Hipro Biotechnology Co.,Ltd

EN
ENGLISH

# BNP

B-type Natriuretic Peptide Test Kit
(Nephelometry Immunoassay Method)

## Instructions for Use

Version: A/2

REF HP-BNP-25


**Manufacturer**

Shijiazhuang Hipro Biotechnology Co., Ltd.
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## Product Name

General Name: B-type Natriuretic Peptide Test Kit (Nephelometry Immunoassay Method)

## Specification

Package Specification
25 Tests/ Kit.

## Intended Use

This product is used to determine the content of brain natriuretic peptide (BNP) in human serum blood.

## Test Principle

The antibody of Sheep anti human brain natriuretic peptide is coated on the latex particles. The brain natriuretic peptide in the sample is specifically combined with the corresponding antibody sensitized latex in the reagent to form an antigen antibody complex. The complex causes the change of scattering intensity under the irradiation of incident light. The change rate of scattering light intensity is positively correlated with the content of BNP in the sample. The change rate of scattering light intensity is measured, and the content of BNP in the sample is calculated through the standard curve.

## Component

The BNP test kit consists of two reagents R1 and R2, as shown on Figure 1.

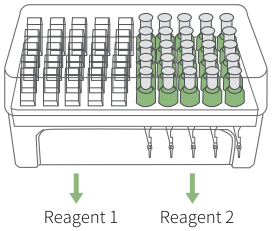



Figure 1

| Name | Content | Quantity |
|---|---|---|
| Reagent 1 (R1) | Tris (Hydroxymethyl) aminomethane buffer (pH 8.0) | 50mmol/L |
| Reagent 2 (R2) | Sheep anti human brain natriuretic peptide antibody latex particles | 5mg/mL |
| IC card (optional) | / | 1 |

Do not mix different batches of reagents.

## Storage&stability

Store the test kit at 2°C-8°C until the expiration date indicated on the label. The test kit is stable for one year when unopened.

Do not freeze the test kit.
Do not mix different lots of the test kit.

## Special Instrument Requirements

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

## Specimen type

(EDTA anticoagulation) plasma samples should be separated and tested in time after blood collection. Samples can be stored at 2 °C ~ 8 °C for 24 hours. For long-term storage, they should be placed at - 20 °C and avoid repeated freezing and thawing.

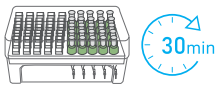
## Procedures

### HP-083/4-I&HP-083/4-II POCT Immunoassay System

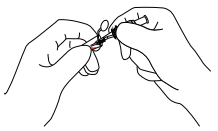
**Note:**

- Please read user manual of HP-083/4-I and HP-083/4-II before use.
- The analyzer will finish self check after start-up.
- Insert the IC card of BNP 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.

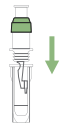
**Step 1 Sample Preparation**




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



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

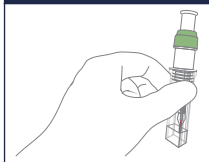


1c Insert the R2 into R1.

**Note:**

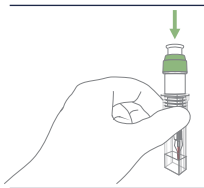
- The parameter is built in the IC card.
- Please insert the corresponding IC card into analyzer to let the analyzer read the parameter before each assay test.
- The capillary of the R2 should be fully filled.

**Step 2 Testing**



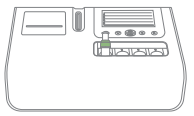
2a Hold the narrow side of R1 and shake from left to right for 12 times to let the sample completely mix with R1.

**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.



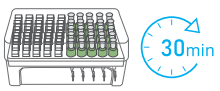
2d Insert the R1 into test channel of HP-083/4-II and the analyzer will finish the test and print out results automatically.

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

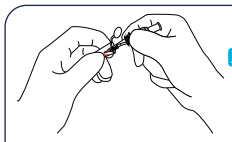
**Note:**

- 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.

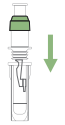
**Step 1 Sample Preparation**




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



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

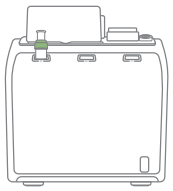


3c Insert the R2 into R1.

**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 the two-dimensional code on the cuvette. Before test the new lot of kits, 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

<100pg/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.

## 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⩽4g/L, triglyceride⩽12.88mmol/L, or bilirubin⩽253μmol/L, it has no interference to this determination.

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

## Performance Characteristics

**1.Linearity range:** 15pg/mL ～ 5000pg/mL,r⩾0.990

**2. Detection limit:** ⩽10pg/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 BNP 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 | 81.8 | 3.44 | 4.2 | 4.17 | 5.1 |
| Control 3 | 1045.3 | 39.72 | 3.8 | 49.13 | 4.7 |

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 | 82.0 | 3.94 | 4.8 | 4.2 | 5.1 |
| Control 3 | 1059.8 | 56.17 | 5.3 | 62.53 | 5.9 |

c.

| HP-AFS/1 Automatic Immunoassay System | | | | | |
|---|---|---|---|---|---|
| Sample | Mean pg/mL | Within-Run | | Between-Run | |
| | | S.D. | %C.V. | S.D. | %C.V. |
| Control 1 | 83.5 | 3.92 | 4.7 | 4.09 | 4.9 |
| Control 3 | 1035.7 | 42.46 | 4.1 | 46.61 | 4.5 |

**4.Methodology comparison**

Compared to Hitachi 7100 BNP TIA(x) by test the same samples, 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= 1.05X-0.52 | 0.95 |

The concentration of sample is about 16pg/mL-4985pg/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: Feb 4, 2021
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