lowest detection limit: 0.45 ng/ml (450 pg./ml)

LIMITATIONS

As with all diagnostic tests, the test result must always be correlated with clinical findings. The results of test are to be interpreted within the epidemiological, clinical and therapeutic context. When it seems indicated, reference correlation should be considered.

Any modification to the above procedure and / or uses of other reagents will invalidate the test procedure.

The test is limited to the determination of NT-proBNP, Other clinically available tests are required if questionable results are obtained. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

DISCLAIMER

The all precautions shall be taken to ensure the diagnostic ability and accuracy of this product. This product is utilized outside the control of manufacturer and distributors. The various factors including storage temperature, environmental conditions and procedure error may affect the results.

REFERENCES

1. de Lemos JA, McGuire DK, Drazner MH. B-type natriurec peptide in cardiovascular disease. Lancet 2003; 362: 316~322.

2. Pfister R, Scholz M, Wielckens K, Erdmann E, Schneider CA. The value of natriurec pepdes NT-pro-BNP and BNP for the assessment of leventricular volume and funcon. A prospecve study of 150 paents. Deutsche medizinische Wochenschri (1946) 2002; 127(49):2605.

IVD	In Vitro Diagnostic Use
	Manufacturer
	Manufacturing Date
	Expiry Date
LOT	Lot Number
	Store at 2°C to 30°C
	Single Use
	Number of tests in the pack
	Do not use if pouch or kit damaged
	This side Up
	Read package insert before use

MANUFACTURED BY

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