Hipro Biotechnology Co.,Ltd

EN
ENGLISH

NT-ProBNP

Amino-terminal pro-brain natriuretic peptide Test Kit
(Immune Fluorescence Detection Method)

Instructions for Use

Version: A/3

REF HP-NT-ProBNP-25

Manufacturer

Shijiazhuang Hipro Biotechnology Co., Ltd.
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After sale service: 400-0191-606
www.hipro.us

EC REP Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
Tel: +31644168999

Product Name

General Name: Amino-terminal pro-brain natriuretic peptide Test Kit (Immune Fluorescence Detection Method)

Specification

Package Specification
25 Tests/ Kit.

Intended Use

This product is used to determine the content of amino-terminal pro-brain natriuretic peptide (NT-proBNP) in human serum .

Test Principle

The amino-terminal pro-brain natriuretic peptide in the sample and the monoclonal antibody in reagent 1 become to immune complexes. The antigenic determinant-DNA coupling template in Reagent 2 binds to the remaining monoclonal antibodies, and the unbound antigenic determinant-DNA coupling template and dNTPs are used to synthesize double-stranded DNA products under the action of polymerase. This product binds to fluorescent dyes and will produce fluorescence which is proportional to the intensity of fluorescence and samples of amino-terminal pro-brain natriuretic peptide levels. Using specific protein analyzer to measure the intensity of fluorescence, the concentration of NT-ProBNP is determined by comparing the fluorescence intensity of samples to the standard concentration.

Component

The NT-ProBNP test kit consists of two reagents R1 and R2, as shown on figure 1.

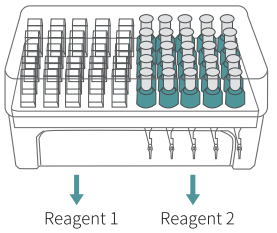


Figure 1

Name	Content	Quantity
Reagent 1 (R1)	Tris Buffer	1mol/L
	Anti-Amino-terminal pro-brain natriuretic peptide antibody	＞70mg/L
	Deoxyribonucleic acid (DNA) polymerase	＞10U
	Deoxyribonucleic acid triphosphate (dNTP)	10mmol/L
	Deoxyribonucleic acid dye	Appropriate
Reagent 2 (R2)	Tris Buffer	1mol/L
	Monoclonal antibodies specifically bind to epitope-DNA-coupled templates	>70mg/L
IC card (optional)	/	1

Do not mix different batches of reagents.

Storage&stability

Store reagent 1 and reagent 2 at: 2°C-8°C until the expiration date indicated on the label.

Avoid exposure to direct sunlight. The two reagents are stable for one year when unopened.

Store the test kit upright in order to ensure complete availability of the micro particles during automatic mixing prior to use.

Do not freeze the reagents.

Special Instrument Requirements

HP-083/4-II POCT Immunoassay System,
HP-AFS/1 Automatic Immunoassay System,
HP-AFS/3 Automatic Immunoassay System.

Specimen type

Serum, avoid hemolysis. Fasting blood collection and separation of serum as soon as possible.

The sample store at 2-8°C for 48 hours, -20°C for 1 month. Avoid repeated freezing. Before test, ensure fully mixed.

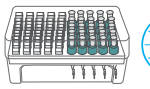
Procedures

HP-083/4-II POCT Immunoassay System

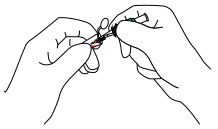
Note:

- Please read user manual of HP-083/4-II before use.
- The analyzer will finish self check after start-up.
- Insert the IC card of NT-ProBNP test kit to let analyzer read the parameter.
- The analyzer calibration can be done with app. It is recommended that analyzer calibration should be done for each new lot of test kit.

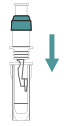
Step 1 Sample Preparation



1a Allow the test kit back to room temperature for 30 minutes before use.



1b Use the R2 with quantitative capillary to collect sample.

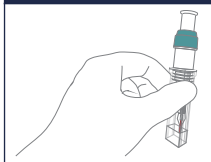


1c Insert the R2 into R1.

Note:

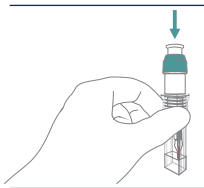
- The parameter is built in the IC card.
- Please insert the corresponding IC card into analyzer to let the analyzer read the parameter before each assay test.
- The capillary of the R2 should be fully filled.

Step 2 Testing



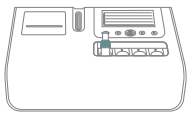
2a Hold the narrow side of R1 and shake from left to right for 12 times to let the sample completely mix with R1.

Note: Do not hold the wide sides of R1.



2b Press the piston on R2.

2c Hold the narrow sides of R1 and shake for 3-5 seconds to let R1 and R2 mix well.



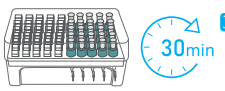
2d Insert the R1 into test channel of HP-083/4-II and the analyzer will finish the test and print out results automatically.

HP-AFS/1&HP-AFS/3 Automatic Immunoassay System

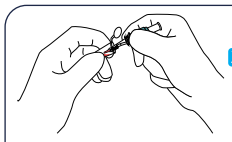
Note:

- Please read user manual of HP-AFS/1 and HP-AFS/3 before use.
- The analyzer will finish the self check after start-up.
- It is recommend to do analyzer calibration monthly and for each new lot of test kit.

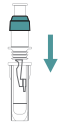
Step 1 Sample Preparation



3a Allow the test kit back to room temperature for 30 minutes before use.



3b Use the R2 with quantitative capillary to collect sample.

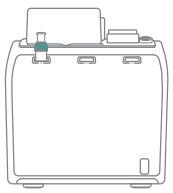


3c Insert the R2 into R1.

Note:

- Please update the standard curve with the barcode on the R1 cuvette if a new lot test kit is to be used.
- The capillary of the R2 should be fully filled.

Step 2 Testing



4a Insert the R1 into test channel of analyzer.

4b The analyzer will mix the sample from R2 capillary with R1 automatically.

4c The analyzer will mix the R2 and R1 automatically.

4d The analyzer will test and print the results automatically.

Calibration

The calibration values for the different lots of the kits are stored on the calibration IC card or the two-dimensional code on the cuvette. Before test the new lot of kits, read the calibration card parameters first. Or the instrument automatically scan the two-dimensional code on the cup to obtain the corresponding calibration curve during testing.

Quality control

3- level calibration system guarantee the results' reliability for each lot of test kits, including the instrument calibration, remote reagent calibration and the third party calibration.

The third party calibration applicable for:

1. The daily indoor quality control test.
2. New lots of reagent.
3. New operator training.
4. The results can not match the clinical symptoms.
5. The first use of the reagent.

If still can not be calibrated, contact the manufacture for further technical support.

Reference Value

<250pg/mL

Recommended that each laboratory establish its own reference range.

Interpretation

The test results of this reagent are only for clinical reference. the clinical diagnosis and treatment of patients should be considered in combination with their symptoms / signs, medical history, other laboratory tests and treatment responses.

Age	Normal levels pg/mL	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
Any Age	250	99	60	77	98
<50	450	97	93	76	99
50-75	900	90	82	83	88
>75	1800	90	84	88	66

Limitations

1.This result is for clinical reference only; comprehensive consideration should be combined with the clinical management of patients with symptoms / signs, medical history, other laboratory tests and treatment response.

2.When hemoglobin≥5g/L, triglyceride≥10mmol/L, or bilirubin>300μmol/L, it has interference to this determination

3.The sample for extended periods may lead to differences in test results.

Performance Characteristics

1. Linearity range: 50pg/ml ~ 25000pg/ml,r≥0.990.
2. Detection limit: ≤20pg/ml.

   The limit of detection means the lowest detectable analyte level that can distinguish the concentration. Calculate based on the minimum standard above the two standard deviation of the data (Blank table, 1+2SD, within-run precision, n=20).

3. Precision

   Test the control material by NT-ProBNP Test Kit 2 times per day for 20 days (n=80) according to EP5-A2 of CLSI.

   The data as below:

a.

HP-083/4-II POCT Immunoassay System					
Sample	Mean pg/mL	Within-Run		Between-Run	
		S.D.	%C.V.	S.D.	%C.V.
Control 1	122.6	7.97	6.5	5.76	4.7
Control 3	2075.8	120.4	5.8	114.17	5.5

b.

HP-AFS/3 Automatic Immunoassay System					
Sample	Mean pg/mL	Within-Run		Between-Run	
		S.D.	%C.V.	S.D.	%C.V.
Control 1	122.0	7.44	6.1	7.80	6.4
Control 3	2058.0	94.67	4.6	92.61	4.5

c.

HP-AFS/1 Automatic Immunoassay System					
Sample	Mean U/mL	Within-Run		Between-Run	
		S.D.	%C.V.	S.D.	%C.V.
Control 1	122.5	6.25	5.1	7.22	5.9
Control 3	2062.4	86.62	4.2	107.24	5.2

4.Methodology comparison

Compared to NT-ProBNP LIA by test the same serum sample, the relative data as below:

HP-AFS/3 Automatic Immunoassay System				
Site No.	Sample Type	No.of Assays	Regression Line	Coefficient correlation
1	Serum	50	Y= 1.02X-0.16	0.95

The concentration of sample is about 55pg/mL-24900pg/mL.

Precautions

⚠ Attention:

Only for in vitro diagnostic.

Only for professional use.

All samples and reactive wastes are treated as sources of infection.

Do not use the kits beyond shelf life.

Do not mix different batches of reagents.

⚠ Warning:

To avoid error, do not forced to take out the cuvette from the device. Follow the device operation manual strictly, If the problem cannot be solved, contact the manufacturer for further technical support.

SYMBOLS USED ON LABELS

Symbol	Usage	Symbol	Usage
	Use-By date		Do not freeze
LOT	Batch code		Biological risks
	Manufacturer		Do Not Reuse
	Temperature Limit		
	Contains sufficient for <n> tests		
	Do not use if package is damaged		
	Consult Instructions for use		
	Keep Away from Sunlight		
IVD	In Vitro Diagnostic Medical device		
EC REP	Authorized Representative in the European Community		

References

Shang Hong, Wang Liu three, Shen Ziyu and so on. National Clinical Laboratory Practice (Fourth Edition) [M] Beijing: People's Medical Publishing House,2015:412-413.

Approval Date&Revision Date

Approval Date: Sept 9,2015
Revision Date: Nov 1, 2022
Revision Date: Jan 1, 2023
Revision Date: Dec 22,2023

CE IVD

尺寸:24*25cm展开尺寸,横向三折页再垂直方向两次对折