CE IVD

BNP

Fast Test Kit

(Immunofluorescence Assay)

User Manual

REF IF1089 for Getein1100
IF2089 for Getein1600

INTENDED USE

BNP Fast Test Kit (Immunofluorescence Assay) is intended for in vitro quantitative determination of B-type natriuretic peptide (BNP) in human plasma and whole blood samples. This test is used as an aid in the diagnosis of congestive heart failure and for the risk stratification of patients with acute coronary syndromes (ACS).

SUMMARY

B-type natriuretic peptide (BNP) is a member of a class of hormones that regulate blood pressure. The heart is the main source of circulating BNP in humans. The molecule is released into the blood in response to increased heart pressure. Various studies have demonstrated that increased levels of circulating BNP are found in early stages of congestive heart failure (CHF, which occurs when the heart cannot deliver a sufficient amount of blood to the body). The level of BNP in the blood continues to increase as the CHF disease advances.
Getein BNP Fast Test Kit can be used for assessing the severity of CHF and risk stratification in patients with acute coronary syndromes.

PRINCIPLE

The test uses an anti-human BNP monoclonal antibody Ⅰ conjugated with fluorescence latex coated on the nitrocellulose membrane and another anti-human BNP monoclonal antibody Ⅱ coated on the test line. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human BNP antibody Ⅰ binds with the BNP in sample and forms marked antigen-antibody complex. The complex moves to the test card detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by anti-human BNP antibody Ⅱ. The fluorescence intensity of test line increases in proportion to the amount of BNP in sample.
Then insert test card into Getein1100 Immunofluorescence Quantitative Analyzer/automatically inserted by Getein1600 Immunofluorescence Quantitative Analyzer (hereafter referred to as Getein1100 and Getein1600), the concentration of BNP in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

1. A kit for Getein1100 contains:
Package specifications: 25 tests/box, 10 tests/box
1) Getein BNP test card in a sealed pouch with desiccant
2) Disposable pipet
3) User manual: 1 piece/box
4) SD card: 1 piece/box
5) Whole blood buffer: 1 bottle/box

2. A kit for Getein1600 contains:
Package specifications: 2×24 tests/box, 2×48 tests/box
Sealed cartridge with 24/48 Getein BNP test cards
User manual: 1 piece/box

Materials required for Getein1600:
1) Sample diluent: 1 bottle/box
2) Box with pipette tips: 96 tips/box
3) Mixing plate: 1 piece/box

3. Sample diluent/whole blood buffer composition:
Phosphate buffered saline, protein stabilizer, surfactant.

4. A test card consists of:
A plastic shell and a reagent strip which is composed of a sample pad (the conjunction of sample pad and nitrocellulose membrane is coated with fluorescence latex-labelled anti-human BNP monoclonal antibody Ⅰ), nitrocellulose membrane (test line is coated with another anti-human BNP monoclonal antibody Ⅱ and the control line C is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

Note: Do not mix or interchange different batches of kits.

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test card at 4~30°C with a valid period of 24 months.
Use the test card for Getein1100 within 1 hour once the foil pouch is opened.
For test card of Getein1600: if the cartridge is opened, it could be stable within 24 hours once exposed to air. If the test cards can't be used up at a time, please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.
Store the whole blood buffer/sample diluent at 0~30°C with a valid period of 24 months.
Store the whole blood buffer/sample diluent at 2~8°C for better results.

PRECAUTIONS

1. For in vitro diagnostic use only.
2. Do not use the kit beyond the expiration date.
3. Do not use the test card if the foil pouch is damaged.
4. Do not open pouches until ready to perform the test.
5. Do not reuse the test card.
6. Do not reuse the pipet.
7. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
8. Carefully read and follow user manual to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for ***plasma and whole blood samples***.
2. EDTA can be used as the anticoagulant for plasma and whole blood samples.
3. Suggest using plasma samples for better results.
4. Plasma samples can be used directly. For whole blood sample, one drop of whole blood buffer must be added before testing.
5. The test should be performed within 4 hours after blood collection. If testing is delayed, plasma samples may be stored up to 2 days at 2~8°C or stored at -20°C for 1 month before testing (whole blood sample may be stored up to 2 days at 2~8°C).
6. Refrigerated or frozen sample (only plasma) should be reached to room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
7. Do not use heat-inactivated samples or hemolysis samples.
8. SAMPLE VOLUME (for Getein1100): ***100 µl***.

TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, sample and reagent should be brought to room temperature before testing.

For Getein1100:

3. Confirm SD card lot No. in accordance with test kit lot No.. Perform “SD card” calibration when necessary.
4. Enter testing interface of Getein1100.
5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
6. Put the test card on a clean table, horizontally placed.
7. Using sample transfer pipette, deliver ***100 µl*** of sample into the sample port on the test card (for whole blood sample, one drop of whole blood buffer must be added after loading 100 µl sample on the test card).
8. Reaction time: ***10 minutes***. Insert the test card into Getein-1100 and start test after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1600:

9. Each cartridge for Getein1600 contains a specific RFID card which can calibrate automatically.
10. Place the sample diluent at the correct position in Getein-1600.
11. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1600 will do the testing and print the result automatically.

Notes:

1. It is required to perform “SD card” calibration when using a new batch of kit for Getein1100.
2. It is suggested to calibrate once for one batch of kits for Getein1100.
3. Make sure the test card insertion is correct and complete.

TEST RESULTS

Getein1100/Getein1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein1100/ Getein1600.

Others:

Measuring range of the BNP test kit is 5.0 pg/mL~5000.0 pg/mL. Dilute the sample which concentration is higher than the upper limit with calf serum, and the dilution ratio should be less than 4 times.

EXPECTED VALUE

The expected normal value for BNP and was determined by testing 300 samples from apparently healthy individuals. The 95th percentile of the concentration for BNP is 100.0 pg/mL.
It is recommended that each laboratory establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range	5.0~5000.0 pg/mL
Lower Detection Limit	≤5.0 pg/mL
Within-run Precision	≤10%
Between-run Precision	≤15%

LIMITATIONS

1. As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.
2. Samples containing interferent may influence the results. The table below listed the maximum allowance of these potential interferent.

Interferent	Triglyceride	Bilirubin
Concentration (Max)	10 g/L	0.1 g/L

REFERENCES

1. Weber. M. Role of B-type natriuretic peptide (BNP) and NT-proBNP in clinical routine. Heart. 2006, 92: 843-849.
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3. Wu A. B-Type natriuretic peptide and its clinical utility in patients with heart failure. Medical Laboratory Observer 2001; 10: 10-14.
4. deLemos JA, Morrow DA, Bentley JH, Omland T, Sabatine MS, McCabe CH, Hall C, Cannon CP, Braunwald E. The prognostic value of B-type natriuretic peptide in patients with acute coronary syndromes. New Engl. J. Med. 2001; 345: 1014-1021.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on BNP Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2016.

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult instructions for use	LOT	Batch code
	Temperature limit	IVD	*In vitro* diagnostic medical device
	Contains sufficient for <n> tests	EC REP	Authorized representative in the European Community
CE	CE mark		Do not use if package is damaged
REF	Catalogue number		

Thank you for purchasing BNP Fast Test Kit (Immunofluorescence Assay).
Please read this user manual carefully before operating to ensure proper use.

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