CE IVD

One Step Test for NT-proBNP

(Colloidal Gold)

User Manual

REF CG1002 for FIA8000
CG3002 for FIA8600

INTENDED USE

One Step Test for NT-proBNP (Colloidal Gold) is intended for *in vitro* quantitative determination of N-terminal B-type natriuretic peptide precursor (NT-proBNP) in serum, plasma or whole blood. This test is used as an aid in the clinical diagnosis, prognosis and evaluation of Heart Failure (HF).

SUMMARY

N-terminal B-type natriuretic peptide precursor (NT-proBNP) is secreted from the left cardiac ventricle in response to volume and pressure overload. It's an inactive N-terminal fragment that split from BNP prohormone. NT-proBNP can be used to evaluate heart contractile, diastolic dysfunction, and ventricular segmental wall motion coordination. Besides, it has high sensitivity and negative predictive value (>97%). As a gold standard recommended by the European Society of Cardiology, American Heart Association, and American College of Cardiology for the diagnosis and prognosis of heart failure, NT-proBNP is used to indicate heart failure patient at the early stage, determine HF risk levels, monitor medical efficiency of HF drug, evaluate prognosis of HF patient and to distinguish dyspnea that caused by HF from other diseases. Furthermore, NT-proBNP is a risk assessment indicator for Acute Coronary Syndrome.

PRINCIPLE

The test uses an anti-human NT-proBNP monoclonal antibody conjugated with colloidal gold and an anti-human NT-proBNP polyclonal antibody coated on the test line. After the sample has been applied to the test strip, the gold-labelled anti-human NT-proBNP monoclonal antibody binds with the NT-proBNP in sample and forms a marked antigen-antibody complex. This complex moves to the test card detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by the anti-human NT-proBNP polyclonal antibody resulting in a purplish red streak appears on the test line. The color intensity of the test line increases in proportion to the amount of NT-proBNP in sample.

Then insert test card into FIA8000/FIA8600 Quantitative Immunoassay Analyzer (hereinafter referred to as FIA8000 and FIA8600), the concentration of NT-proBNP in sample will be measured and displayed on the screen. The value will be stored in FIA8000/FIA8600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

1. A kit for FIA8000/FIA8600 contains:

Package specifications: 25 tests/kit, 10 tests/kit

1) Getein NT-proBNP test card in a sealed pouch with desiccant
2) Disposable pipet
3) Whole blood buffer: 1 bottle/kit
4) User manual: 1 piece/kit
5) SD card: 1 piece/kit

2. A test card consists of:

A plastic shell and a reagent strip which is composed of a sample pad, a colloidal gold pad (coated with gold-labelled anti-human NT-proBNP monoclonal antibody), nitrocellulose membrane (the test line is coated with an anti-human NT-proBNP polyclonal antibody, and the control line is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

3. Whole blood buffer composition:

Phosphate buffered saline, proteins, detergent, preservative, stabilizer.

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

APPLICABLE DEVICE

FIA8000 Quantitative Immunoassay Analyzer
FIA8600 Quantitative Immunoassay Analyzer

STORAGE AND STABILITY

Store the test kit at 4~30℃ with a valid period of 24 months.
Use the test card within 1 hour once the foil pouch is opened.

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 ***serum, plasma and whole blood samples. Heparin and sodium citrate*** can be used as the anticoagulant for plasma and whole blood. Samples should be free of hemolysis.
2. Suggest using serum or plasma for better results.
3. Serum or plasma can be used directly. For whole blood sample, one drop of whole blood buffer must be added before testing.
4. If testing is delayed, serum and plasma samples may be stored up to 1 day at 2~8℃ or stored at -20℃ for 3 months before testing (whole blood sample may be stored up to 3 days at 2~8℃).
5. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
6. Do not use heat-inactivated samples.
7. SAMPLE VOLUME: ***120 μL***.

TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, sample and reagent should be brought to room temperature before testing.
3. Confirm SD card lot No. in according with test kit lot No..Perform calibration when necessary (Details refer to FIA8000/8600 User Manual).
4. On the main interface of FIA8000/FIA8600, press "ENT" button (FIA8000) or click on “Measure” icon (FIA8000/8600) to enter testing interface.
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 ***120 μL*** of sample into

the sample well on the test card (for whole blood sample, one drop of whole blood buffer must be added after loading 120 μL sample on the test card).

8. ***Reaction time: 15 minutes.*** Insert the test card into FIA8000/FIA8600, press "ENT" button (FIA8000) or click on "Measure" icon (FIA8000/FIA8600) after reaction time is elapsed. The result will be shown on the screen and printed automatically.

Notes:

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

TEST RESULTS

Valid: When a purplish-red band appears at the control area (C), use FIA8000/FIA8600 to analyze the test card and get the result.

Invalid: If no colored band appears in the control area (C), the test result is invalid. The test should be repeated and if the same situation happened again, please stop using this batch of products and contact your supplier.

Others: Dilute the sample which concentration is higher than the upper limit with calf serum, the dilution ratio should be less than 4 times.

EXPECTED VALUE

The expected normal value for NT-proBNP was determined by testing samples from 2,500 apparently healthy individuals. The 95th percentile of the concentration for NT-proBNP is 185 pg/ml and the 97.5th percentile of the concentration for NT-proBNP is 300 pg/ml. Because of the apparent difference of the concentration of NT-proBNP among different age groups, the reference values of the NT-proBNP are reported in groups. Details refer to Table 1. Clinical diagnosis value: refer to Roche criterion, details see Table 2.

Table 1 NT-proBNP reference value

Age / Percentile	≤44	45-54	55-64	65-74	≥75	Statistic analysis
95	98.5	130	215	290	530	185
97.5	116	170	270	350	740	300

Table 2 Standard of excluding/diagnosing HF by NT-proBNP

Age	<50	50-75	≥75	Diagnosis of HF
NT-proBNP (pg/ml)	≥450	≥900	≥1800	High probability of HF
	300-450	300-900	300-1800	Low probability of HF, need to combine with other clinical evaluation
	<300	<300	<300	Exclude HF

It is recommended that each laboratory establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range	100~35000 pg/ml
Lower Detection Limit	≤100 pg/ml
Within-Run Precision (n=10)	≤10%
Between-Run Precision	≤15%
Recovery:	
NT-proBNP for low-sensitivity test line	103% (mean)
NT-proBNP for high-sensitivity test line	98% (mean)

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. Interferents in samples may influence the results.The table below listed the maximum allowance of these potential interferents.

Interferent	Hemoglobin	Triglyceride	Bilirubin
Concentration (Max)	10 g/L	15 g/L	0.3 g/L

REFERENCES

1. de Lemos JA, McGuire DK, Drazner MH. B-type natriuretic peptide in cardiovascular disease. Lancet 2003; 362:316~322.
2. Pfister R, Scholz M, Wielckens K, Erdmann E, Schneider CA. The value of natriuretic peptides NT-pro-BNP and BNP for the assessment of left-ventricular volume and function. A prospective study of 150 patients. Deutsche medizinische Wochenschrift (1946) 2002; 127(49):2605.
3. EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
4. EN ISO 18113-2:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use .

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on One Step Test for NT-proBNP (Colloidal Gold) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult *instructions for use* or consult electronic *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/ European Union
CE	CE mark		Do not use if package is damaged and consult *instructions for use*
REF	Catalogue number		

Thank you for purchasing One Step Test for NT-proBNP (Colloidal Gold). Please read this user manual carefully before operating to ensure proper use.

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