

# NT-proBNP

N-terminal pro B-type natriuretic peptide (FIA)

# infinosis™

REF: IN047705



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## Intended use

The infinosis™ NT-proBNP is a fluorescence immunoassay (FIA) for the in vitro quantitative determination of N-terminal pro B-type natriuretic peptide (NT-proBNP) in Human whole blood, serum or plasma. For professional use only.

## Summary

References<sup>1-5</sup>

NT-proBNP is a physiologically inactive fragment which is released when the active hormone BNP is cleaved from its precursor protein proBNP. Synthesis of the precursor protein in the cardiomyocytes is controlled by mechanical factors (dilatation of the ventricular wall) and neurohormonal factors (noradrenalin and angiotensin II). The secretion of NT-proBNP into the blood as a result of cleavage correlates directly with an increase in ventricular volume and ventricular pressure in heart failure. Consequently, when the concentration of NT-proBNP in the blood is low, cardiac dysfunction can be ruled out with high probability. Although the normal range for NT-proBNP is subject to gender and age-specific variability, a clinical cut-off of 125 pg/mL allows sufficient diagnostic accuracy. However, NT-proBNP values should always be interpreted in conjunction with the medical history, clinical findings and other diagnostic information (imaging methods and laboratory results).

## Test principle

**Sandwich principle.** Total duration of assay: **15 minutes**

Sample is added to the sample well of the test, then 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. 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 instrument for infinosis™ tests shows NT-proBNP concentrations in blood specimen.

## Reagents

### Materials provided

- **Test Cartridge**, 25 pcs, individually packaged
- **ID chip**, 1 pcs
- **Sample Buffer**, 25 vials
- **IFU**, 1 copy

### Materials required (but not provided)

- infinosis™ 2020 FIA analyzer
- NT-proBNP control (DiaSino control is recommended)
- Transfer pipette set (100 µL size)
- Centrifuge (for plasma and serum only)
- Timer

## Precautions and warnings

- For in vitro diagnostic use only.
- Carefully follow the instructions and procedures described in this instructions before testing.
- The test cartridge should remain in its original sealed pouch until ready to use. Do not use it if the pouch is damaged or the seal is broken.
- Do not use reagents beyond the labeled expiry date.
- Do not mix or use components from kits with different Lots.
- Don't use Test Cartridge if its Lot does not match with ID Chip that is inserted onto the instrument.
- The infinosis™ NT-proBNP should be used only in conjunction with the instrument for infinosis™ tests.
- The tests should be applied by professionally trained staff working in certified laboratories at some remove from the patient and clinic at which the sample is taken by qualified medical personnel.
- infinosis™ NT-proBNP assay is single use only. Do not reuse it.
- The Test Cartridge and instrument for infinosis™ tests should be used away from vibration and magnetic field. During normal usage, the Test Cartridge may generate slight vibration, which should be regarded as normal.
- Use separate clean pipette tips and buffer tubes for different specimens. The pipette tips and detector buffer tubes should be used for one specimen only.
- Do not smoke, eat, or drink in areas in which specimens or kit reagents are handled.
- Blood specimens, used test cartridges, pipette tips and sample buffer tubes are potentially infectious. Proper laboratory safety techniques, handling and

disposal methods should be followed in accordance with standard procedures and relevant regulations observed by microbiological hazard materials.

- The results should be interpreted by the physician along with clinical findings and other laboratory test results.

## Incident report

Any suspected serious incidents related to this assay shall be immediately reported to DiaSino, DiaSino's Authorized Representative in the EU, and the national competent authorities of the Member States where the users and/or patients are located.

## Storage and stability

- Store the test kit at 2-30°C, the stability is up to the expiration date printed on package.
- Test cartridge and sample buffer should be used within 1 hour after opening the pack.

## Specimen collection and preparation

- The test can be performed with either whole blood, serum or plasma.
- Collect serum samples in accordance with correct medical practices.
- Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube. If collecting plasma use a blood collection tube containing suitable anticoagulant (EDTA recommended).
- Separate the serum/plasma from blood as soon as possible to avoid hemolysis.
- 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°C for up to 3 days. For long-term storage, specimens should be kept below -20°C.

## 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 provided on demand with infinosis™ tests. For more information regarding obtaining the control materials, contact [DiaSino Laboratories Co., Ltd](#) for assistance.

## Test setup

- Ensure that the lot number of the cartridge matches that of the sample buffer, and the ID Chip.
- If the sealed cartridge and sample buffer have been stored in refrigerator, place them at room temperature (18-25 °C) at least 30 minutes before measurement.
- Turn on the instrument for infinosis™ tests. Refer to the *'instrument for infinosis™ tests Operation Manual'* for the complete information and operating instructions.

## Test procedure

1. Insert ID Chip into the instrument for infinosis™ tests and read ID chip information.
2. Using a pipette to transfer **20 µL** of sample (Human whole blood/plasma/serum) to the **sample buffer tube** provided in the kit.
3. Close the lid of the sample mixing tube and mix the sample thoroughly for **5-10 seconds** by tapping or inverting the tube.
4. Pipette out **100 µL** of **sample mixture** and load it onto the sample well on the cartridge.
5. Leave the sample-loaded cartridge at room temperature for **15 minutes**.
6. Insert the sample-loaded cartridge into the cartridge holder of instrument for infinosis™ tests. Ensure proper orientation of the cartridge before pushing it all the way inside the cartridge holder.
7. Press **"Test"** button on the instrument for infinosis™ tests.
8. Instrument for infinosis™ tests will start scanning the sample-loaded cartridge immediately.
9. Read the test result on the display screen of the instrument for infinosis™ tests.
10. Print out the testing results when press **"Print"** button on the instrument for infinosis™ tests.

## Limitations - interference

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- This test has been developed for testing human whole blood, serum, plasma specimen only.
- The results of Infinosis™ NT-proBNP 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.
- 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.
- The false negative results may from some unknown substance blocking epitope adhering antibodies, unstable or degenerated NT-proBNP that cannot be identified due to prolonged time and temperature and storage condition of sample and reagent.
- Other factors may interfere with Infinosis™ NT-proBNP and may cause erroneous results. These include technical or procedural errors, as well as additional substances in blood specimens.
- For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

### Measuring range

50-20000 pg/mL (defined by the lower detection limit and the maximum of the master curve). Values below the lower detection limit are reported as < 50 pg/mL. Values above the measuring range are reported as > 20000 pg/mL.

### Lower detection limit

50 pg/mL

The detection limit represents the lowest analyte level that can be distinguished from zero. It is calculated as the value lying two standard deviations above that of the lowest standard (master calibrator, standard 1 + 2 SD, repeatability study, n = 21).

### Expected values

- < 75 years old: 0-300 pg/mL
- ≥ 75 years old: 0-450 pg/mL

Expected values may vary with age, sex, diet and geographical location. Each laboratory should determine its own expected values as dictated by good laboratory practice.

### Specific performance data

Representative performance data are given below. Results obtained in individual laboratories may differ.

### Precision

#### Intra-assay

Determined by by using 10 replicates of specimen of 800 pg/mL NT-proBNP

CV ≤ 15%

#### Inter-assay

Determined by using 3 replicates for each of three lots using NT-proBNP specimen levels at 800 pg/mL, CV ≤ 15%.

### Linearity

A serial concentration of NT-proBNP controls at 60 pg/mL, 100 pg/mL, 200 pg/mL, 400 pg/mL, 800 pg/mL, 1200 pg/mL were each tested for three times, the Correlation Coefficient is:  $r \geq 0.9948$

### Method comparison

A comparison of the Infinosis™ NT-proBNP assay (y) with the Roche Elecsys NT-proBNP assay (x) using 121 clinical samples gave the correlation:  $r=0.9615$

### Functional sensitivity

51.20 pg/mL

The functional sensitivity is the lowest analyte concentration that can be reproducibly measured with an intermediate precision CV of ≤ 20 %

### References

1. Bayés-Genís A et al. N-terminal probrain natriuretic peptide (NT- proBNP) in the emergency diagnosis and in-hospital monitoring of patients with dyspnoea and ventricular dysfunction. Eur J Heart Fail 2004;6:301-308.
2. McDonagh TA et al. NT-proBNP and the diagnosis of heart failure: a pooled analysis of three European epidemiological studies. Eur J Heart Fail 2004;6:269-273.
3. Richards AM et al. Plasma N-terminal pro-brain natriuretic peptide and adrenomedullin: new neurohormonal predictors of left ventricular function and prognosis after myocardial infarction. Circulation 1998;97:1921-1929.

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4. Svendstrup Nielsen L, et al. N-terminal pro-brain natriuretic peptide for discriminating between cardiac and non-cardiac dyspnoea. Eur J Heart Failure 2004;6:63-70.
5. Troughton RW, et al. Treatment of heart failure guided by plasma aminoterminal brain natriuretic peptide (N-BNP) concentrations. Lancet 2000;355:1126-1130.

### Symbols



In vitro diagnostic  
medical device



Temperature  
limit



Consult  
instructions for use



Catalog number



Batch code



Date of  
manufacture



Use-by date



Contains sufficient  
for <n> tests



Manufacturer



Do not re-use



Do not use if package is damaged  
and consult instructions for use



European  
Conformity



Authorized representative in  
the European Community



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