**INTENDED USE**

ichroma™ NT-proBNP is a fluorescence immunoassay (FIA) for the quantitative determination of NT-proBNP in human whole blood/serum/plasma. It is useful as an aid in the diagnosis of persons suspected of having congestive heart failure. For in vitro diagnostic use only.

**INTRODUCTION**

N-terminal pro-brain natriuretic peptide (NT-proBNP) is produced predominantly by the cardiac ventricular myocytes[3,4] and is released in response to myocardial stress and filling pressure[5] and is involved in maintaining intravascular volume homeostasis[6,7]. After stimulation of heart muscle cells, the natriuretic peptides are produced as prohormones (proBNP) and this is cleaved into two fragments which are secreted into the bloodstream as the 32 amino acids active BNP and the N-terminal fragment of 76 amino acids designated as NT-proBNP. NT-proBNP immunoassays are widely used and are now considered to be a useful marker and have a high degree of diagnostic accuracy in clinical practice and cardiovascular research as a diagnostic tool for the occurrence and severity of heart failure (HF) [5,6,7]. Therefore NT-proBNP measurements in human blood are helpful not only for the cardiac disease diagnosis but also for evaluation of patients with suspected HF and assessment of severity of the disease.

**PRINCIPLE**

The test uses a sandwich immunodetection method; dried detector antibody in the buffer binds to antigen in the sample, forming antigen-antibody complexes, and migrates onto the nitrocellulose matrix to be captured by the other immobilized-antibodies on test strip.

The more antigen in sample forms the more antigen-antibody complex and leads to stronger intensity of fluorescence signal on detector antibody, which is processed by instrument for ichroma™ tests to show NT-proBNP concentration in sample.

**COMPONENTS**


- The cartridge contains a test strip, the membrane which has anti human NT-proBNP at the test line, while chicken IgY at the control line.
- Each cartridge is individually sealed in an aluminum foil pouch containing a desiccant. 25 sealed cartridges are packed in a box which also contains an ID chip and 25 sealed capillary tubes.
- The detector contains anti human NT-proBNP-fluorescence conjugate, anti chicken IgY-fluorescence conjugate, bovine serum albumin (BSA) as a stabilizer and sodium azide as a preservative in phosphate buffered saline.
- Each detector contains a granule. 25 tubes of detector are packed in a pouch and packed in a box with 5 ml of diluent.

**WARNINGS AND PRECAUTIONS**

- For in vitro diagnostic use only.
- Carefully follow the instructions and procedures described in this ‘Instruction for use’.
- Use only fresh samples and avoid direct sunlight.
- Lot numbers of all the test components (cartridge, ID chip, detector and diluent) must match each other.
- Do not interchange the test components between different lots or use the test components after the expiration date, either of which might yield misleading test results.
- Do not reuse. A detector should be used for processing one sample only. So should a cartridge.
- The cartridge should remain sealed in its original pouch before use. Do not use the cartridge, if is damaged or already opened.
- Frozen sample should be thawed only once. For shipping, samples must be packed in accordance with the regulations. Sample with severe hemolytic and hyperlipidemia cannot be used and should be recollected.
- Just before use, allow the cartridge, detector, diluent and sample to be at room temperature for approximately 30 minutes.
- ichroma™ NT-proBNP as well as the instrument for ichroma™ tests should be used away from vibration and/or magnetic field. During normal usage, it can be noted that instrument for ichroma™ tests may produce minor vibration.
- Used detectors, pipette tips and cartridges should be handled carefully and discarded by an appropriate method in accordance with relevant local regulations.
- An exposure to larger quantities of sodium azide may cause certain health issues like convulsions, low blood pressure and heart rate, loss of consciousness, lung injury and respiratory failure.
- ichroma™ NT-proBNP will provide accurate and reliable results subject to the following conditions.
  - Use ichroma™ NT-proBNP should be used only in conjunction with instrument for ichroma™ tests.
  - Any anticoagulants other than EDTA, heparin, sodium citrate should be avoided.

**STORAGE AND STABILITY**

- The cartridge is stable for 20 months (while sealed in an aluminum foil pouch) if stored at 4-30 °C.
- The detector and the diluent is stable for 20 months if stored at 2-8 °C.
- Frozen sample should be thawed only once. For shipping, samples with severe hemolytic and hyperlipidemia cannot be used and should be recollected.
- After the cartridge pouch is opened, the test should be performed immediately.

**LIMITATION OF THE TEST SYSTEM**

- The test may yield false positive result(s) due to the cross-reactions and/or non-specific adhesion of certain sample components to the capture/detector antibodies.
- The test may yield false negative result. The non-responsiveness of the antigen to the antibodies is most common where the epitope is masked by some unknown components, so as not to be detected or captured by the antibodies. The instability or degradation of the antigen with time and/or temperature may cause the false negative as it makes antigen unrecognizable by the antibodies.
- Other factors may interfere with the test and cause erroneous results, such as technical/procedural errors, degradation of the test components/reagents or presence of interfering substances in the test samples.
- Any clinical diagnosis based on the test result must be supported by a comprehensive judgment of the concerned physician including clinical symptoms and other relevant test results.

**MATERIALS SUPPLIED**

**REFERENCE**

CFPC-49

Components of ichroma™ NT-proBNP

- Cartridge Box:
  - Cartridges 25
  - 50 µl Capillary tube 25
  - ID Chip 1
  - Instruction For Use 1
- Buffer Box
  - For ichroma™ II
  - Detectors (Capped with plastic lid) 25
  - Diluent 1
TEST PROCEDURE

ichroma™ II
1) Transfer 150 µL of diluent using a pipette to a tube containing detector.
2) Transfer 50 µL of sample (Human whole blood/ serum/plasma/control) to the detector tube. If the test is to be done with whole blood, transfer the fingertip blood (collected in a capillary tube) to the detector tube.
3) Close the lid of the detector tube and mix the sample thoroughly by shaking about 20 times.
4) Pipette out 75 µL of a sample mixture and load it into the sample well on the cartridge.
5) Leave the sample-loaded cartridge at room temperature for 12 minutes.

Scan the sample-loaded cartridge immediately when the incubation time is over. If not, it will cause inexact test result.

6) To scan the sample-loaded cartridge, insert it into the cartridge holder of the instrument for ichroma™ tests. Ensure proper orientation of the cartridge before pushing it all the way inside the cartridge holder. An arrow has been marked on the cartridge especially for this purpose.
7) Press ‘Select’ button on the instrument for ichroma™ tests to start the scanning process.
8) Instrument for ichroma™ tests will start scanning the sample-loaded cartridge immediately.
9) Read the test result on the display screen of the instrument for ichroma™ tests. (Please refer to the ichroma™ II operation manual for complete information and operation instructions.)

AFIAS-50
1) Insert the tip array in the tip station.
2) Insert the detector array in the Reagent station and cover the reagent station.
3) Open the cover of the magazine station and pull and lift the cartridge magazine.
4) Insert the cartridge loaded cartridge magazine one by one.
5) Insert the cartridge loaded cartridge magazine into the magazine station and close the cover of the magazine station.
6) Insert the sample tube into the blood collection tube rack and load the blood collection tube rack into the sampling station (loading part).
7) Tap the button which is provided in the upper side of the No. of test cartridge region to select ID chip what you want to use.
8) When the selected slot is activated, set the number of test cartridge by tapping.
9) Tap the button which is provided in the upper side of the No. of reagent region to select ID chip what you want to use.

10) When the selected slot is activated, set the number of Detector by tapping.
11) Set the number of pipette tips by tapping.
12) Tap the ‘START’ button on the left upper of the main screen to start test.

( Please refer to the AFIAS-50 operation manual for complete information and operation instructions.)

INTERPRETATION OF TEST RESULT

The instrument for ichroma™ tests calculates the test result automatically and displays NT-proBNP concentration of the test sample in terms of pg/mL.

The cut-off (reference value): 300 pg/mL

The working range of the ichroma™ NT-proBNP is 10-30,000 pg/mL.
QUALITY CONTROL

- Quality control tests are a part of the good testing practice to confirm the expected results and validity of the assay and should be performed at regular intervals.
- The control tests should be performed immediately after opening a new test lot to ensure the test performance is not altered.
- Quality control tests should also be performed whenever there is any question concerning the validity of the test results.
- Control materials are not provided with ichroma™ NT-proBNP. For more information regarding obtaining the control materials, contact Boditech Med Inc.’s Sales Division for assistance.
  (Please refer to the instruction for use of control material.)

PERFORMANCE CHARACTERISTICS

- Analytical sensitivity
  Sample Type | Whole Blood | Serum/Plasma
  --- | --- | ---
  Limit of Blank (LOB) | 6 pg/mL | 5 pg/mL
  Limit of Detection (LOD) | 9 pg/mL | 8 pg/mL
  Limit of Quantitation (LOQ) | 42 pg/mL | 35 pg/mL

- Analytical specificity
  - Cross-reactivity
    There was no significant cross-reactivity with CK-MB and myoglobin.
  - Interference
    There was no significant interference with L-ascorbic acid, hemoglobin, cholesterol and D-glucose.

- Precision
  - Between lot
    One person tested three different lots of ichroma™ NT-proBNP, ten times at each concentration of the control standard.
  - Between person
    Three different persons tested ichroma™ NT-proBNP; five times at each concentration of the control standard.
  - Between day
    One person tested ichroma™ NT-proBNP during five days; five times at each concentration of the control standard.
  - Between site
    One person tested ichroma™ NT-proBNP at three different sites; five times at each concentration of the control standard.

Accuracy

The accuracy was confirmed by testing with three different lots of ichroma™ NT-proBNP. The tests are repeated 10 times in each different concentration.

Comparability

NT-proBNP concentration of 100 clinical samples were independently with ichroma™ NT-proBNP and Cobas e411 (Roche Diagnostics Inc. Switzerland) as per prescribed test procedures. Test results were compared and their comparability was investigated with linear regression and coefficient of correlation (R). Linear regression and coefficient of correlation between the two tests were Y=0.9267X – 72.76 and R = 0.9905 respectively.

REFERENCES

**Note:** Please refer to the table below to identify various symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>📚</td>
<td>Sufficient for (&lt;n&gt;) tests</td>
</tr>
<tr>
<td>💬</td>
<td>Read instruction for use</td>
</tr>
<tr>
<td>📋</td>
<td>Use by Date</td>
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<tr>
<td>📋</td>
<td>Batch code</td>
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<td>📋</td>
<td>Catalog number</td>
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<tr>
<td>🚨</td>
<td>Caution</td>
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<tr>
<td>🧵</td>
<td>Manufacturer</td>
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<tr>
<td>🇪🇺</td>
<td>Authorized representative of the European Community</td>
</tr>
<tr>
<td>🔬</td>
<td>In vitro diagnostic medical device</td>
</tr>
<tr>
<td>🔄</td>
<td>Temperature limit</td>
</tr>
<tr>
<td>✗</td>
<td>Do not reuse</td>
</tr>
<tr>
<td>🎗</td>
<td>This product fulfills the requirements of the Directive 98/79/EC on in vitro diagnostic medical devices</td>
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For technical assistance; please contact:

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