Cardiac Troponin T Test Cassette (Whole Blood/Serum/Plasma) Package Insert

REF FI-CTNT-402	English

A Fluorescence Immunoassay for the detection of myocardial infarction (MI) to quantitatively detect cardiac Troponin T (cTnT) in human whole blood, serum or plasma with the use of the Fluorescence Immunoassay Analyzer.
For professional in vitro diagnostic use only.

【INTENDED USE】

The Cardiac Troponin T Test Cassette (Whole Blood/Serum/Plasma) is intended for *in vitro* quantitative determination of human cardiac Troponin T in human whole blood, serum or plasma as an aid in the diagnosis of Myocardial Infarction (MI).

【SUMMARY】

Cardiac Troponin T(cTnT) is a structurally bound protein found in striated muscle cells with a molecular weight of 37kD.[1] Troponin T is part of a three subunit complex comprising of Troponin I and Troponin C. Along with tropomyosin, this structural complex forms the main component that regulates the calcium sensitive ATPase activity of actomyosin in striated skeletal and cardiac muscle.[2] After acute myocardial infarction (AMI), serum cTnT levels are elevated 2 to 8 hours after onset, peak in 12-24 hours and can persist for up to 14 days.[3] Cardiac Troponin T(cTnT) as currently recognized as the most valuable diagnostic index for myocardial injury, has shown broad application prospects and replaced creatine phosphate kinase MB isoenzyme (CK-MB) as the "gold standard" for judging myocardial injury, especially for diagnosing acute myocardial infarction. It plays an important role in the diagnosis of heart failure, unstable angina pectoris, myocarditis, drug-induced myocardial injury, cardiac injury monitoring in thoracic surgery, various critical diseases and multiple organ failure.[4]
The Cardiac Troponin T Test Cassette (Whole Blood/Serum/Plasma) is a simple test that utilizes a combination of anti-cTnT antibody coated particles and capture reagent to detect cTnT in whole blood, serum or plasma.

【PRINCIPLE】

The Cardiac Troponin T Test Cassette (Whole Blood/Serum/Plasma) detects cardiac Troponin T (cTnT) based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. If the specimen contains cTnT, it attaches to the fluorescent microspheres-conjugated anti-cTnT antibodies. Then the complex will be captured by the capture antibodies coated on the nitrocellulose membrane (Test line). The concentration of cTnT in the sample correlates with the fluorescence signal intensity captured on the T line. According to the fluorescence intensity of the test and product standard curve, the concentration of cTnT in the sample can be calculated by analyzer to show cTnT concentration in specimen.

【REAGENTS】

The test kit includes anti-cTnT antibody coated fluorophores and anti-cTnT antibody coated on the membrane.

【PRECAUTIONS】

1. For professional *in vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse.
3. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
4. Do not eat, drink or smoke in the area where the specimens and tests are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. Do not interchange or mix reagents from different lots.
6. Humidity and temperature can adversely affect results.
7. Used testing materials should be discarded in accordance with local regulations.
8. Read the entire procedure carefully prior to any testing.
9. The cTnT Test Cassette should only be used with the analyzer by medical professionals.

【STORAGE AND STABILITY】

1. The test should be stored at 4-30 °C until the expiry date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.
3. **Do not freeze.**
4. Care should be taken to protect the components of the kit from contamination.
5. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

【SPECIMEN COLLECTION AND PREPARATION】

1. Collect the specimen according to standard procedures.
2. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.
3. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8 °C for up to 1 day, for long term storage, specimens should be kept below -20 °C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be used within 1 day of collection. Do not freeze whole blood specimens. Whole blood collected by finger stick should be tested immediately.
4. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
5. EDTA K_2, Heparin sodium, Citrate sodium and Oxalate potassium can be used as the anticoagulant tube for collecting the blood specimen.

【MATERIALS】

Materials Provided

- Test Cassettes
- ID Card
- Specimen Collection Tubes with Buffer
- Package Insert
- Capillary Droppers
- Disposable Droppers

Materials Maybe Provided when Requested

- Sterile Lancets
- Alcohol Pads

Materials Required But Not Provided

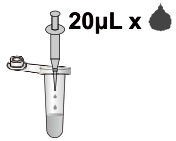
- Timer
- Centrifuge
- Fluorescence Immunoassay Analyzer
- Pipette
- Specimen Collection Containers

【DIRECTIONS FOR USE】

Refer to Fluorescence Immunoassay Analyzer User Manual for the complete instructions for the use of the analyzer.
Allow the test, specimen and buffer to reach room temperature (15-30 °C) prior to testing.

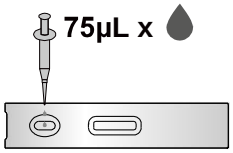
1. Turn on the Analyzer power.
2. Import the test information into the analyzer with the ID Card provided in the kit. Choose test mode and/or sample type according to needs.
3. Remove the test cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
4. Place the test on a flat and clean surface.

<u>For Venous whole blood/Serum/Plasma specimen:</u>



Pipette **20μL of whole blood/serum/ plasma** into the buffer tube.

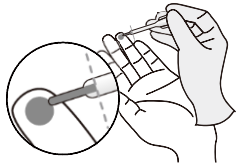
Mix the specimen and the buffer well.



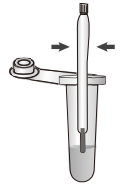
Pipette **75 μL of diluted specimen** into the sample well of the test cassette and start the timer.

<u>For Fingerstick whole blood specimen:</u>

- Wash the hand with soap and warm water or clean with an alcohol pad. Allow to dry.
- Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
- Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
- Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Collect the fingerstick whole blood specimen as following:

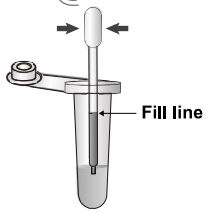


Without squeezing the **capillary dropper**, put the open end in contact with the blood. The blood will migrate into the capillary tube automatically.
Note: Make sure the dropper is **level** and do not squeeze the dropper bulb.

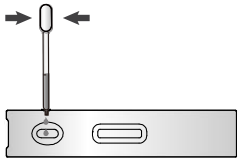


Dispense collected specimen into the buffer tube.
Mix specimen and buffer **2-3 times** by squeezing the bulb.

Mix the specimen and the buffer well.



Squeeze the bulb of the **disposable dropper and slowly release**; draw the diluted solution to the **fill line (Approx. 75μL)**.



Squeeze the bulb vertically to release **diluted solution** into the specimen well of the test cassette and start the timer.

5. Test results should be interpreted at **15 minutes** with the use of Fluorescence Immunoassay Analyzer.

Caution: Operator must consult the Fluorescence Immunoassay Analyzer User Manual prior to use and become familiar with the processes and quality control procedures.

【INTERPRETATION OF RESULTS】

Results read by the Fluorescence Immunoassay Analyzer.
The result of tests for cTnT is calculated by Fluorescence Immunoassay Analyzer and display the result on the screen. For additional information, please refer to the user manual of Fluorescence Immunoassay Analyzer.
Linearity range of cTnT Test is 0.2-40 ng/mL.

【QUALITY CONTROL】

Each cTnT Test Cassette contains internal control that satisfies routine quality control requirements. This internal control is performed each time a sample is tested. This control indicates that the test cassette was inserted and read properly by Fluorescence Immunoassay Analyzer. An invalid result from the internal control causes an error message on Fluorescence Immunoassay Analyzer indicating that the test should be repeated. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【LIMITATIONS】

1. The Cardiac Troponin T Test Cassette (Whole Blood/Serum/Plasma) is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of Cardiac Troponin T.
2. The Cardiac Troponin T Test Cassette (Whole Blood/Serum/Plasma) will only indicate the presence of Cardiac Troponin T antigen in the specimen and should not be used as the sole criteria for evaluating Myocardial Infarction.
3. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
4. High concentrations of Cardiac Troponin T may produce a dose hook effect, resulting in incorrect interpretation of Cardiac Troponin T levels. High dose hook effect has not been observed with this test up to 40ng/mL of Cardiac Troponin T.
5. The hematocrit of the whole blood should be between 25% and 65%.
6. The results of cTnT Test Cassettes are based on measuring the levels of cTnT in a specimen. It should not be used as the sole criterion for treatment decisions. If the result is positive, other clinical findings and alternative test methods are recommended to reach proper medical treatments.

【EXPECTED VALUES】

Concentrations	Clinical Reference
<0.5 ng/mL	Not indicative of Acute Myocardial Infarction

>0.5 ng/mL	Indicative of Acute Myocardial Infarction

【PERFORMANCE CHARACTERISTICS】

1. Accuracy

The test deviation is ≤±15%.

2. Sensitivity

The Cardiac Troponin T Test Cassette (Whole Blood/Serum/Plasma) can detect levels of Cardiac Troponin T as low as 0.2ng/mL.

3. Detection range

0.2~40 ng/mL

4. Linearity range

0.2~40 ng/mL, R≥0.990

5. Precision

C.V.≤15%

6. Method comparison

The Cardiac Troponin T Test Cassette was compared with the results obtained with CLIA for 130 samples. The correlation coefficient (r) is R=0.992.

【LITERATURE REFERENCES】

1. Mair J, Artner-Dworzak E, Lechleitner P, et al. Cardiac troponin T in diagnosis of acute myocardial infarction[J]. Clin Chem, 1991, 37(6):845-852.
2. Mehegan JP, Tobacman LS. Cooperative interaction between troponin molecules bound to the cardiac thin filament[J].Biol.Chem, 1991, 266:966.
3. Diagnostic efficiency of troponin T measurement in acute myocardial infarction[J]. Clin Chem, 1991, 83(3F):902-912.
4. Lv xing, Cai xiao-hui, qing zhi-ju. Cardiac troponin T detection method and its clinical application[J]. Int J Lab Med, 2012, 33(13):1627-1630.

Index of Symbols

	Consult instructions for use or consult electronic instructions for use		Contains sufficient for <n> tests		Temperature limit
IVD	*In vitro* diagnostic medical device	LOT	Batch code	REF	Catalogue number
EC REP	Authorized representative in the European Community		Use-by date		Do not re-use
	Do not use if package is damaged and consult instructions for use		Manufacturer		

Hangzhou AllTest Biotech Co.,Ltd.
#550,Yinhai Street
Hangzhou Economic & Technological Development Area
Hangzhou, 310018 P.R. China
Web: www.alltests.com.cn Email: info@alltests.com.cn

EC REP
MedNet EC-REP GmbH
Borkstrasse 10,
48163 Muenster,
Germany

Number: F145392500
Revision date:2024-12-27

High-Sensitivity Cardiac Troponin T Test Cassette (Whole Blood/Serum/Plasma)
Package Insert

REF FI-SCTT-402	English

A Fluorescence Immunoassay for the quantitative detection of Cardiac Troponin T (cTnT) in human whole blood, serum or plasma with the use of the Fluorescence Immunoassay Analyzer.

For professional in vitro diagnostic use only.

【INTENDED USE】

The High-Sensitivity Cardiac Troponin T Test Cassette (Whole Blood/Serum/Plasma) is intended for the *in vitro* quantitative detection of human Cardiac Troponin T (cTnT) in human whole blood, serum or plasma as an aid in the diagnosis of Myocardial Infarction (MI).

【SUMMARY】

Cardiac Troponin T(cTnT) is a structurally bound protein found in striated muscle cells with a molecular weight of 37kD.[1] Troponin T is part of a three subunit complex comprising of Troponin I and Troponin C. Along with tropomyosin, this structural complex forms the main component that regulates the calcium sensitive ATPase activity of actomyosin in striated skeletal and cardiac muscle.[2] After acute myocardial infarction (AMI), serum cTnT levels are elevated 2 to 8 hours after onset, peak in 12-24 hours and can persist for up to 14 days.[3] Cardiac Troponin T(cTnT) as currently recognized as the most valuable diagnostic index for myocardial injury, has shown broad application prospects and replaced creatine phosphate kinase MB isoenzyme (CK-MB) as the "gold standard" for judging myocardial injury, especially for diagnosing acute myocardial infarction. It plays an important role in the diagnosis of heart failure, unstable angina pectoris, myocarditis, drug-induced myocardial injury, cardiac injury monitoring in thoracic surgery, various critical diseases and multiple organ failure.[4]

The High-Sensitivity Cardiac Troponin T Test Cassette (Whole Blood/Serum/Plasma) is a simple test that utilizes a combination of anti-cTnT antibody coated particles and capture reagent to detect cTnT in human whole blood, serum or plasma.

【PRINCIPLE】

The High-Sensitivity Cardiac Troponin T Test Cassette (Whole Blood/Serum/Plasma) detects Cardiac Troponin T (cTnT) based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. If the specimen contains cTnT, it attaches to the fluorescent microspheres-conjugated anti-cTnT antibodies. Then the complex will be captured by the capture antibodies coated on the nitrocellulose membrane (Test line). The concentration of cTnT in the sample correlates with the fluorescence signal intensity captured on the T line. According to the fluorescence intensity of the test and product standard curve, the concentration of cTnT in the sample can be calculated by the analyzer to show cTnT concentration in specimen.

【REAGENTS】

The test includes anti-cTnT antibody coated fluorophores and anti-cTnT antibody coated on the membrane.

【PRECAUTIONS】

1. For professional *in vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse.
3. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
4. Do not eat, drink or smoke in the area where the specimens and tests are handled.
5. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens.
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7. Do not interchange or mix reagents from different lots.
8. Humidity and temperature can adversely affect results.
9. Used testing materials should be discarded in accordance with local regulations.
10. Read the entire procedure carefully prior to any testing.
11. The High-Sensitivity Cardiac Troponin T Test Cassette should only be used with the analyzer by medical professionals.

【STORAGE AND STABILITY】

1. The test should be stored at 4-30 °C until the expiry date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.
3. **Do not freeze.**
4. Care should be taken to protect the components of the kit from contamination.
5. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

【SPECIMEN COLLECTION AND PREPARATION】

1. Collect the specimens according to standard procedures.
2. Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
3. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8 °C for up to 3 days, for long term storage, specimens should be kept below -20 °C. Whole blood collected by venipuncture should be stored at 2-8 °C if the test is to be run within 1 day of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
4. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.

【MATERIALS】

Materials Provided

- Test Cassettes
- Specimen Collection Tubes with Buffer
- ID Card
- Package Insert
- Capillary Droppers
- Disposable Droppers

Materials Maybe Provided when Requested

- Sterile Lancets
- Alcohol Pads

Materials Required But Not Provided

- Timer
- Centrifuge
- Fluorescence Immunoassay Analyzer
- Pipette
- Specimen Collection Containers

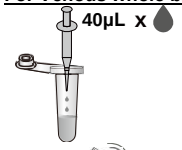
【DIRECTIONS FOR USE】

Refer to the Fluorescence Immunoassay Analyzer User Manual for the complete instructions for the use of the analyzer.

Allow the test, specimen and buffer to reach room temperature (15-30 °C) prior to testing.

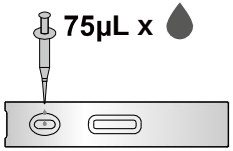
1. Turn on the Analyzer power.
2. Import the test information into the analyzer with the ID Card provided in the kit. Choose test mode and/or sample type according to needs.
3. Remove the test cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
4. Adding sample:

For Venous whole blood/Serum/Plasma specimen:



Pipette **40μL of whole blood/serum/plasma** into the buffer tube.

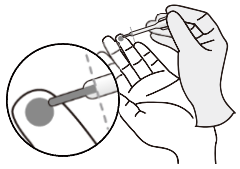
Mix the specimen and the buffer well.



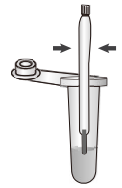
Pipette **75 μL of diluted specimen** into the sample well of the test cassette and start the timer.

For Fingerstick whole blood specimen:

- Wash the hand with soap and warm water or clean with an alcohol pad. Allow to dry.
- Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
- Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
- Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Collect the fingerstick whole blood specimen as following:

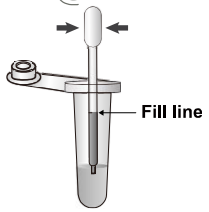


Without squeezing the **capillary dropper**, put the open end in contact with the blood. The blood will migrate into the capillary tube automatically.
Note: Make sure the dropper is **level** and do not squeeze the dropper bulb.

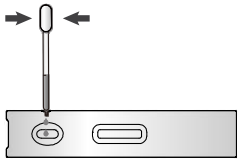


Dispense collected specimen into the buffer tube. Mix specimen and buffer **2-3 times** by squeezing the bulb.

Mix the specimen and the buffer well.



Squeeze the bulb of the **disposable dropper and slowly release**; draw the diluted solution to the **fill line (Approx. 75μL)**.



Squeeze the bulb vertically to release **diluted solution** into the specimen well of the test cassette and start the timer.

5. Test results should be interpreted at **15 minutes** with the use of the Fluorescence Immunoassay Analyzer.

Caution: Operator must consult the Fluorescence Immunoassay Analyzer User Manual prior to use and become familiar with the processes and quality control procedures.

【INTERPRETATION OF RESULTS】

Results read by the Fluorescence Immunoassay Analyzer.

The result of test for cTnT is calculated by the analyzer and is displayed on the screen. For additional information, please refer to the user manual of the Fluorescence Immunoassay Analyzer.

Assay range of cTnT is 0.01-10 ng/mL.

【QUALITY CONTROL】

Each High-Sensitivity Cardiac Troponin T Test Cassette contains internal control that satisfies routine quality control requirements. This internal control is performed each time a sample is tested. This control indicates that the test cassette was inserted and read properly by the analyzer. An invalid result from the internal control causes an error message on the analyzer indicating that the test should be repeated. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【LIMITATIONS】

1. The High-Sensitivity Cardiac Troponin T Test Cassette (Whole Blood/Serum/Plasma) is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of cTnT.
2. The High-Sensitivity Cardiac Troponin T Test Cassette will only indicate the presence of cTnT in the specimen and should not be used as the sole criteria for Myocardial Infarction.
3. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
4. The results are only for the analysis of the results on the tests. It should not be used as the sole criteria for treatment decisions.

【EXPECTED VALUES】

Concentrations	Clinical Reference
<0.1 ng/mL	Not indicative of Acute Myocardial Infarction
>0.1 ng/mL	Indicative of Acute Myocardial Infarction

【PERFORMANCE CHARACTERISTICS】

1. Accuracy

The deviation is ≤15%.

2. Assay Range and Detection Limit

•Assay Range: 0.01-10 ng/mL.

•Minimum Detection Limit (Analytical Sensitivity): 0.01ng/mL.

3. Linearity range

0.01-10 ng/mL, R≥0.990

4. Precision

Intra-lot precision

Within-run precision has been determined by using 10 replicates of 2 specimens containing 0.1ng/mL, 1ng/mL of cTnT. C.V. is ≤ 15%.

Inter-lot precision

Between-run precision has been determined by using 10 replicates for each of three lots using 2 specimens containing 0.1ng/mL, 1ng/mL of cTnT. C.V. is ≤15%.

5. Interfering Substances

The following compounds have also been tested using the High-Sensitivity Cardiac Troponin T Test Cassette (Whole Blood/Serum/Plasma) and no interference was observed.

Triglyceride: 15 mg/mL	Bilirubin: 1 mg/mL
Ascorbic Acid: 2 g/dL	Hemoglobin: 10 mg/mL

6. Method comparison

The product was evaluated with 135 clinical samples compared with commercial CLIA test kit. The correlation coefficient(r) is 0.9832.

【LITERATURE REFERENCES】

1. Mair J, Artner-Dworzak E, Lechleitner P, et al. Cardiac troponin T in diagnosis of acute myocardial infarction[J]. Clin Chem, 1991, 37(6):845-852.
2. Mehegan JP, Tobacman LS. Cooperative interaction between troponin molecules bound to the cardiac thin filament[J].Biol.Chem, 1991, 266:966.
3. Diagnostic efficiency of troponin T measurement in acute myocardial infarction[J]. Clin Chem, 1991, 83(3F):902-912.
4. Lv xing, Cai xiao-hui, qing zhi-ju. Cardiac troponin T detection method and its clinical application[J]. Int J Lab Med, 2012, 33(13):1627-1630.

Index of Symbols

	Consult instructions for use or consult electronic instructions for use		Contains sufficient for <n> tests		Temperature limit
IVD	*In vitro* diagnostic medical device	LOT	Batch code	REF	Catalogue number
EC REP	Authorized representative in the European Community/European Union		Use-by date		Do not re-use
	Do not use if package is damaged and consult instructions for use		Manufacturer		Caution

Hangzhou AllTest Biotech Co.,Ltd.
#550,Yinhai Street
Hangzhou Economic & Technological Development Area
Hangzhou, 310018 P.R. China
Web: www.alltests.com.cn Email: info@alltests.com.cn

EC REP
VidaQuick Biotech S.L.
No.132, Rosello Street, Barcelona,
Barcelona Province, 08036, Spain
E-mail: info@vidaquick.com

Number: F145461500
Revision date: 2025-03-23

D-Dimer Test Cassette (Whole Blood/Plasma) Package Insert

REF FI-DDM-402	English

A Fluorescence Immunoassay for measuring D-Dimer in human whole blood or plasma with the use of the Fluorescence Immunoassay Analyzer.
For professional in vitro diagnostic use only.

【INTENDED USE】

The D-Dimer Test Cassette (Whole Blood/Plasma) is based on Fluorescence Immunoassay to measure D-Dimer in human whole blood or plasma as an aid in the diagnosis of DVT and PE.

【SUMMARY】

D-dimer (or D dimer) is a fibrin degradation product (or FDP), a small protein fragment present in the blood after a blood clot is degraded by fibrinolysis. Its formation or increase reflects the activation of coagulation and fibrinolysis system, and its plasma level can represent the production of thrombin active agent fibrin in vivo. It can be used as an indicator of thrombosis in the body. The D-dimer content in patients with thrombosis is significantly elevated.[1]

In addition, studies have shown that low levels of D-Dimer (0.1-0.5mg/L) are closely related to the occurrence of cardiovascular diseases, and high levels of D-Dimer may be early exclusion diagnostic indicators for DVT and PE. [2]

【PRINCIPLE】

The D-Dimer Test Cassette (Whole Blood/Plasma) detects D-Dimer based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. If the specimen contains D-Dimer, it attaches to the fluorescent microspheres-conjugated anti-D-Dimer antibodies. Then the complex will be captured by the capture antibodies coated on the nitrocellulose membrane (Test line). The concentration of D-Dimer in the sample correlates with the fluorescence signal intensity captured on the T line. According to the fluorescence intensity of the test and the standard curve, the concentration of D-Dimer in the sample can be calculated by Analyzer to show D-Dimer concentration in specimen.

【REAGENTS】

The test includes anti-D-Dimer antibody coated fluorphores and anti-D-Dimer antibody coated on the membrane.

【PRECAUTIONS】

1. For professional *in vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse.
3. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
4. Do not eat, drink or smoke in the area where the specimens and tests are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. Do not interchange or mix reagents from different lots.
6. Humidity and temperature can adversely affect results.
7. Used testing materials should be discarded in accordance with local regulations.
8. Read the entire procedure carefully prior to any testing.
9. The D-Dimer Test Cassette should only be used with the analyzer by medical professionals.

【STORAGE AND STABILITY】

1. The kit should be stored at 4-30°C before the expiry date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.
3. **Do not freeze.**
4. Care should be taken to protect the components of the kit from contamination.
5. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

【SPECIMEN COLLECTION AND PREPARATION】

1. Collect the specimen according to standard procedures.
2. Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
3. Do not leave specimens at room temperature for prolonged periods. Plasma specimens may be stored at 2-8 °C for up to half-day, for long term storage, specimens should be kept below -20 °C. Whole blood collected by venipuncture should be stored at 2-8 °C if the test is to be run within half-day of collection. Do not freeze whole blood specimens. Whole blood collected by finger stick should be tested immediately.
4. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
5. EDTA K2, Heparin sodium, Citrate sodium and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.

【MATERIALS】

Materials Provided

- Test Cassettes
- Specimen Collection Tubes with Buffer
- ID Card
- Package Insert
- Capillary Droppers
- Disposable Droppers

Materials Maybe Provided when Requested

- Sterile Lancets
- Alcohol Pads

Materials Required But Not Provided

- Timer
- Centrifuge
- Fluorescence Immunoassay Analyzer
- Pipette
- Specimen Collection Containers

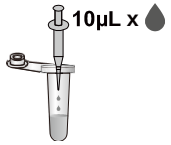
【DIRECTIONS FOR USE】

Refer to Fluorescence Immunoassay Analyzer User Manual for the complete instructions for the use of the analyzer.

Allow the test, specimen and buffer to reach room temperature (15-30 °C) prior to testing.

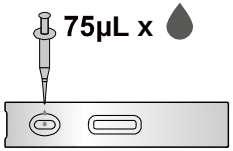
1. Turn on the Analyzer power.
2. Import the test information into the analyzer with the ID Card provided in the kit. Choose test mode and/or sample type according to needs.
3. Remove the test cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
4. Place the test on a flat and clean surface.

For Venous whole blood/Plasma specimen:



Pipette **10µL of whole blood/plasma** into the buffer tube.

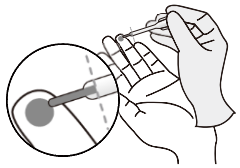
Mix the specimen and the buffer well.



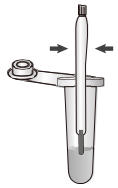
Pipette **75 µL of diluted specimen** into the sample well of the test cassette and start the timer.

For Fingerstick whole blood specimen:

- Wash the hand with soap and warm water or clean with an alcohol pad. Allow to dry.
- Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
- Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
- Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Collect the fingerstick whole blood specimen as following:

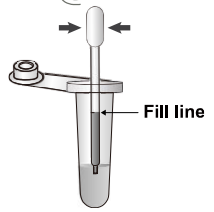


Without squeezing the **capillary dropper**, put the open end in contact with the blood. The blood will migrate into the capillary tube automatically.
Note: Make sure the dropper is **level** and do not squeeze the dropper bulb.

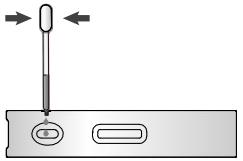


Dispense collected specimen into the buffer tube.
Mix specimen and buffer **2-3 times** by squeezing the bulb.

Mix the specimen and the buffer well.



Squeeze the bulb of the **disposable dropper and slowly release**; draw the diluted solution to the **fill line (Approx. 75µL)**.



Squeeze the bulb vertically to release **diluted solution** into the specimen well of the test cassette and start the timer.

5. Test results should be interpreted at **15 minutes** with the use of Fluorescence Immunoassay Analyzer.

Caution: Operator must consult the Fluorescence Immunoassay Analyzer User Manual prior to use and become familiar with the processes and quality control procedures.

【INTERPRETATION OF RESULTS】

Results read by Fluorescence Immunoassay Analyzer.

The result of tests for D-Dimer is calculated by Fluorescence Immunoassay Analyzer and display the result on the screen. For additional information, please refer to the user manual of Fluorescence Immunoassay Analyzer.

Linearity range of D-Dimer Test is 0.1~10 mg/L.

Reference range: <0.5 mg/L

【QUALITY CONTROL】

Each D-Dimer Test Cassette contains internal control that satisfies routine quality control requirements. This internal control is performed each time a sample is tested. This control indicates that the test cassette was inserted and read properly by Fluorescence Immunoassay Analyzer. An invalid result from the internal control causes an error message on Fluorescence Immunoassay Analyzer indicating that the test should be repeated. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【LIMITATIONS】

1. The D-Dimer Test Cassette (Whole Blood/Plasma) is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of D-Dimer.
2. The D-Dimer Test Cassette (Whole Blood/Plasma) will only indicate the presence of D-Dimer in the specimen and should not be used as the sole criterion for evaluating DVT and PE.
3. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
4. High concentrations of D-Dimer may produce a dose hook effect, resulting in incorrect interpretation of D-Dimer levels. High dose hook effect has not been observed with this test up to 10 mg/L of D-Dimer.
5. The hematocrit level of the whole blood should be between 25% and 65%.
6. The results of D-Dimer Tests are based on measuring the levels of D-Dimer in a specimen. It should not be used as the sole criterion for treatment decisions. If the result is positive, other clinical findings and alternative test methods are recommended to reach proper medical treatments.

【EXPECTED RESULTS】

Concentrations	Clinical Reference
<0.5 mg/L	Healthy
0.5 ~ 1.5 mg/L	Low DVT and PE risk
1.5 ~ 3 mg/L	Moderate DVT and PE risk
3 ~ 5 mg/L	High DVT and PE risk
>5 mg/L	High DVT and PE risk (Increased mortality)

【PERFORMANCE CHARACTERISTICS】

1.Accuracy

The test deviation is ≤±15%.

2.Sensitivity

The D-Dimer Test Cassette (Whole Blood/Plasma) can detect levels of D-Dimer as low

as 0.1 mg/L in whole blood or plasma.

3. Detection range

0.1 ~ 10 mg/L

4. Linearity range

0.1 ~ 10 mg/L, R≥0.990

5. Precision

Intra-lot precision

Within-run precision has been determined by using 10 replicates of 2 specimens containing 0.5 mg/L, 5 mg/L of D-Dimer. C.V. is ≤ 15%.

Inter-lot precision

Between-run precision has been determined by using 10 replicates for each of three lots using 2 specimens containing 0.5mg/L, 5 mg/L of D-Dimer. C.V. is ≤15%.

6.Cross-reactivity

Cross-reactivity studies were carried out with following analytes:

HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, anti-syphilis IgG, anti-HIV IgG, anti-*H.pylori* IgG, anti-MONO IgM , anti-Rubella IgG, anti-Rubella IgM, anti-CMV IgG, anti-CMV IgM, anti-Toxo IgG and anti-Toxo IgM positive specimens.

The results showed no cross-reactivity.

7.Interfering Substances

The following potentially interfering substances were added to 2 specimens containing 0.5mg/L, 5 mg/L of D-Dimer, respectively.

Acetaminophen: 20 mg/dL	Caffeine: 20 mg/dL
Acetylsalicylic Acid: 20 mg/dL	Gentisic Acid: 20 mg/dL
Ascorbic Acid: 20mg/dL	Albumin: 10,500 mg/dL
Creatin: 200 mg/dL	Hemoglobin: 1,000 mg/dL
Bilirubin: 1,000 mg/dL	Oxalic Acid: 600 mg/dL
Cholesterol: 800 mg/dL	Triglycerides: 1,600 mg/dL

None of the substances at the concentration tested interfered in the assay.

8. Method comparison

The D-Dimer assay was compared with the results obtained with ADVIA2400 for 90 samples. The correlation coefficient(r) is 0.991.

【LITERATURE REFERENCES】

1. Adam S S, Key N S, Greenberg C S. D-dimer antigen: current concepts and future prospects[J]. Blood, 2009, 113(13):2878.
2. General Practice Notebook > D-dimer. Retrieved September 2011.

Index of Symbols

	Consult instructions for use or consult electronic instructions for use		Contains sufficient for <n> tests	4°C 30°C	Temperature limit
IVD	*In vitro* diagnostic medical device	LOT	Batch code	REF	Catalogue number
EC REP	Authorized representative in the European Community		Use-by date		Do not re-use
	Do not use if package is damaged and consult instructions for use		Manufacturer		

Hangzhou AllTest Biotech Co., Ltd.
#550, Yinhai Street,
Hangzhou Economic & Technological Development Area
Hangzhou, 310018 P.R. China
Web:www.alltests.com.cn Email:info@alltests.com.cn

EC REP
MedNet EC-REP GmbH
Borkstrasse 10
48163 Muenster
Germany

Number: F145452300
Revision date: 2025-03-17

CK-MB Test Cassette (Whole Blood/Serum/Plasma) Package Insert

REF FI-CKMB-402	English

A Fluorescence Immunoassay for the quantitative detection of Creatine Kinase MB in human whole blood, serum or plasma with the use of fluorescence Immunoassay Analyzer.

For professional in vitro diagnostic use only

【INTENDED USE】

The CK-MB Test Cassette (Whole Blood/Serum/Plasma) is a chromatographic immunoassay for the quantitative detection of human CK-MB in human whole blood, serum or plasma as an aid in the diagnosis of Myocardial infarction (MI).

【SUMMARY】

Creatine Kinase MB (CK-MB) is an enzyme present in the cardiac muscle with a molecular weight of 87.0 kDa.[1] Creatine Kinase is a dimeric molecule formed from two subunits designated as "M" and "B" which combine to form three different isoenzymes, CK-MM, CK-BB, and CK-MB. CK-MB is the isoenzyme of Creatine Kinase most involved in the metabolism of cardiac muscle tissue.[2] The release of CK-MB into the blood following MI can be detected within 3-8 hours after the onset of symptoms. It peaks within 9 to 30 hours, and returns to baseline levels within 48 to 72 hours.[3] CK-MB is one of the most important cardiac markers and is widely recognized as the traditional marker for the diagnosis of MI.

The CK-MB Test Cassette (Whole Blood/Serum/Plasma) is a simple test that utilizes a combination of antibody coated particles and capture reagents to quantitatively detect CK-MB in whole blood, serum or plasma.

【PRINCIPLE】

The CK-MB Test Cassette (Whole Blood/Serum/Plasma) detects CK-MB based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. If the test sample contains CK-MB, it attaches to the CK-MB antibody which is conjugated with fluorescent microspheres. Then the complex will be captured by the capture antibody coated on the nitrocellulose membrane (Test line).The concentration of CK-MB in the sample correlates linearly with the fluorescence signal intensity captured on the T line. According to the fluorescence intensity of the test and product standard curve, the concentration of CK-MB in the sample can be calculated by Reader to show CK-MB concentration in specimen.

【REAGENTS】

The test kit include anti-CK-MB antibody conjugated fluorophores and CK-MB antibody coated on the membrane.

【PRECAUTIONS】

1. For professional *in vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse.
3. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
4. Do not eat, drink or smoke in the area where the specimens and tests are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. Do not interchange or mix reagents from different lots.
6. Humidity and temperature can adversely affect results.
7. Used testing materials should be discarded in accordance with local regulations.
8. Read the entire procedure carefully prior to any testing.
9. The CK-MB Test Cassette is only operational in the analyzer. And tests should be applied by professionally trained staff working in certified laboratories at some remove from the patient and clinic at which the sample(s) is taken by qualified medical personnel.

【STORAGE AND STABILITY】

1. The kit should be stored at 4-30 °C until the expiry date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.
3. **Do not freeze.**
4. Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

【SPECIMEN COLLECTION AND PREPARATION】

Blood Sample Taking

1. Collect the specimen according to standard procedures.
2. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days, for long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be used within 2 day of collection. Do not freeze whole blood specimens. Whole blood collected by finger stick should be tested immediately.
3. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.

Sample Dilution/Sample Stability

1. The specimen **(75μL of serum/plasma or 100μL of whole blood)** can be added directly with the micro pipette into the buffer.
2. Close the tube and shake the sample by hand for approximately 10 seconds so sample and dilution buffer mix well.
3. Let the diluted sample rest for approximately **1 minute**.

【MATERIALS】

Materials Provided

- Test Cassettes
- Specimen Collection Tubes with Extraction Buffer
- ID Card
- Package Insert

Materials Required But Not Provided

- Timer
- Centrifuge
- Fluorescence Immunoassay Analyzer
- Pipette
- Specimen Collection Containers

【DIRECTIONS FOR USE】

Refer to Fluorescence Immunoassay Analyzer User Manual for the complete instructions for the use of the analyzer.

Allow the test, specimen and buffer to reach room temperature (15-30 °C) prior to testing.

1. Turn on the Analyzer power.
2. Take out the ID card and insert it into the ID Card Slot. Choose test mode and/or sample type according to needs.
3. Remove the test cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
4. Place the test on a flat and clean surface.

Serum/plasma: Pipette **75μL of serum/plasma** into the buffer tube; mix the specimen and the buffer well.

Whole blood: Transfer **100μL of whole blood** into the buffer tube with pipette; mix the specimen and the buffer well.

5. Add diluted specimen with a Pipette: Pipette **75μL of diluted specimen** into the sample well. Start the timer at the same time.
6. Test results should be interpreted at **15 minutes** with the use of Fluorescence Immunoassay Analyzer.

Caution: Operator must consult the Fluorescence Immunoassay Analyzer User Manual prior to use and become familiar with the processes and quality control procedures.

【INTERPRETATION OF RESULTS】

Results read by the Fluorescence Immunoassay Analyzer.

The result of tests for CK-MB is calculated by Fluorescence Immunoassay Analyzer and display the result on the screen. For additional information, please refer to the user manual of Fluorescence Immunoassay Analyzer.

Working range of CK-MB is 0.2-75ng/mL.

【QUALITY CONTROL】

Each CK-MB Test Cassette contains internal control that satisfies routine quality control requirements. This internal control is performed each time a sample is tested. This control indicates that the test cassette was inserted and read properly by Fluorescence Immunoassay Analyzer. An invalid result from the internal control causes an error message on Fluorescence Immunoassay Analyzer indicating that the test should be repeated. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【LIMITATIONS】

1. The CK-MB Test Cassette (Whole Blood/Serum/Plasma) is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of Creatine Kinase MB.
2. The CK-MB Test cassette (Whole Blood/Serum/Plasma) will only indicate the presence of Creatine Kinase MB antigen in the specimen and should not be used as the sole criteria for evaluating Myocardial Infarction.
3. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
4. High concentrations of Creatine Kinase MB may produce a dose hook effect, resulting in incorrect interpretation of Creatine Kinase MB levels. High dose hook effect has not been observed with this test up to 75ng/mL of Creatine Kinase MB.
5. The hematocrit of the whole blood should be between 25% and 65%.
6. The results of Fluorescence Immunoassay Analyzer are only for the analysis of the results on the tests. It should not be used as the sole criteria for treatment decisions. If the result is positive, other clinical findings and alternative test methods are recommended to reach proper medical treatments.

【EXPECTED VALUES】

Concentrations	Clinical Reference
<5ng/mL	Not indicative of Acute Myocardial Infarction
>5ng/mL	Indicative of Acute Myocardial Infarction

【PERFORMANCE CHARACTERISTICS】

1. Accuracy

The test deviation ≤±15%

2. Sensitivity

The CK-MB Test Cassette (Whole Blood/Serum/Plasma) can detect levels of Creatine Kinase MB as low as 0.2ng/mL in whole blood, serum or plasma.

3. Detection range

0.2-75ng/mL

4. Linear range

0.2-75ng/mL, R≥0.990

5. Precision

Intra-lot precision

Within-run precision has been determined by using 10 replicates of 2 specimens containing 5ng/mL and 40ng/mL of Creatine Kinase MB. C.V. is ≤15%.

Inter-lot precision

Between-run precision has been determined by using 10 replicates for each of three lots using 2 specimens containing 5ng/mL and 40ng/mL of Creatine Kinase MB. C.V. is ≤15%.

6. Cross-reactivity

The CK-MB Test Cassette (Whole Blood/Serum/Plasma) has been tested by 3,200ng/mL CK-MM, 1,700ng/mL CK-BB, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, syphilis, anti-HIV, anti-*H.pylori*, MONO, anti-CMV, anti-Rubella and anti-Toxoplasmosis positive specimens. The results showed no cross-reactivity.

7. Interfering Substances

The following potentially interfering substances were added to 2 specimens containing 5ng/mL and 40ng/mL of Creatine Kinase MB

Acetaminophen: 20 mg/dL	Caffeine: 20 mg/dL
Acetylsalicylic Acid: 20 mg/dL	Gentisic Acid: 20 mg/dL
Ascorbic Acid: 20mg/dL	Albumin: 10,500mg/dL
Creatin: 200 mg/dL	Hemoglobin: 1,000 mg/dL
Bilirubin: 1,000mg/dL	Oxalic Acid: 600mg/dL
Cholesterol: 800mg/dL	Triglycerides: 1,600mg/dL

None of the substances at the concentration tested interfered in the assay.

8. Method comparison

The CK-MB Test Cassette was compared with the results obtained with Leadman for 116 samples. The correlation coefficient (r) is R=0.989.

【LITERATURE REFERENCES】

1. Apple FS, Preese LM. Creatine kinase-MB: detection of myocardial infarction and monitoring reperfusion. J Clin Immunoassay, 17:24-9, 1994.
2. Lee, T.H., Goldman, L. Serum enzyme assays in the diagnosis of acute myocardial infarction. Ann Intern Med, 105:221-233, 1986.
3. Kallner A,Sylven C,Brodin.U,etal.Early diagnosis of acute myocardial infarction;a comparison between chemical predictors. Scand J Clin Lab Invest, 49:633-9, 1989.

Index of Symbols

	Consult instructions for use or consult electronic instructions for use		Contains sufficient for <n> tests	4°C 30°C	Temperature limit
IVD	*In vitro* diagnostic medical device	LOT	Batch code	REF	Catalogue number
EC REP	Authorized representative in the European Community		Use-by date		Do not re-use
	Do not use if package is damaged and consult instructions for use		Manufacturer		

Hangzhou AllTest Biotech Co.,Ltd.
#550,Yinhai Street
Hangzhou Economic & Technological Development Area
Hangzhou, 310018 P.R. China
Web: www.alltests.com.cn Email: info@alltests.com.cn

EC REP
MedNet EC-REP GmbH
Borkstrasse 10,
48163 Muenster,
Germany

Number: F145360300
Revision date: 2024-11-21

Myoglobin Test Cassette (Whole Blood/Serum/Plasma) Package Insert

REF FI-MYO-402	English

A Fluorescence Immunoassay for the quantitative detection of Myoglobin in human whole blood, serum or plasma with the use of the Fluorescence Immunoassay Analyzer. For professional in vitro diagnostic use only.

【INTENDED USE】

The Myoglobin Test Cassette (Whole Blood/Serum/Plasma) is intended for *in vitro* quantitative determination of Myoglobin in human whole blood, serum or plasma as an aid in the diagnosis of Myocardial Infarction (MI).

【SUMMARY】

Myoglobin (MYO) is a heme-protein normally found in skeletal and cardiac muscle with a molecular weight of 17.8 kDa. It constitutes about 2 percent of total muscle protein and is responsible for transporting oxygen within the muscle cells.[1] When the muscle cells are damaged, Myoglobin is released to the blood rapidly due to its relatively small size. Following the death of tissue associated with MI, Myoglobin is one of the first markers to rise above normal levels. The level of Myoglobin increases measurably above baseline within 2-4 hours post-infarct, peaking at 9-12 hours and returning to baseline within 24-36 hours.[2,3] A number of reports suggest the measurement of Myoglobin as a diagnostic aid in confirming the absence of myocardial infarction with negative predictive values of up to 100% reported at certain time periods after onset of symptoms.[4]

【PRINCIPLE】

The Myoglobin Test Cassette (Whole Blood/Serum/Plasma) detects Myoglobin based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. If the specimen contains Myoglobin, it attaches to the fluorescent microspheres-conjugated anti-Myoglobin antibodies. Then the complex will be captured by the capture antibodies coated on the nitrocellulose membrane (Test line). The concentration of Myoglobin in the sample correlates with the fluorescence signal intensity captured on the T line. According to the fluorescence intensity of the test and the standard curve, the concentration of Myoglobin in the sample can be calculated by the analyzer to show Myoglobin concentration in specimen.

【REAGENTS】

The test includes anti-Myoglobin antibody coated fluorophores and anti-Myoglobin antibody coated on the membrane.

【PRECAUTIONS】

1. For professional *in vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse.
3. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
4. Do not eat, drink or smoke in the area where the specimens and tests are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. Do not interchange or mix reagents from different lots.
6. Humidity and temperature can adversely affect results.
7. Used testing materials should be discarded in accordance with local regulations.
8. Read the entire procedure carefully prior to any testing.
9. The Myoglobin Test Cassette should only be used with the analyzer by medical professionals.

【STORAGE AND STABILITY】

1. The kit should be stored at 4-30 °C until the expiry date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.
3. **Do not freeze.**
4. Care should be taken to protect the components of the kit from contamination.
5. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

【SPECIMEN COLLECTION AND PREPARATION】

1. Collect the specimen according to standard procedures.
2. Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
3. Do not leave specimens at room temperature for prolonged periods. Serum/Plasma specimens may be stored at 2-8 °C for up to 3 days, for long term storage, specimens should be kept below -20 °C. Whole blood collected by venipuncture should be stored at 2-8 °C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by finger stick should be tested immediately.
4. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
5. EDTA K2, Heparin sodium, Citrate sodium and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.

【MATERIALS】

Materials Provided

• Test Cassettes	• Specimen Collection Tubes with Buffer
• ID Card	• Package Insert
• Capillary Droppers	• Disposable Droppers

Materials Maybe Provided when Requested

• Sterile Lancets	• Alcohol Pads

Materials Required But Not Provided

• Timer • Centrifuge • Fluorescence Immunoassay Analyzer
• Pipette • Specimen Collection Containers

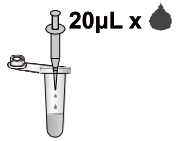
【DIRECTIONS FOR USE】

Refer to Fluorescence Immunoassay Analyzer User Manual for the complete instructions for the use of the analyzer.

Allow the test, specimen and buffer to reach room temperature (15-30 °C) prior to testing.

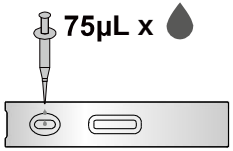
1. Turn on the Analyzer power.
2. Import the test information into the analyzer with the ID Card provided in the kit. Choose test mode and/or sample type according to needs.
3. Remove the test cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
4. Place the test on a flat and clean surface.

For Venous whole blood/Serum/Plasma specimen:



Pipette **20μL of whole blood/serum/ plasma** into the buffer tube.

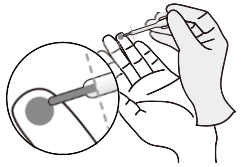
Mix the specimen and the buffer well.



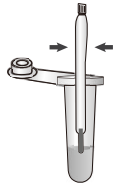
Pipette **75 μL of diluted specimen** into the sample well of the test cassette and start the timer.

For Fingerstick whole blood specimen:

- Wash the hand with soap and warm water or clean with an alcohol pad. Allow to dry.
- Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
- Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
- Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Collect the fingerstick whole blood specimen as following:

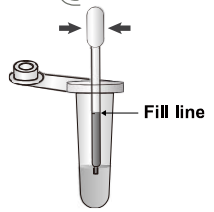


Without squeezing the **capillary dropper**, put the open end in contact with the blood. The blood will migrate into the capillary tube automatically.
Note: Make sure the dropper is **level** and do not squeeze the dropper bulb.

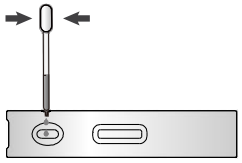


Dispense collected specimen into the buffer tube. Mix specimen and buffer **2-3 times** by squeezing the bulb.

Mix the specimen and the buffer well.



Squeeze the bulb of the **disposable dropper and slowly release**; draw the diluted solution to the **fill line (Approx. 75μL)**.



Squeeze the bulb vertically to release **diluted solution** into the specimen well of the test cassette and start the timer.

5. Test results should be interpreted at **15 minutes** with the use of Fluorescence Immunoassay Analyzer.

Caution: Operator must consult the Fluorescence Immunoassay Analyzer User Manual prior to use and become familiar with the processes and quality control procedures.

【INTERPRETATION OF RESULTS】

Results read by the Fluorescence Immunoassay Analyzer.

The result of tests for Myoglobin is calculated by Fluorescence Immunoassay Analyzer and display the result on the screen. For additional information, please refer to the user manual of Fluorescence Immunoassay Analyzer.

Linearity range of Myoglobin Test is 5~200 ng/mL.

【QUALITY CONTROL】

Each Myoglobin Test Cassette contains internal control that satisfies routine quality control requirements. This internal control is performed each time a sample is tested. This control indicates that the test cassette was inserted and read properly by Fluorescence Immunoassay Analyzer. An invalid result from the internal control causes an error message on Fluorescence Immunoassay Analyzer indicating that the test should be repeated. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【LIMITATIONS】

1. The Myoglobin Test Cassette (Whole Blood/Serum/Plasma) is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of Myoglobin.
2. The Myoglobin Test Cassette (Whole Blood/Serum/Plasma) will only indicate the presence of Myoglobin in the specimen and should not be used as the sole criterion for evaluating AMI.
3. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
4. High concentrations of Myoglobin may produce a dose hook effect, resulting in incorrect interpretation of Myoglobin levels. High dose hook effect has not been observed with this test up to 200 ng/mL of Myoglobin.
5. The hematocrit level of the whole blood should be between 25% and 65%.
6. The results of Myoglobin Test Cassette are based on measuring the levels of Myoglobin in a specimen. It should not be used as the sole criterion for treatment decisions. If the result is positive, other clinical findings and alternative test methods are recommended to reach proper medical treatments.

【EXPECTED VALUES】

Concentrations	Clinical Reference
<90 ng/mL	Not indicative of Acute Myocardial Infarction
>90 ng/mL	Indicative of Acute Myocardial Infarction

【PERFORMANCE CHARACTERISTICS】

1. Accuracy

The test deviation is ≤±15%.

2. Sensitivity

The Myoglobin Test Cassette (Whole Blood/Serum/Plasma) can detect levels of Myoglobin as low as 5 ng/mL in whole blood, serum or plasma.

3. Detection range

5~200 ng/mL

4. Linearity range
5~200 ng/mL, R≥0.990
5. Precision
Intra-lot precision
Within-run precision has been determined by using 10 replicates of 2 specimens containing 50ng/mL and 100ng/mL of Myoglobin. C.V. is ≤ 15%.
Inter-lot precision
Between-run precision has been determined by using 2 specimens containing 50ng/mL and 100ng/mL of Myoglobin. C.V. is ≤ 15%.
6. Cross-reactivity
Cross-reactivity studies were carried out with following analytes:
HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, syphilis, anti-HIV, anti-*H.pylori*, MONO, anti-CMV, anti-Rubella and anti-Toxoplasmosis positive specimens. The results showed no cross-reactivity.
7. Interfering Substances
The following potentially interfering substances were added to 2 specimens containing 50ng/mL and 100ng/mL of Myoglobin.

Acetaminophen: 20 mg/dL	Caffeine: 20 mg/dL
Acetylsalicylic Acid: 20 mg/dL	Gentisic Acid: 20 mg/dL
Ascorbic Acid: 20mg/dL	Albumin: 10,500mg/dL
Creatin: 200 mg/dL	Hemoglobin: 1,000 mg/dL
Bilirubin: 1,000mg/dL	Oxalic Acid: 600mg/dL
Cholesterol: 800mg/dL	Triglycerides: 1,600mg/dL

None of the substances at the concentration tested interfered in the assay.
8. Method comparison
The Myoglobin Test Cassette was compared with the results obtained with Cobas for 112 samples. The correlation coefficient(R) is 0.990.
【BIBLIOGRAPHY】

1. Wong SS. Strategic utilization of cardiac markers for diagnosis of acute myocardial infarction. Ann Clin Lab Sci, 26:301-12, 1996.
2. Kagen LJ.Myoglobin methods and diagnostic uses.CRC Crit.Rev. Clin.Lab.Sci., 2:273,1978.
3. Chapelle JP.et al.Serum Myoglobin determinations in the assessment of acute myocardial infarction. Eur. Heart Journal, 3:122, 1982.
4. Hamfelt A. et al.Use of biochemical tests for myocardial infarction in the county of Vasternorrland, a clinical chemistry routine for the diagnosis of myocardial infarction. Scand. J. Clin. Lab. Invest. Suppl., 200:20, 1990.

Index of Symbols

	Consult instructions for use or consult electronic instructions for use		Contains sufficient for <n> tests		Temperature limit
IVD	*In vitro* diagnostic medical device	LOT	Batch code	REF	Catalogue number
EC REP	Authorized representative in the European Community		Use-by date		Do not re-use
	Do not use if package is damaged and consult instructions for use		Manufacturer		

Hangzhou AllTest Biotech Co., Ltd.
#550, Yinhai Street,
Hangzhou Economic & Technological Development Area
Hangzhou, 310018 P.R. China
Web:www.alltests.com.cn Email:info@alltests.com.cn

EC REP
MedNet EC-REP GmbH
Borkstrasse 10
48163 Muenster
Germany

NT-proBNP Test Cassette (Whole Blood/Serum/Plasma) Package Insert

REF FI-NBNP-402	English

A Fluorescence Immunoassay for the quantitative detection of NT-proBNP quantitatively in human whole blood, serum or plasma with the use of the Fluorescence Immunoassay Analyzer.

For professional in vitro diagnostic use only.

【INTENDED USE】

The NT-proBNP Test Cassette (Whole Blood/Serum/Plasma) is intended for the *in vitro* quantitative detection of human NT-proBNP in human whole blood, serum or plasma as an aid in the diagnosis of heart failure (HF).

【SUMMARY】

The N-terminal of the prohormone brain natriuretic peptide (NT-proBNP) is a 76 amino acid N-terminal inactive protein that is cleaved from proBNP to release brain natriuretic peptide. Both BNP and NT-proBNP levels in the blood are used for screening, diagnosis of acute congestive heart failure (CHF) and may be useful to establish prognosis in heart failure, as both markers are typically higher in patients with worse outcome.[1] The plasma concentrations of both BNP and NT-proBNP are also typically increased in patients with asymptomatic or symptomatic left ventricular dysfunction and is associated with coronary artery disease and myocardial ischemia.[2.3.]

The NT-proBNP Test Cassette (Whole Blood/Serum/Plasma) is a test that utilizes a combination of anti-NT-proBNP antibody coated particles and capture reagents to quantitatively detect NT-proBNP in whole blood, serum or plasma. The minimum detection level is 300 pg/mL.

【PRINCIPLE】

The NT-proBNP Test Cassette (Whole Blood/Serum/Plasma) is a based on Fluorescence Immunoassay for the quantitative detection of NT-proBNP in whole blood, serum or plasma. The sample moves through the strip from sample pad to absorbent pad. If the specimen contains NT-proBNP, it attaches to the fluorescent microspheres-conjugated anti- NT-proBNP antibodies. Then the complex will be captured by the capture antibodies coated on the nitrocellulose membrane (Test line). The concentration of NT-proBNP in the sample correlates linearly with the fluorescence signal intensity captured on the T line. According to the fluorescence intensity of the test and standard curve, the concentration of NT-proBNP in the sample can be calculated by the analyzer to show NT-proBNP concentration in specimen.

【REAGENTS】

The test contains anti-NT-proBNP antibody conjugated fluorophores and capture reagents coated on the membrane.

【PRECAUTIONS】

1. For professional *in vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse.
3. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
4. Do not eat, drink or smoke in the area where the specimens and tests are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. Do not interchange or mix reagents from different lots.
6. Humidity and temperature can adversely affect results.
7. Used testing materials should be discarded in accordance with local regulations.
8. Read the entire procedure carefully prior to any testing.
9. The NT-proBNP Test Cassette should only be used with the analyzer by medical professionals.

【STORAGE AND STABILITY】

1. The kit should be stored at 4-30 °C until the expiry date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.
3. **Do not freeze.**
4. Care should be taken to protect the components of the kit from contamination.
5. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

【SPECIMEN COLLECTION AND PREPARATION】

Sample Handling

·Collect the specimen according to standard procedures.

·To collect **Fingerstick Whole blood specimens**:

- ·Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
- ·Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
- ·Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
- ·Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- ·Add the Fingerstick Whole blood specimen to the tube with buffer by using pipette.

·Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.

·Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8 °C for up to 2 days. For long term storage, specimens should be kept below -20 °C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.

·Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.

·If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

Sample Dilution/Sample Stability

1. The specimen **(50μL of whole blood/serum/plasma)** can be added directly with the micro pipette into the tube with buffer.
2. Close the tube and shake the sample by hand vigorously for approximately **10 seconds** to mix the sample and dilution buffer.
3. Let the diluted sample homogenize for approximately **1 minute**.

It is best to place the diluted sample on an ice pack and leave the sample at room temperature for no more than 8 hours.

【MATERIALS】

Materials Provided

- Test Cassettes
- Specimen Collection Tubes with Extraction Buffer
- ID Card
- Package Insert

Materials Required But Not Provided

- Timer
- Centrifuge
- Fluorescence Immunoassay Analyzer
- Pipette
- Specimen Collection Containers

【DIRECTIONS FOR USE】

Refer to Fluorescence Immunoassay Analyzer User Manual for the complete instructions for the use of the analyzer.

Allow the test, specimen and buffer to reach room temperature (15-30 °C) prior to testing.

1. Turn on the Analyzer power.
2. Take out the ID card and insert it into the ID Card Slot. Choose test mode and/or sample type according to needs.
3. Remove the test cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
4. Place the test on a flat and clean surface.

Pipette **50μL of whole blood/serum/plasma** into the buffer tube; mix the specimen and the buffer well.

5. **Add diluted specimen with a Pipette:** Pipette **85μL of diluted specimen** into the sample well of the test cassette. Start the timer at the same time.
6. Test results should be interpreted at **15 minutes** with the use of Fluorescence Immunoassay Analyzer.

Caution: Operator must consult the Fluorescence Immunoassay Analyzer User Manual prior to use and become familiar with the processes and quality control procedures.

【INTERPRETATION OF RESULTS】

Results read by the Fluorescence Immunoassay Analyzer.

The result of NT-proBNP Test is calculated by analyzer and is displayed on the screen. For additional information, please refer to the user manual of Fluorescence Immunoassay Analyzer.

Linearity range of NT-proBNP Test is 300-22000 pg/mL.

【QUALITY CONTROL】

Each NT-proBNP Test Cassette contains internal control that satisfies routine quality control requirements. This internal control is performed each time a sample is tested. This control indicates that the test cassette was inserted and read properly by the analyzer. An invalid result from the internal control causes an error message on the analyzer indicating that the test should be repeated. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor

【LIMITATIONS】

1. The NT-proBNP Test Cassette (Whole Blood/Serum/Plasma) is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of NT-proBNP.
2. The NT-proBNP Test Cassette (Whole Blood/Serum/Plasma) will only indicate the presence of NT-proBNP in the specimen and should not be used as the sole criterion for evaluating heart failure.
3. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
4. High concentrations of NT-proBNP may produce a dose hook effect, resulting in incorrect interpretation of NT-proBNP levels. High dose hook effect has not been observed with this test up to 22000 pg/mL of NT-proBNP.
5. The hematocrit level of the whole blood should be between 25% and 65%.

【EXPECTED VALUES】

Result interpretation in patients presenting acute dyspnea

Age	< 50 years	50-75 years	> 75 years	Acute HF diagnosis
NT-proBNP (pg/mL)	≥450	≥900	≥1800	Acute HF likely
	300-450	300-900	300-1800	Acute HF less likely
	< 300	< 300	< 300	Acute HF unlikely

【PERFORMANCE CHARACTERISTICS】

1. Accuracy

The test deviation is ≤±15%.

2. Sensitivity

The NT-proBNP Test Cassette (Whole Blood/Serum/Plasma) can detect levels of NT-proBNP as low as 300 pg/mL in whole blood, serum or plasma.

3. Detection range

300~22000 pg/mL

4. Linearity range

300~22000 pg/mL, R≥0.990

5. Precision

Intra-lot precision

Within-run precision has been determined by using 10 replicates of 2 specimens of NT-proBNP. C.V. is ≤ 15%.

Inter-lot precision

Between-run precision has been determined by using 10 replicates for each of three lots using 2 specimens of NT-proBNP. C.V. is ≤ 15%.

6. Cross-reactivity

The NT-proBNP Test Cassette (Whole Blood/Serum/Plasma) has been tested by HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, syphilis, anti-HIV, anti-*H.pylori*, MONO, anti-CMV, anti-Rubella and anti-Toxoplasmosis positive specimens. The results showed no cross-reactivity.

7. Interfering Substances

The following potentially interfering substances were added to 2 specimens of NT-proBNP, respectively.

Acetaminophen: 20 mg/dL	Caffeine: 20 mg/dL
Acetylsalicylic Acid: 20 mg/dL	Gentisic Acid: 20 mg/dL
Ascorbic Acid: 20mg/dL	Albumin: 10,500mg/dL
Creatin: 200 mg/dL	Hemoglobin: 1,000 mg/dL
Bilirubin: 1,000mg/dL	Oxalic Acid: 600mg/dL
Cholesterol: 800mg/dL	Triglycerides: 1,600mg/dL

None of the substances at the concentration tested interfered in the assay.

8. Method comparison

The product was evaluated with 107 clinical samples compared with commercial FIA test kit. The correlation coefficient(r) is 0.990.

【BIBLIOGRAPHY】

1. Bhalla V, Willis S, Maisel AS (2004). "B-type natriuretic peptide: the level and the drug--partners in the diagnosis of congestive heart failure". Congest Heart Fail 10 (1 Suppl 1): 3–27.
2. Atisha D, Bhalla MA, Morrison LK, Felicio L, Clopton P, Gardetto N, Kazanegra R, Chiu A, Maisel AS (September 2004). "A prospective study in search of an optimal B-natriuretic peptide level to screen patients for cardiac dysfunction". Am. Heart J. 148 (3): 518–23.
3. Nakamura T, Sakamoto K, Yamano T, Kikkawa M, Zen K, Hikosaka T, Kubota T, Azuma A, Nishimura T (May 2002). "Increased plasma brain natriuretic peptide level as a guide for silent myocardial ischemia in patients with non-obstructive hypertrophic cardiomyopathy". J. Am. Coll. Cardiol. 39 (10): 1657–63.

Index of Symbols

	Consult instructions for use or consult electronic instructions for use	Σ	Contains sufficient for <n> tests	30°C 4°C	Temperature limit
IVD	*In vitro* diagnostic medical device	LOT	Batch code	REF	Catalogue number
EC REP	Authorized representative in the European Community		Use-by date		Do not re-use
	Do not use if package is damaged and consult instructions for use		Manufacturer		

Hangzhou AllTest Biotech Co., Ltd.
#550, Yinhai Street,
Hangzhou Economic & Technological Development Area
Hangzhou, 310018 P.R. China
Web:www.alltests.com.cn Email:info@alltests.com.cn

EC REP
MedNet EC-REP GmbH
Borkstrasse 10
48163 Muenster
Germany

Number: F145360801
Revision date: 2025-05-30

High-Sensitivity NT-proBNP Test Cassette (Whole Blood/Serum/Plasma) Package Insert

REF FI-SNBNP-402	English

A Fluorescence Immunoassay for the quantitative detection of NT-proBNP in human whole blood, serum or plasma with the use of the Fluorescence Immunoassay Analyzer.

For professional in vitro diagnostic use only.

【INTENDED USE】

The High-Sensitivity NT-proBNP Test Cassette (Whole Blood/Serum/Plasma) is intended for the *in vitro* quantitative detection of human NT-proBNP in human whole blood, serum or plasma, as an aid in the diagnosis of heart failure.

【SUMMARY】

The N-terminal of the prohormone brain natriuretic peptide (NT-proBNP) is a 76 amino acid N-terminal inactive protein that is cleaved from proBNP to release brain natriuretic peptide. Both BNP and NT-proBNP levels in the blood are used for screening, diagnosis of acute congestive heart failure (CHF) and may be useful to establish prognosis in heart failure, as both markers are typically higher in patients with worse outcome.[1] The plasma concentrations of both BNP and NT-proBNP are also typically increased in patients with asymptomatic or symptomatic left ventricular dysfunction and is associated with coronary artery disease and myocardial ischemia.[2,3]

The High-Sensitivity NT-proBNP Test Cassette (Whole Blood/Serum/Plasma) is a test that utilizes a combination of anti-NT-proBNP antibody coated particles and capture reagents to quantitatively detect NT-proBNP in whole blood, serum or plasma. The minimum detection level is 30 pg/mL.

【PRINCIPLE】

The High-Sensitivity NT-proBNP Test Cassette (Whole Blood/Serum/Plasma) is a test based on Fluorescence Immunoassay for the quantitative detection of NT-proBNP in whole blood, serum or plasma. The sample moves through the strip from sample pad to absorbent pad. If the specimen contains NT-proBNP, it attaches to the fluorescent microspheres-conjugated anti-NT-proBNP antibodies. Then the complex will be captured by the capture antibodies coated on the nitrocellulose membrane (Test line). The concentration of NT-proBNP in the sample correlates linearly with the fluorescence signal intensity captured on the T line. According to the fluorescence intensity of the test and standard curve, the concentration of NT-proBNP in the sample can be calculated by the analyzer to show NT-proBNP concentration in specimen.

【REAGENTS】

The test contains anti-NT-proBNP antibody conjugated fluorophores and capture reagents coated on the membrane.

【PRECAUTIONS】

1. For professional *in vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse.
3. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
4. Do not eat, drink or smoke in the area where the specimens and tests are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. Do not interchange or mix reagents from different lots.
6. Humidity and temperature can adversely affect results.
7. Used testing materials should be discarded in accordance with local regulations.
8. Read the entire procedure carefully prior to any testing.
9. The High-Sensitivity NT-proBNP Test Cassette should only be used with the analyzer by medical professionals.

【STORAGE AND STABILITY】

1. The test should be stored at 4-30 °C until the expiry date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.
3. **Do not freeze.**
4. Care should be taken to protect the components of the kit from contamination.
5. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

【SPECIMEN COLLECTION AND PREPARATION】

·Collect the specimens according to standard procedures.

·Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.

·Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8 °C for up to 2 days. For long term storage, specimens should be kept below -20 °C. Whole blood collected by venipuncture should be stored at 2-8 °C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.

·Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.

·If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

·EDTA, Heparin sodium, can be used as the anticoagulant tube for collecting the blood specimen. A clean tube without anticoagulants can be used to collect serum specimens.

【MATERIALS】

Materials Provided

- Test Cassettes
- Specimen Collection Tubes with Buffer
- ID Card
- Package Insert
- Capillary Droppers
- Disposable Droppers

Materials Maybe Provided when Requested

- Sterile Lancets
- Alcohol Pads

Materials Required But Not Provided

- Timer
- Centrifuge
- Fluorescence Immunoassay Analyzer
- Pipettes
- Specimen Collection Containers

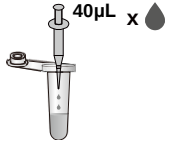
【DIRECTIONS FOR USE】

Refer to the Fluorescence Immunoassay Analyzer User Manual for the complete instructions for the use of the analyzer.

Allow the test, specimen and buffer to reach room temperature (15-30 °C) prior to testing.

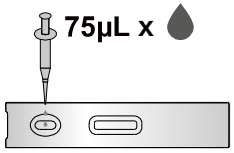
1. Turn on the Analyzer power.
2. Import the test information into the analyzer with the ID Card provided in the kit. Choose test mode and/or sample type according to needs.
3. Remove the test cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
4. Add sample:

For Venous whole blood/Serum/Plasma specimen:



Pipette **40μL of whole blood/serum/ plasma** into the buffer tube.

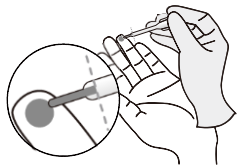
Mix the specimen and the buffer well.



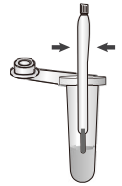
Pipette **75 μL of diluted specimen** into the sample well of the test cassette.

For Fingerstick whole blood specimen:

- Wash the hand with soap and warm water or clean with an alcohol pad. Allow to dry.
- Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
- Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
- Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Collect the fingerstick whole blood specimen as following:

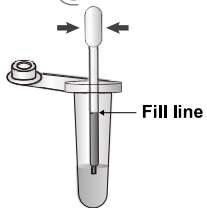


Without squeezing the **capillary dropper**, put the open end in contact with the blood. The blood will migrate into the capillary tube automatically.
Note: Make sure the dropper is **level** and do not squeeze the dropper bulb.

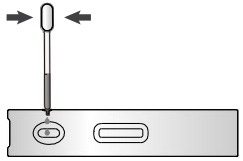


Dispense collected specimen into the buffer tube. Mix specimen and buffer **2-3 times** by squeezing the bulb.

Mix the specimen and the buffer well.



Squeeze the bulb of the **disposable dropper and slowly release**; draw the diluted solution to the **fill line (Approx. 75μL)**.



Squeeze the bulb vertically to release **diluted solution** into the specimen well of the test cassette.

5. Test results should be interpreted at **15 minutes** with the use of the Fluorescence Immunoassay Analyzer.

Caution: Operator must consult the Fluorescence Immunoassay Analyzer User Manual prior to use and become familiar with the processes and quality control procedures.

【INTERPRETATION OF RESULTS】

Results read by the Fluorescence Immunoassay Analyzer.

The result of test for NT-proBNP is calculated by the analyzer and is displayed on the screen. For additional information, please refer to the user manual of the Fluorescence Immunoassay Analyzer.

Linearity range of High-Sensitivity NT-proBNP Test is 30-30000 pg/mL.

【QUALITY CONTROL】

Each High-Sensitivity NT-proBNP Test Cassette contains internal control that satisfies routine quality control requirements. This internal control is performed each time a sample is tested. This control indicates that the test cassette was inserted and read properly by the analyzer. An invalid result from the internal control causes an error message on the analyzer indicating that the test should be repeated. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor

【LIMITATIONS】

1. The High-Sensitivity NT-proBNP Test Cassette (Whole Blood/Serum/Plasma) is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of NT-proBNP, and should not be used as the sole criterion for evaluating heart failure.
2. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
3. High concentrations of NT-proBNP may produce a dose hook effect, resulting in incorrect interpretation of NT-proBNP levels. High dose hook effect has not been observed with this test up to 30000 pg/mL of NT-proBNP.
4. The hematocrit level of the whole blood should be between 25% and 65%.

【EXPECTED VALUES】

NT-proBNP Reference interval

Age	≤44 years	45-54 years	55-64 years	65-74 years	≥75 years
NT-proBNP (pg/mL)	≤98	≤125	≤198	≤290	≤530

Result interpretation in patients presenting acute dyspnea

Age	< 50 years	50-75 years	> 75 years	Acute HF diagnosis
NT-proBNP (pg/mL)	≥450	≥900	≥1800	Acute HF likely
	300-450	300-900	300-1800	Acute HF less likely
	< 300	< 300	< 300	Acute HF unlikely

【PERFORMANCE CHARACTERISTICS】

1. Accuracy

The test deviation is ≤±15%.

2. Sensitivity

The High-Sensitivity NT-proBNP Test Cassette (Whole Blood/Serum/Plasma) can detect levels of NT-proBNP as low as 30 pg/mL in whole blood, serum or plasma.

3. Detection range

30-30000 pg/mL

4. Linearity range

30-30000 pg/mL, R≥0.990

5. Precision

Intra-lot precision

Within-run precision has been determined by using 10 replicates of 2 specimens of NT-proBNP. C.V. is ≤ 15%.

Inter-lot precision

Between-run precision has been determined by using 10 replicates for each of three lots using 2 specimens of NT-proBNP. C.V. is ≤ 15%.

6. Cross-reactivity

The High-Sensitivity NT-proBNP Test Cassette (Whole Blood/Serum/Plasma) has been tested by HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, syphilis, anti-HIV, anti-*H.pylori*, MONO, anti-CMV, anti-Rubella and anti-Toxoplasmosis positive specimens. The results showed no cross-reactivity.

7. Interfering Substances

The following potentially interfering substances were added to 2 specimens of NT-proBNP, respectively.

Acetaminophen: 20 mg/dL	Caffeine: 20 mg/dL
Acetylsalicylic Acid: 20 mg/dL	Gentisic Acid: 20 mg/dL
Ascorbic Acid: 20mg/dL	Albumin: 10,500 mg/dL
Creatin: 200 mg/dL	Hemoglobin: 1,000 mg/dL
Bilirubin: 1,000 mg/dL	Oxalic Acid: 600 mg/dL
Cholesterol: 800 mg/dL	Triglycerides: 1,600 mg/dL

None of the substances at the concentration tested interfered in the assay.

8. Method comparison

The product was evaluated with 126 clinical samples compared with commercial CLIA test kit. The correlation coefficient(r) is 0.9882.

【BIBLIOGRAPHY】

1. Bhalla V, Willis S, Maisel AS (2004). "B-type natriuretic peptide: the level and the drug--partners in the diagnosis of congestive heart failure". Congest Heart Fail 10 (1 Suppl 1): 3–27.
2. Atisha D, Bhalla MA, Morrison LK, Felicio L, Clopton P, Gardetto N, Kazanegra R, Chiu A, Maisel AS (September 2004). "A prospective study in search of an optimal B-natriuretic peptide level to screen patients for cardiac dysfunction". Am. Heart J. 148 (3): 518–23.
3. Nakamura T, Sakamoto K, Yamano T, Kikkawa M, Zen K, Hikosaka T, Kubota T, Azuma A, Nishimura T (May 2002). "Increased plasma brain natriuretic peptide level as a guide for silent myocardial ischemia in patients with non-obstructive hypertrophic cardiomyopathy". J. Am. Coll. Cardiol. 39 (10): 1657–63.

Index of Symbols

	Consult instructions for use or consult electronic instructions for use	Σ	Contains sufficient for <n> tests	4°C 30°C	Temperature limit
IVD	*In vitro* diagnostic medical device	LOT	Batch code	REF	Catalogue number
EU REP	European Authorized Representative		Use-by date		Do not re-use
	Do not use if package is damaged and consult instructions for use		Manufacturer		

Hangzhou AllTest Biotech Co.,Ltd.
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EU REP
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Barcelona Province, 08036, Spain
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Number: F145494501
Revision date: 2025-05-27

Digitally signed by Varman Irina
Date: 2025.06.10 15:57:53 EEST
Reason: MoldSign Signature
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