Prestige Diagnostics
Clinical Diagnostics & Point of Care Products

RADNTP1 NT-proBNP Rapid Test Device (Whole blood/Serum/Plasma)

INTENDED USE

The NT-proBNP Rapid Test Device is intended for the qualitative determination of NT-proBNP in human whole blood/Serum/Plasma. Measurement of NT-proBNP values is useful in the diagnosis and assessment of severity of heart failure.

INTRODUCTION

N-terminal pro-brain (or B-type) natriuretic peptide (NT-proBNP) is produced predominately by the cardiac ventricular myocytes.[1] It is released in response to volume expansion and filling pressure and is involved in maintaining intravascular volume homeostasis. [2] After synthesis, the peptide is cleaved first to proBNP and subsequently to BNP (active form) and NT-proBNP(inactive form).
Natriuretic peptide (NP) levels (BNP and NT-proBNP) are widely used in clinical practice and cardiovascular research as a diagnotic tool for the occurrence and severity of heart failure (HF) and coronary syndrome. [3,4,5]

Elevated plasma levels of BNP and NT-proBNP have been observed at times of cardiac stress and damage. It has also been shown that increased NP values in patients with renal dysfunction can suggest the presence of cardiac disease. [6] Low circulating NP levels have been observed in obese people, however the prognostic capacity of these biomarkers were not affected for those patients. [7,8]

In summary, NP levels are quantitative plasma biomarkers of an accurate diagnosis of heart failure. Measurements of NP levels may help in risk stratification of patients suffering heart attacks in emergency care and in accurate and rapid diagnosis of heart failure in primary care..

PRINCIPLE

The NT-proBNP Rapid Test Device (Whole blood/Serum/Plasma) detects NT-proBNP through visual interpretation of color development in the internal strip. Anti-NT-proBNP antibodies are immobilized on the test region of the membrane, and anti-mouse antibodies immobilized on the control region. During testing, the specimen reacts with anti-NT-proBNP antibodies conjugated to colored particles and precoated onto the sample pad of the strip. The mixture then migrates through the membrane by capillary action and interacts with reagents on the membrane. If there is sufficient NT-proBNP in the specimen, a colored band will form at the test region of the membrane. The presence of this colored band indicates a positive result, while its absence indicates a negative result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS

Materials Provided

- Individually pouched test devices
- Package insert
- Disposable pipettes
- Buffer

Materials Required but Not provided

- Specimen collection container
- Timer
- Centrifuge

PRECAUTIONS

- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Do not interchange or mix reagents from different lots.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded according to local regulations.

STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- **Do not freeze.**
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipments, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND STORAGE

- The NT-proBNP Rapid Test Device (Whole Blood/Serum/ Plasma) is intended for use with human whole blood, serum, or plasma specimens only.
- Only clear, non-hemolyzed specimens are recommended for use with this test. Serum or plasma should be separated as soon as possible to avoid hemolysis.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- Containers containing anticoagulants such as EDTA, citrate, or heparin should be used for whole blood storage.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.
- Icteric, lipemic, hemolysed, heat treated and contaminated specimens may cause erroneous results.

PROCEDURE

Bring tests, specimens, and/or controls to room temperature (15-30°C) before use.

1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. For best results the assay should be performed within one hour.
2. Transfer 3 drops of whole blood/serum/plasma to the specimen well (S) of the device with the provided disposable pipette, and start the timer.
   OR
   Allow 3 hanging drops of fingerstick whole blood to fall into the center of the specimen well (S) of the test device, and start the timer.
   Avoid trapping air bubbles in the specimen well (S), and do not add any solution to the result area.
3. If the test fails to migrate across the membrane after 1 minute, add 1 drop of buffer to the specimen well (S).
4. Wait for the colored band(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes.

INTERPRETATION OF RESULTS

POSITIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

NEGATIVE: Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (T).

INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. 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. For diagnostic purposes, the NT-proBNP results should be used in conjunction with other clinical data; e.g., symptoms, medical history, etc. If NT-proBNP results are not consistent with other clinical observations, additional information may be required for diagnosis.
2. Specimens from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain human anti-mouse antibodies (HAMA). Such specimens may show either falsely elevated or depressed values when tested with assay kits which employ mouse monoclonal antibodies.
3. Heterophilic antibodies in human plasma can react with reagent immunoglobulins, interfering with in vitro immunoassays. The presence of heterophilic antibodies in a patient may cause anomalous values to be observed.

PERFORMANCE CHARACTERISTICS

- **Sensitivity**

The minimum detectable concentration of NT-proBNP Rapid Test Device is 125 pg/ml.

- **Cross-Reactivity**

Based on the specificity of the capture and detection antibodies, the NT-proBNP Rapid Test assay detects the NT-proBNP only and does not cross-react with proBNP and BNP.

LITERATURE REFERENCES

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GLOSSARY OF SYMBOLS

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by
	Manufacturer		Do not reuse

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