



Cardiac Troponin I Fast Test Kit

User Manual

Cat.# CG1001

INTENDED USE

Cardiac Troponin I Fast Test Kit is intended for *in vitro* quantitative determination of cardiac Troponin I (cTnI) in serum, plasma or whole blood. This test is used as an aid in the diagnosis of myocardial injury such as Acute Myocardial Infarction (AMI), Unstable Angina, Acute Myocarditis and Acute Coronary Syndrome (ACS).

SUMMARY

Troponin, a molecular complex that is bound to the thin filament (actin) of striated muscle fibers, acts with intracellular calcium to control the interaction of the thin filament with the thick filament (myosin), thus regulating muscle contraction. Troponin consists of three subunits: T, which connects the troponin complex and tropomyosin (another cardiac muscle regulatory protein); I, which prevents muscle contraction in the absence of calcium; and C, which binds calcium. Cardiac Troponin I (MW 22.5 kDa) and the two skeletal muscle isoforms of Troponin I have considerable amino acid sequence homology, but cTnI contains an additional N-terminal sequence and is highly specific for myocardium.

Clinical studies have demonstrated the release of cTnI into the blood stream within hours following acute myocardial infarctions (AMI) or ischemic damage. Elevated levels of cTnI are detectable in blood within 4 to 6 hours after the onset of chest pain, reaching peak concentrations in approximately 8 to 28 hours, and remain elevated for 3 to 10 days following AMI. Due to the high myocardial specificity and the long duration of elevation, cTnI has become an important marker in the diagnosis and evaluation of patients suspected of having an AMI.

The current guideline of The Joint European Society of

Cardiology/American College of Cardiology Committee support the use of cTnI as a preferred marker of myocardial injury. Several major studies have shown that cTnI is also a predictor of cardiac risk in patients with unstable angina. The American College of Cardiology and the American Heart Association's current guidelines recommend using troponin results when making treatment decisions regarding unstable angina and non-ST segment elevation MI (NSTEMI).

PRINCIPLE

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

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

CONTENTS

A kit contains:

1. Getein cTnI test card in a sealed pouch with desiccant 25
2. Disposable pipet 25
3. User manual 1
4. SD card 1
5. Whole blood buffer 1

A test card consists of:

A plastic shell and a reagent strip which is composed of a sample pad, a colloidal gold pad (coated with gold-labelled anti-human cTnI monoclonal antibody), nitrocellulose membrane (the test line is coated with anti-human cTnI monoclonal antibody, and the control line is coated with rabbit

anti-mouse IgG antibody), absorbent paper and liner.

Whole blood buffer composition:

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

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

APPLICABLE DEVICE

FIA8000 Quantitative Immunoassay Analyzer

STORAGE AND STABILITY

Store the test card at 4-30°C with a valid period of 24 months. Use the test card within 1 hour once the foil pouch is opened. Store the whole blood buffer at 0-30°C with a valid period of 24 months.

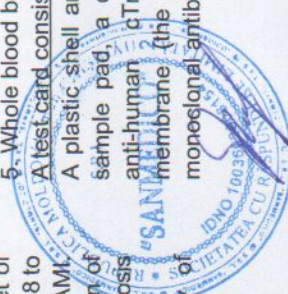
Store the whole blood buffer at 2-8°C for better results.

PRECAUTIONS

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

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for serum, plasma and whole blood samples. Heparin and sodium citrate can be used as the anticoagulant for plasma and whole blood. Samples should be free of hemolysis.
2. Suggest using serum or plasma for better results.
3. Serum or plasma can be used directly. For whole blood sample, one drop of whole blood buffer must be added before testing.
4. If testing will be delayed, serum and plasma samples may be stored up to 7 days at 2-8°C or stored at -20°C for 6



- months before testing (whole blood sample may be stored up to 3 days at 2-8°C).
5. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
 6. Do not use heat-inactivated samples.
 7. **SAMPLE VOLUME: 120 µl.**

TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, sample and reagent should be brought to room temperature before testing.
3. Confirm SD card lot No. in accordance with test kit lot No.. Perform "QC (SD)" calibration when necessary (Details refer to 8.2.1 of FIA8000 User Manual).
4. On the main interface of FIA8000, press "ENT" button to enter testing interface.
5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
6. Put the test card on a clean table, horizontally placed.
7. Using sample transfer pipette, deliver 120 µl of sample (or 4 drops of sample when using disposable pipet) into the sample port on the test card (for whole blood sample, one drop of whole blood buffer must be added after loading 120 µl sample on the test card).
8. **Reaction time: 15 minutes.** Insert the test card into FIA8000 and press "ENT" button after reaction time is elapsed. The result will be shown on the screen and printed automatically.

Notes:

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

TEST RESULTS

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

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

EXPECTED VALUE

The expected normal value for cTnI was determined by testing samples from 500 apparently healthy individuals. The 99th percentile of the concentration for cTnI is 0.5 ng/ml. (The probability that value of a normal person below 0.5 ng/ml is 99%.) It is recommended that each laboratory establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range 0.5-50.0 ng/ml
 Lower Detection Limit ≤ 0.5 ng/ml
 Within-Run Precision (n=10) ≤10%
 Between-Run Precision ≤15%
 Recovery 95% (mean)

Method Comparison:

The assay was compared with SIEMENS IMMULITE 2000 and its matching cTnI test kits with 200 serum samples (60 positive samples and 140 negative samples). The correlation coefficient (r) for cTnI is 0.952.

LIMITATIONS

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

Interferent	Hemoglobin	Triglyceride	Bilirubin
Concentration (Max)	5 g/L	10 g/L	0.2 g/L

REFERENCES

1. Mauro Pantaghini; Undefined International Federation of Clinical Chemistry and Laboratory Medicine (IFCC). Scientific Division Committee on Standardization of Markers of Cardiac Damage. Clin Chem Lab Med, 1998, 36:887-893.
2. Antman EM, Anbe DT, Armstrong PW, et al. ACC/AHA guidelines for the management of patients with ST-elevation myocardial infarction: a report of the American College of

Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1999 Guidelines for the Manage 2004).

3. EN ISO 18113-1:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
4. EN ISO 18113-2:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: *In vitro* diagnostic reagents for professional use (ISO 18113-2:2009).

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on Cardiac Troponin I Fast Test Kit are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN 980:2008 and International Standard ISO 15223-1:2007.

Key to symbols used			
	Manufacturer		Expiration date
	Do not reuse		Batch code
	Consult instructions for use		<i>In vitro</i> diagnostic medical device
	Temperature limitation		Authorized representative in the European Community
	Sufficient for		Do not use if package is damaged
	CE mark		

Thank you for purchasing Cardiac Troponin I Fast Test Kit. Please read this user manual carefully before operating to ensure proper use.

Version: WCG02-DL-S-01



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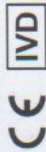
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One Step Test for D-Dimer (Colloidal Gold)

User Manual

Cat.# CG1006

INTENDED USE

One Step Test for D-Dimer (Colloidal Gold) is intended for *in vitro* quantitative determination of D-Dimer in plasma or whole blood. The test is used as an aid in the assessment and evaluation of patients suspected of deep-vein thrombosis or pulmonary embolism.

SUMMARY

Deep-vein thrombosis is a common condition, with a lifetime cumulative incidence of 2 to 5 percent. Untreated deep-vein thrombosis can result in pulmonary embolism, a potentially fatal outcome. Anticoagulant therapy reduces both morbidity and mortality from venous thromboembolism, and early diagnosis is therefore important. Accurate diagnosis of deep-vein thrombosis minimizes the risk of thromboembolic complications and averts the exposure of patients without thrombosis to the risks of anticoagulant therapy.

D-Dimer is a marker of endogenous fibrinolysis and should therefore be detectable in patients with deep-vein thrombosis. In recent years, an increasing number of studies have shown the D-Dimer assay has a high negative predictive value and D-Dimer is a sensitive but nonspecific marker of deep-vein thrombosis. Negative D-Dimer can exclude deep-vein thrombosis and pulmonary embolism.

PRINCIPLE

The test uses an anti-human D-Dimer monoclonal antibody conjugated with colloidal gold and another anti-human D-Dimer monoclonal antibody coated on the test line. After the

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

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

CONTENTS

A kit contains:

1. Getein D-Dimer test card in a sealed pouch with desiccant	25
2. Disposable pipet	25
3. User manual	1
4. SD card	1
5. Sample diluent	25

A test card consists of:

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

Sample diluent composition:

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

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



STORAGE AND STABILITY

Store the test card at 4~30°C with a valid period of 24 months. Use the test card within 1 hour once the foil pouch is opened. Store the sample diluent at 0~30°C with a valid period of 24 months.

Store the sample diluent at 2~8°C for better results.

PRECAUTIONS

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

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for *plasma and whole blood samples*. *Sodium citrate* should be used as the anticoagulant for plasma and whole blood. Samples should be free of hemolysis.
2. Suggest using plasma for better results.
3. If testing will be delayed, plasma sample may be stored up to 3 days at 2~8°C or stored at -20°C for 1 months before testing (whole blood sample may be stored up to 3 days at 2~8°C).
4. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
5. Do not use heat-inactivated samples.
6. SAMPLE VOLUME: 120 µl.

TEST PROCEDURE

1. Collect specimens according to user manual.

2. Test card, sample and reagent should be brought to room temperature before testing.
3. Confirm SD card lot No. in accordance with test kit lot No.. Perform "QC (SD)" calibration when necessary (Details refer to 8.2.1 of FIA8000 User Manual).
4. On the main interface of FIA8000, press "ENT" button to enter testing interface.
5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
6. Put the test card on a clean table, horizontally placed.
7. Using sample transfer pipette, deliver 120 µl of sample into one tube of sample diluent, mix gently and thoroughly. Then drop 120 µl (or 4 drops of sample when using disposable pipet) of sample mixture into the sample port on the test card.
8. **Reaction time: 7 minutes.** Insert the test card into FIA8000 and press "ENT" button after reaction time is elapsed. The result will be shown on the screen and printed automatically.

Notes:

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

TEST RESULTS

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

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

EXPECTED VALUE

The expected normal value for D-Dimer was determined by testing samples from 500 apparently healthy individuals. The 95th percentile of the concentration for D-Dimer is 0.5 mg/L (The probability that value of a normal person below 0.5 mg/L is 95%.)

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

PERFORMANCE CHARACTERISTICS

Measuring Range	0.1~10.0 mg/L
Lower Detection Limit	≤0.1 mg/L
Within-Run Precision (n=10)	≤10%
Between-Run Precision	≤15%
Recovery	99%

Method Comparison:

The assay was compared with SIEMENS CA-7000 and its matching D-Dimer test kits with 200 plasma samples (60 positive samples and 140 negative samples). The correlation coefficient (r) for D-Dimer is 0.978.

LIMITATIONS

1. As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.
2. Samples containing interferents such as rheumatoid factor, human anti-mouse antibody and heterophile antibody may influence the results. In this case, results of this test should be used in conjunction with clinical findings and other tests. The table below listed the maximum allowance of these potential interferents.

Interferent	Hemoglobin	Triglyceride	Bilirubin
Concentration (Max)	5 g/L	25 g/L	0.1 g/L

REFERENCES

1. Sarig G, Kil-Drori AJ, Chap-Marshak D, Brenner B, Drugan A. Activation of coagulation in amniotic fluid during normal human pregnancy. *Thromb Res.* 2011 Apr 18.
2. Roldán V, Marín F, Muñia B, Torregrosa JM, Hernández-Romero D, Valdés M, Vicente V, Lip GY. Plasma von Willebrand Factor Levels Are an Independent Risk Factor for Adverse Events Including Mortality and Major Bleeding in Anticoagulated Atrial Fibrillation Patients. *J Am Coll Cardiol.* 2011 Apr 11.
3. Sakamoto K, Yamamoto Y, Okamoto H, Okabe M. D-dimer is helpful for differentiating acute aortic dissection and acute

- pulmonary embolism from acute myocardial infarction. *Hellenic J Cardiol.* 2011 Mar-Apr; 52(2):123~127.
4. EN ISO 18113-1:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
 5. EN ISO 18113-2:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: *In vitro* diagnostic reagents for professional use (ISO 18113-2:2009).

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on One Step Test for D-Dimer (Colloidal Gold) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN 980:2008 and International Standard ISO 15223-1:2007.

Key to symbols used			
	Manufacturer		Expiration date
	Do not reuse		Date of manufacture
	Consult instructions for use		Batch code
	Temperature limitation		<i>In vitro</i> diagnostic medical device
	Sufficient for		Authorized representative in the European Community
	CE mark		Do not use if package is damaged

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

Version: WCG05-DL-S-01



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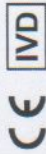
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Cardiac Troponin I

Fast Test Kit

(Immunofluorescence Assay)

User Manual

Getein1100: Cat.# IF1001
Getein1600: Cat.# IF2001

INTENDED USE

Cardiac Troponin I Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of Cardiac Troponin I (cTnI) in serum, plasma or whole blood. This test is used as an aid in the diagnosis of myocardial injury such as Acute Myocardial Infarction (AMI), Unstable Angina, Acute Myocarditis and Acute Coronary Syndrome (ACS).

SUMMARY

Troponin, a molecular complex that is bound to the thin filament (actin) of striated muscle fibers, acts with intracellular calcium to control the interaction of the thin filament with the thick filament (myosin), thus regulating muscle contraction. Troponin consists of three regulatory proteins: T, which connects the troponin complex and tropomyosin (another cardiac muscle regulatory protein); I, which prevents muscle contraction in the absence of calcium; C, which binds calcium. Cardiac Troponin I (MW 22.5 kDa) and the two skeletal muscle isoforms of Troponin I have considerable amino acid sequence homology, but cTnI contains an additional N-terminal sequence and is highly specific for myocardium.

Clinical studies have demonstrated the release of cTnI into the blood stream within hours following acute myocardial infarction (AMI) or ischemic damage. Elevated levels of cTnI are detectable in blood within 4 to 6 hours after the onset of chest pain, reaching peak concentrations in approximately 8 to 28 hours, and remain elevated for 3 to 10 days following AMI. Due to the high myocardial specificity and the long duration of elevation, cTnI has become an important marker in the diagnosis and evaluation of patients suspected of having an AMI.

The current guideline of The Joint European Society of Cardiology/American College of Cardiology Committee support the use of cTnI as a preferred marker of myocardial injury. Several major studies have shown that cTnI is also a predictor of cardiac risk in patients with unstable angina. The American College of Cardiology and the American Heart Association's current

guidelines recommend using troponin results when making treatment decisions regarding unstable angina and non-ST segment elevation MI (NSTEMI).

PRINCIPLE

The test uses an anti-human cTnI monoclonal antibody conjugated with fluorescence latex and another anti-human cTnI monoclonal antibody coated on the test line. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human cTnI monoclonal antibody binds with the cTnI in sample and forms a marked antigen-antibody complex. This complex moves to the test card detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by the anti-human cTnI monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of cTnI in sample.

Then insert test card into Getein1100 Immunofluorescence Quantitative Analyzer/Getein1600 Immunofluorescence Quantitative Analyzer (hereinafter referred to as Getein1100 and Getein1600), the concentration of cTnI in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

1. A kit for Getein1100 contains:
Getein cTnI test card in a sealed pouch with desiccant 25
Disposable pipet 25
Whole blood buffer 1
SD card 1
User manual 1
2. A kit for Getein1600 contains:
Sealed cartridge with 24/48 Getein cTnI test cards 2
User manual 1
Package specifications:
2x24 tests/kit, 2x48 tests/kit
Materials required for Getein1600:
Sample diluent 1
Box with pipette tips 1
Mixing plate 1
3. Sample diluent/Whole blood buffer composition:
Phosphate buffered saline, proteins, detergent, preservative, Phosphate buffer stabilizer.

4. A test card consists of:

A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane (one end of the membrane is coated with a fluorescence latex-labelled anti-

human cTnI monoclonal antibody, the test line is coated with another anti-human cTnI monoclonal antibody, and the control line is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

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

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test card at 4-30°C with a valid period of 24 months. Use the test card for Getein1100 within 1 hour once the foil pouch is opened.

For test card of Getein1600: if the cartridge is opened, it could be stable within 24 hours once exposed to air. If the test cards can't be used up at a time, please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.

Store the sample diluent/whole blood buffer at 0-30°C with a valid period of 24 months.

Store the sample diluent/whole blood buffer at 2-8°C for better results.

PRECAUTIONS

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

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for serum, plasma and whole blood samples. Heparin and sodium citrate should be used as the anticoagulant for plasma and whole blood. Samples should be free of hemolysis.



2. Suggest using serum or plasma for better results.
3. Serum or plasma can be used directly. For whole blood sample, one drop of whole blood buffer must be added before testing.
4. If testing will be delayed, serum and plasma samples may be stored up to 7 days at 2-8°C or stored at -20°C for 6 months before testing (whole blood sample may be stored up to 3 days at 2-8°C).
5. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
6. Do not use heat-inactivated samples.
7. **SAMPLE VOLUME (for Getein1100): 100 µl.**

TEST PROCEDURE

1. Collect specimens according to user manual.
 2. Test card, sample and reagent should be brought to room temperature before testing.
 3. **For Getein1100:**
 3. Confirm SD card lot No. in accordance with test kit lot No..
 - Perform "SD Card Calib" calibration when necessary (Details refer to 8.5.2 of Getein1100 User Manual).
 4. On the main interface of Getein1100, press "ENT" button to enter testing interface.
 5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
 6. Put the test card on a clean table, horizontally placed.
 7. Using sample transfer pipette, deliver 100 µl of sample (or 3-4 drops of sample when using disposable pipet) into the sample port on the test card (for whole blood sample, one drop of whole blood buffer must be added after loading 100 µl sample on the test card).
 8. **Reaction time: 10 minutes.** Insert the test card into Getein1100 and press "ENT" button after reaction time is elapsed. The result will be shown on the screen and printed automatically.
- For Getein1600:**
9. Each cartridge for Getein1600 contains a specific RFID card which can calibrate automatically.
 10. Place samples in the designed area of the sample holder, insert the holder and select the right test item. Getein1600 will do the testing and print the result automatically.

Notes:

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

TEST RESULTS

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

EXPECTED VALUE

The expected normal value for Troponin I was determined by testing samples from 500 apparently healthy individuals. The 99th percentile of the concentration for cTnI is 0.1 ng/ml. (The probability that value of a normal person below 0.1 ng/ml is 99%.)

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

PERFORMANCE CHARACTERISTICS

Measuring Range 0.1~50 ng/ml
 Lower Detection Limit ≤ 0.1 ng/ml
 Within-Run Precision ≤ 10%
 Between-Run Precision ≤ 15%
 Method Comparison:

The assay was compared with SIEMENS IMMULITE 2000 and its matching cTnI test kits with 200 serum samples (60 positive samples and 140 negative samples). The correlation coefficient (r) for cTnI is 0.952.

LIMITATIONS

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

Interferent	Hemoglobin	Triglyceride	Bilirubin
Concentration (Max)	5 g/L	10 g/L	0.2 g/L

REFERENCES

1. Mauro Pantaghini. Undefined International Federation of Clinical Chemistry and Laboratory Medicine (IFCC). Scientific Division Committee on Standardization of Markers of Cardiac Damage. Clin Chem Lab Med, 1998, 36:887~893.
2. Antman EM, Anbe DT, Armstrong PW, et al. ACC/AHA guidelines for the management of patients with ST-elevation myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Practice

Guidelines (Committee to Revise the 1999 Guidelines for the Manage 2004).

3. EN ISO 18113-1:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
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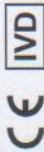
Key to symbols used			
	Manufacturer		Expiration date
	Do not reuse		Date of manufacture
	Consult instructions for use		Batch code
	Temperature limitation		<i>In vitro</i> diagnostic medical device
	Sufficient for		Authorized representative in the European Community
	CE mark		Do not use if package is damaged

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

Version: WIF02-S-02

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D-Dimer Fast Test Kit (Immunofluorescence Assay)

Getein1100: Cat.# IF1006
Getein1600: Cat.# IF2006

User Manual

INTENDED USE

D-Dimer Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of D-Dimer in plasma or whole blood. The test is used as an aid in the assessment and evaluation of patients suspected of deep-vein thrombosis or pulmonary embolism.

SUMMARY

Deep-vein thrombosis is a common condition, with a lifetime cumulative incidence of 2 to 5 percent. Untreated deep-vein thrombosis can result in pulmonary embolism, a potentially fatal outcome. Anticoagulant therapy reduces both morbidity and mortality from venous thromboembolism, and early diagnosis is therefore important. Accurate diagnosis of deep-vein thrombosis minimizes the risk of thromboembolic complications and averts the exposure of patients without thrombosis to the risks of anticoagulant therapy.

D-Dimer is a marker of endogenous fibrinolysis and should therefore be detectable in patients with deep-vein thrombosis. In recent years, an increasing number of studies have shown the D-Dimer assay has a high negative predictive value and D-Dimer is a sensitive but nonspecific marker of deep-vein thrombosis. Negative D-Dimer can exclude deep-vein thrombosis and pulmonary embolism.

PRINCIPLE

The test uses an anti-human D-Dimer monoclonal antibody conjugated with fluorescence latex and another anti-human D-Dimer monoclonal antibody coated on the test line. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human D-Dimer monoclonal antibody binds with the D-Dimer in sample and forms a marked antigen-antibody

complex. This complex moves to the test card detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by another anti-human D-Dimer monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of D-Dimer in sample.

Then insert test card into Getein1100 Immunofluorescence Quantitative Analyzer/Getein1600 Immunofluorescence Quantitative Analyzer (hereinafter referred to as Getein1100 and Getein1600), the concentration of D-Dimer in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

1. A kit for Getein1100 contains:
Getein D-Dimer test card in a sealed pouch with desiccant 25
Disposable pipet 25
Sample diluent 25
SD card 1
User manual 1
2. A kit for Getein1600 contains:
Sealed cartridge with 24/48 Getein D-Dimer test cards 2
User manual 1
Package specifications: 1
2x24 tests/kit, 2x48 tests/kit 1
Materials required for Getein1600:
Sample diluent 1
Box with pipette tips 1
Mixing plate 1

3. Sample diluent composition:
Phosphate buffered saline, proteins, detergent, preservative, stabilizer.

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

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

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test card at 4-30°C with a valid period of 24 months. Use the test card for Getein1100 within 1 hour once the foil pouch is opened.

For test card of Getein1600: if the cartridge is opened, it could be stable within 24 hours once exposed to air. If the test cards can't be used up at a time, please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.

Store the sample diluent/whole blood buffer at 0-30°C with a valid period of 24 months.

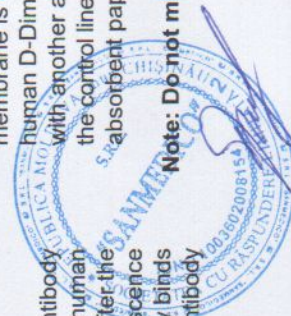
Store the sample diluent/whole blood buffer at 2-8°C for better results.

PRECAUTIONS

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

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for *plasma and whole blood samples*. *Sodium citrate* can be used as the anticoagulant for plasma and whole blood. Samples should be free of hemolysis.
2. Suggest using plasma for better results.
3. If testing will be delayed, plasma sample may be stored up to 3 days at 2-8°C or stored at -20°C for 1 month before testing (whole blood sample may be stored up to 3 days at 2-8°C).
4. Refrigerated or frozen sample should reach room temperature



- and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
5. Do not use heat-inactivated samples.
 6. **SAMPLE VOLUME** (for Getein1100): 100 µl.

TEST PROCEDURE

1. Collect specimens according to user manual.
 2. Test card, sample and reagent should be brought to room temperature before testing.
- For Getein1100:
3. Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD Card Calib" calibration when necessary (Details refer to 6.5.2 of Getein1100 User Manual).
 4. On the main interface of Getein1100, press "ENT" button to enter testing interface.
 5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
 6. Put the test card on a clean table, horizontally placed.
 7. Using sample transfer pipette, deliver 100 µl of sample into one tube of sample diluent, mix gently and thoroughly. Then drop 100 µl of sample mixture (or 3~4 drops of sample when using disposable pipet) into the sample port on the test card.
 8. **Reaction time: 10 minutes.** Insert the test card into Getein1100 and press "ENT" button after reaction time is elapsed.. The result will be shown on the screen and printed automatically.

For Getein1600:

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

Notes:

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

TEST RESULTS

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

EXPECTED VALUE

The expected normal value for D-Dimer was determined by testing samples from 500 apparently healthy individuals. The 95th percentile of the concentration for D-Dimer is 0.5 mg/L. (The probability that value of a normal person below 0.5 mg/L is 95%.)

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

PERFORMANCE CHARACTERISTICS

Measuring Range 0.1~10.0 mg/L
 Lower Detection Limit ≤0.1 mg/L
 Within-Run Precision ≤10%
 Between-Run Precision ≤15%

Method Comparison:

The assay was compared with SIEMENS CA-7000 and its matching D-Dimer test kits with 200 plasma samples (60 positive samples and 140 negative samples). The correlation coefficient (r) for D-Dimer is 0.978.

LIMITATIONS

1. As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.
2. Samples containing interferents such as rheumatoid factor, human anti-mouse antibody and heterophile antibody may influence the results. In this case, results of this test should be used in conjunction with clinical findings and other tests. The table below listed the maximum allowance of these potential interferents.

Interferent	Hemoglobin	Triglyceride	Bilirubin
Concentration (Max)	5 g/L	25 g/L	0.1 g/L

REFERENCES

1. Sarig G, Kil-Drori AJ, Chap-Marshak D, Brenner B, Dragan A. Activation of coagulation in amniotic fluid during normal human pregnancy. *Thromb Res.* 2011 Apr 18.
2. Roldán V, Marín F, Muñia B, Torregrosa JM, Hernández-Romero D, Valdes M, Vicente V, Lip GY. Plasma von Willebrand Factor Levels Are an Independent Risk Factor for Adverse Events Including Mortality and Major Bleeding in Anticoagulated

3. Sakamoto K, Yamamoto Y, Okamatsu H, Okabe M. D-dimer is helpful for differentiating acute aortic dissection and acute pulmonary embolism from acute myocardial infarction. *Hellenic J Cardiol.* 2011 Mar-Apr; 52(2):123-127.
4. EN ISO 18113-1:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
5. EN ISO 18113-2:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: *In vitro* diagnostic reagents for professional use (ISO 18113-2:2009).

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on D-Dimer Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN 980:2008 and International Standard ISO 15223-1:2007.

Key to symbols used			
	Manufacturer		Expiration date
	Do not reuse		Date of manufacture
	Consult instructions for use		Batch code
	Temperature limitation		<i>In vitro</i> diagnostic medical device
	Sufficient for		Authorized representative in the European Community
	CE mark		Do not use if package is damaged

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

Version: WIF05-S-02



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NT-proBNP Fast Test Kit

(Immunofluorescence Assay)

Getein1100: Cat.# IF1002
Getein1600: Cat.# IF2002

User Manual

INTENDED USE

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

SUMMARY

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

PRINCIPLE

The test uses an anti-human NT-proBNP monoclonal antibody conjugated with fluorescence latex and an anti-human NT-proBNP polyclonal antibody coated on the test line. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human NT-proBNP monoclonal antibody binds with the NT-proBNP in sample and forms a marked antigen-antibody complex. This complex moves to the test card detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by the anti-human NT-proBNP polyclonal antibody. The fluorescence

intensity of the test line increases in proportion to the amount of NT-proBNP in sample.

Then insert test card into Getein1100 Immunofluorescence Quantitative Analyzer/Getein1600 Immunofluorescence Quantitative Analyzer (hereinafter referred to as Getein1100 and Getein1600), the concentration of NT-proBNP in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

1. A kit for Getein1100 contains:
Getein NT-proBNP test card in a sealed pouch with desiccant 25
Disposable pipet 25
Whole blood buffer 1
SD card 1
User manual 1
2. A kit for Getein1600 contains:
Sealed cartridge with 24/48 Getein NT-proBNP test cards 2
User manual 1
Package specifications:
2x24 tests/kit, 2x48 tests/kit 1
Materials required for Getein1600:
Sample diluent 1
Box with pipette tips 1
Mixing plate 1
3. Sample diluent/Whole blood buffer composition:
Phosphate buffered saline, proteins, detergent, preservative, stabilizer.

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

Note: Components from different batches must not be interchanged.

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer



STORAGE AND STABILITY

Store the test card at 4-30°C with a valid period of 24 months. Use the test card for Getein1100 within 1 hour once the foil pouch is opened.

For test card of Getein1600: if the cartridge is opened, it could be stable within 24 hours once exposed to air. If the test cards can't be used up at a time, please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.

Store the sample diluent/whole blood buffer at 0-30°C with a valid period of 24 months.

Store the sample diluent/whole blood buffer at 2-8°C for better results.

PRECAUTIONS

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

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for serum, plasma and whole blood samples. Heparin and sodium citrate should be used as the anticoagulant for plasma and whole blood. Samples should be free of hemolysis.
2. Suggest using serum or plasma for better results.
3. Serum or plasma can be used directly. For whole blood sample, one drop of whole blood buffer must be added before testing.
4. If testing will be delayed, serum and plasma samples may be stored up to 1 day at 2-8°C or stored at -20°C for 3 months before testing (whole blood sample may be stored up to 3 days at 2-8°C).
5. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
6. Do not use heat-inactivated samples.
7. SAMPLE VOLUME (for Getein1100): 100 µl.

TEST PROCEDURE

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

For Getein1100:

3. Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD Card Calib" calibration when necessary (Details refer to 8.5.2 of Getein1100 User Manual).
4. On the main interface of Getein1100, press "ENT" button to enter testing interface.
5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
6. Put the test card on a clean table, horizontally placed.
7. Using sample transfer pipette, deliver 100 µl of sample (or 3-4 drops of sample when using disposable pipet) into the sample port on the test card (for whole blood sample, one drop of whole blood buffer must be added after loading 100 µl sample on the test card).
8. **Reaction time: 10 minutes.** Insert the test card into Getein1100 and press "ENT" button after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1600:

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

Notes:

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

TEST RESULTS

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

EXPECTED VALUE

The expected normal value for NT-proBNP was determined by testing samples from 2,500 apparently healthy individuals. The 95th percentile of the concentration for NT-proBNP is 185 pg/ml and the 97.5th percentile of the concentration for NT-proBNP is 300 pg/ml. Because of the apparent difference of the concentration

of NT-proBNP among different age groups, the reference values of the NT-proBNP are reported in groups. Details refer to Table 1. Clinical diagnosis value: refer to Roche criterion, details see Table 2.

Table 1 NT-proBNP reference value

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

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

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

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

PERFORMANCE CHARACTERISTICS

Measuring Range 100~35000 pg/ml
Lower Detection Limit ≤100 pg/ml
Within-Run Precision ≤10%
Between-Run Precision ≤15%
Method Comparison:

The assay was compared with Roche MODULAR ANALYTICS E170 and its matching NT-proBNP test kits with 200 serum samples (63 positive samples and 137 negative samples). The correlation coefficient (r) for NT-proBNP is 0.959.

LIMITATIONS

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

Interferent	Hemoglobin	Triglyceride	Bilirubin
Concentration (Max)	5 g/L	10 g/L	0.2 g/L

REFERENCES

1. de Lemos JA, McGuire DK, Drazner MH. B-type natriuretic peptide in cardiovascular disease. Lancet 2003; 362:316-322.

2. Pfister R, Scholz M, Wielckens K, Erdmann E, Schneider CA. The value of natriuretic peptides NT-pro-BNP and BNP for the assessment of left-ventricular volume and function. A prospective study of 150 patients. Deutsche medizinische Wochenschrift (1946) 2002; 127(49):2605.

3. EN ISO 18113-1:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.

4. EN ISO 18113-2:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: *In vitro* diagnostic reagents for professional use (ISO 18113-2:2009).

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on NT-proBNP Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN 980:2008 and International Standard ISO 15223-1:2007.

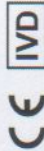
Key to symbols used			
	Manufacturer		Expiration date
	Do not reuse		Date of manufacture
	Consult instructions for use		Batch code
	Temperature limitation		<i>In vitro</i> diagnostic medical device
	Sufficient for		Authorized representative in the European Community
	CE mark		Do not use if package is damaged

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

Version: WIF03-S-02

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One Step Test for mAlb (Colloidal Gold)

User Manual

Cat.# CG1009

INTENDED USE

One Step Test for mAlb (Colloidal Gold) is intended for *in vitro* quantitative determination of microalbuminuria (mAlb) in urine. An elevated mAlb concentration below the proteinuric level has long been recognized as a marker of kidney disease and increased cardiovascular risk in diabetic nephropathy.

SUMMARY

Albumin is one of the major plasma proteins. In normal circumstances, albumin molecules are too large to cross the glomerular basement membrane. Therefore, albumin is usually present in very low concentration in urine. Damage to the glomerular basement membrane can alter its permeability. Albumin is then able to enter the urine. Sustained elevation of urinary albumin concentration is called Microalbuminuria (mAlb). mAlb arises from increased leakage of glomerular basement membrane. So, mAlb is recognized as a marker of kidney damage.

Recent years, determination of mAlb is linked with increased risk for cardiovascular events rather than progression to end-stage kidney disease. It is a valuable tool for the detection of cardiovascular risk in diabetic nephropathy. Early detection of microalbuminuria in diabetes is critical because immediate intervention can slow the progression of disease. The epidemiology of microalbuminuria reveals a close association between systemic endothelial dysfunction and vascular disease, also implicating glomerular endothelial dysfunction in microalbuminuria.

PRINCIPLE

The test is based on the competition immune-detection method and uses an anti-human mAlb monoclonal antibody conjugated with colloidal gold and recombinant mAlb antigen coated on the test line. After the sample has been applied to the test strip, mAlb in the sample will compete with recombinant mAlb antigen on nitrocellulose matrix for gold-labelled mAlb monoclonal antibody. As a result, the concentration of mAlb antigen in specimen shows inverse proportionally with the color intensity of mAlb. The color intensity of the test line increases in proportion to the amount of mAlb in sample.

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

CONTENTS

A kit contains:

1. Getein mAlb test card in a sealed pouch with desiccant 25
2. Disposable pipet 25
3. User manual 1
4. SD card 1

A test card consists of:

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

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

APPLICABLE DEVICE

FIA8000 Quantitative Immunoassay Analyzer



STORAGE AND STABILITY

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

PRECAUTIONS

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

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for *urine sample*.
2. *Urine sample* can be preserved at room temperature for 4 hours, please test it as soon as possible. If testing will be delayed, urine sample may be stored up to 3 days at 2~8°C before testing.
3. Samples should be brought to room temperature before testing.
4. Do not use frozen urine samples.
5. Do not use heat-inactivated samples.
6. SAMPLE VOLUME: 120 µl.

TEST PROCEDURE

1. Collect specimen according to user manual.
2. Test card, sample should be brought to room temperature before testing.
3. Confirm SD card lot No. in accordance with test kit lot No.. Perform "QC (SD)" calibration when necessary (Details refer to 8.2.1 of FIA8000 User Manual).
4. On the main interface of FIA8000, press "ENT" button to

enter testing interface.

5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
6. Put the test card on a clean table, horizontally placed.
7. Using sample transfer pipette, deliver 120 µl of sample (or 4 drops of sample when using disposable pipet) into the sample port on the test card.
8. **Reaction time: 3 minutes.** Insert the test card into FIA8000 and press "ENT" button after reaction time is elapsed. The result will be shown on the screen and printed automatically.

Notes:

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

TEST RESULTS

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

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

EXPECTED VALUE

The expected normal value for mAlb was determined by testing samples from 500 apparently healthy individuals. The 95th percentile of the concentration for mAlb is 20.0 mg/L. (The probability that value of a normal person below 20.0 mg/L is 95%.)

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

PERFORMANCE CHARACTERISTICS

Measuring Range 10.0~200.0 mg/L
Lower Detection Limit ≤10.0 mg/L
Within-Run Precision ≤10%

Between-Run Precision

≤15%

Method Comparison:

The assay was compared with OLYMPUS AU5400 analyzer and its matching Randox mAlb test kits with 200 urine samples (62 positive samples and 138 negative samples). The correlation coefficient (*r*) is 0.980.

LIMITATIONS

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

Interferent	Creatinine	Glucose	Urea
Concentration (Max)	10 g/L	10 g/L	100 g/L

REFERENCES

1. Cöli M, Ocaktan E, Ozdemir O, et al. Microalbuminuria: prevalence in hypertensives and diabetics. Acta Med Austriaca. 2004, 31(1):23-29.
2. McTaggart MP, Price CP, Pinnock RG, et al. The diagnostic accuracy of a urine albumin-creatinine ratio point-of-care test for detection of albuminuria in primary care. Am J Kidney Dis. 2012, 60(5):787-794.
3. Denis Sviridov, Glen L. Hortin. Urine albumin measurement: Effects of urine matrix constituents. Clinica Chimica Acta. 2009, 404(2):140-143.
4. Rebaldi G, Gentile G, Angeli F, et al. Microalbuminuria and hypertension. Minerva Med. 2005, 96(4):261-75.
5. EN ISO 18113-1:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
6. EN ISO 18113-2:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: *In vitro* diagnostic reagents for professional use (ISO

18113-2:2009).

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on One Step Test for mAlb (Colloidal Gold) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN 980:2008 and International Standard ISO 15223-1:2007.

Key to symbols used	
	Manufacturer
	Do not reuse
	Consult instructions for use
	Temperature limitation
	Sufficient for
	CE mark
	Expiration date
	Batch code
	<i>In vitro</i> diagnostic medical device
	Authorized representative in the European Community
	Do not use if package is damaged

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

Version: WCG10-DL-S-01

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CE IVD

One Step Test for NT-proBNP (Colloidal Gold)

User Manual

Cat.# CG1002

INTENDED USE

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

SUMMARY

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

PRINCIPLE

The test uses an anti-human NT-proBNP monoclonal antibody conjugated with colloidal gold and an anti-human NT-proBNP polyclonal antibody coated on the test line. After the sample has been applied to the test strip, the gold-labelled anti-human NT-proBNP monoclonal antibody binds with the NT-proBNP in sample and forms a marked antigen-antibody complex. This

complex moves to the test card detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by the anti-human NT-proBNP polyclonal antibody resulting in a purplish red streak appears on the test line. The color intensity of the test line increases in proportion to the amount of NT-proBNP in sample.

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

CONTENTS

A kit contains:

1. Getein NT-proBNP test card in a sealed pouch with desiccant	25
2. Disposable pipet	25
3. User manual	1
4. SD card	1
5. Whole blood buffer	1

A test card consists of:

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

Whole blood buffer composition:

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

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

APPLICABLE DEVICE

FIA8000 Quantitative Immunoassay Analyzer

STORAGE AND STABILITY

Store the test card at 4-30°C with a valid period of 24 months. Use the test card within 1 hour once the foil pouch is opened. Store the whole blood buffer at 0-30°C with a valid period of 24 months. Store the whole blood buffer at 2-8°C for better results.

PRECAUTIONS

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

SPECIMEN COLLECTION AND PREPARATION

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

TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, sample and reagent should be brought to room temperature before testing.
3. Confirm SD card lot No. in accordance with test kit lot No.. Perform "QC (SD)" calibration when necessary (Details refer to 8.2.1 of FIA8000 User Manual).
4. On the main interface of FIA8000, press "ENT" button to enter testing interface.
5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control



identification.

- Put the test card on a clean table, horizontally placed.
- Using sample transfer pipette, deliver 120 µl of sample (or 4 drops of sample when using disposable pipet) into the sample port on the test card (for whole blood sample, one drop of whole blood buffer must be added after loading 120 µl sample on the test card).

8. **Reaction time: 15 minutes.** Insert the test card into FIA8000 and press "ENT" button after reaction time is elapsed. The result will be shown on the screen and printed automatically.

Notes:

- It is required to perform "QC (SD)" calibration when using a new batch of kits.
- It is suggested to calibrate once for one batch of kits.
- Make sure the test card insertion is correct and complete.

TEST RESULTS

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

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

EXPECTED VALUE

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

Table 1 NT-proBNP reference value

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

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

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

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

PERFORMANCE CHARACTERISTICS

Measuring Range
100~35000 pg/ml
Lower Detection Limit
≤100 pg/ml
Within-Run Precision (n=10)
≤10%
Between-Run Precision
≤15%

Recovery:

NT-proBNP for low-sensitivity test line 103% (mean)
NT-proBNP for high-sensitivity test line 98% (mean)

Method Comparison:

The assay was compared with Roche MODULAR ANALYTICS E170 and its matching NT-proBNP test kits with 200 serum samples (63 positive samples and 137 negative samples). The correlation coefficient (r) for NT-proBNP is 0.959.

LIMITATIONS

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

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

REFERENCES

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prospective study of 150 patients. Deutsche medizinische Wochenschrift (1946) 2002; 127(49):2605.

- EN ISO 18113-1:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
- EN ISO 18113-2:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: *In vitro* diagnostic reagents for professional use (ISO 18113-2:2009).

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on One Step Test for NT-proBNP (Colloidal Gold) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN 980:2008 and International Standard ISO 15223-1:2007.

Key to symbols used			
	Manufacturer		Expiration date
	Do not reuse		Date of manufacture
	Consult instructions for use		Batch code
	Temperature limitation		In vitro diagnostic medical device
	Sufficient for		Authorized representative in the European Community
	CE mark		Do not use if package is damaged

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

Version: WCG03-DL-S-01



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CE IVD

One Step Test for PCT (Colloidal Gold)

User Manual

Cat.# CG1007

INTENDED USE

One Step Test for PCT (Colloidal Gold) is intended for *in vitro* quantitative determination of Procalcitonin (PCT) in serum, plasma or whole blood. The test is used as an aid in the assessment and evaluation of patients suspected of bacterial infection, trauma or shock.

SUMMARY

PCT is a peptide precursor of the hormone calcitonin, the latter being involved with calcium homeostasis. It is composed of 116 amino acids and is produced by parafollicular cells (C cells) of the thyroid and by the neuroendocrine cells of the lung and the intestine.

Measurement of PCT can be used as a marker of severe sepsis and generally grades well with the degree of sepsis, although levels of PCT in the blood are very low. PCT has the greatest sensitivity and specificity for differentiating patients with systemic inflammatory response syndrome (SIRS) from those with sepsis.

PCT levels may be useful to distinguish bacterial infections from nonbacterial infections. It has shown that PCT may help guide therapy and reduce antibiotic use, which can help save on cost of antibiotic prescriptions and drug resistance.

PRINCIPLE

The test uses an anti-human PCT monoclonal antibody conjugated with colloidal gold. For PCT product, test line 1 was coated with anti-human PCT polyclonal antibody and test line 2 was coated with another anti-human PCT monoclonal antibody. After the sample has been applied to the test strip, the gold-labelled anti-human PCT monoclonal antibody or polyclonal antibody binds with the PCT in sample and forms a

marked antigen antibody complex. This complex moves to the test card detection zone by capillary action. Then marked antigen antibody complex is captured on the test line by the other anti-human PCT monoclonal antibody or the polyclonal antibody. The color intensity of the test line increases in proportion to the amount of PCT in sample.

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

CONTENTS

A kit contains:

1. Getein PCT test card in a sealed pouch with desiccant	25
2. Disposable pipet	25
3. User manual	1
4. SD card	1
5. Whole blood buffer	1

A test card consists of:

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

Whole blood buffer composition:

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

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

APPLICABLE DEVICE

FIA8000 Quantitative Immunoassay Analyzer

STORAGE AND STABILITY

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

Store the whole blood buffer at 0-30°C with a valid period of 24 months.

Store the whole blood buffer at 2-8°C for better results.

PRECAUTIONS

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

SPECIMEN COLLECTION AND PREPARATION

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

TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, sample and reagent should be brought to room temperature before testing.
3. Confirm SD card lot No. in accordance with test kit lot No.. Perform "QC (SD)" calibration when necessary (Details refer to 8.2.1 of FIA8000 User Manual).
4. On the main interface of FIA8000, press "ENT" button to enter testing interface.
5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control



identification.

- Put the test card on a clean table, horizontally placed.
- Using sample transfer pipette, deliver 120 µl of sample (or 4 drops of sample when using disposable pipet) into the sample port on the test card (for whole blood sample, one drop of whole blood buffer must be added after loading 120 µl sample on the test card).

8. **Reaction time: 15 minutes.** Insert the test card into FIA8000 and press "ENT" button after reaction time is elapsed. The result will be shown on the screen and printed automatically.

Notes:

- It is required to perform "QC (SD)" calibration when using a new batch of kits.
- It is suggested to calibrate once for one batch of kits.
- Make sure the test card insertion is correct and complete.

TEST RESULTS

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

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

EXPECTED VALUE

The expected normal value for PCT was determined by testing samples from 500 apparently healthy individuals. The 99th percentile of the concentration for PCT is 0.1 ng/ml. (The probability that value of a normal person below 0.1 ng/ml is 99%.)

The table below comes from the research of ACCP/SCCM (American College of Chest Physicians/Society of Critical Care Medicine), showing the PCT value and its clinical meaning⁽⁴⁾:

PCT concentration	Clinical significance
< 0.5 ng/ml	Local bacterial infection is possible, systemic infection (sepsis) is not likely.
≥ 0.5 and < 2.0 ng/ml	Systemic infection (sepsis) is possible, a moderate risk of severe sepsis and/or septic shock.
≥ 2.0 ng/ml	Systemic infection (sepsis) is likely, a high risk of severe sepsis and/or septic shock.

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

PERFORMANCE CHARACTERISTICS

Measuring Range 0.1~50.0 ng/ml
 Lower Detection Limit ≤0.1 ng/ml
 Within-Run Precision ≤10%
 Between-Run Precision ≤15%
 Recovery 98%

Method Comparison:

The assay was compared with Roche MODULAR ANALYTICS E170 automatic immunoassay system and its matching PCT test kits with 200 serum samples (68 positive samples and 132 negative samples). The correlation coefficient (r) for PCT is 0.983.

LIMITATIONS

1. As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.

2. Samples containing interferents such as rheumatoid factor, human anti-mouse antibody and heterophile antibody may influence the results. In this case, results of this test should be used in conjunction with clinical findings and other tests.

Interferent	Hemoglobin	Triglyceride	Bilirubin
Concentration (Max)	5 g/L	10 g/L	0.2 g/L

REFERENCES

- Bald C, Sungurtekin H, Gürses E, Sungurtekin U, Kaptanoglu B. Usefulness of procalcitonin for diagnosis of sepsis in the intensive care unit, Crit Care. 2003 February 7 (1):85-90.
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- Briel M, Schuetz P, Mueller B, et al. Procalcitonin-guided antibiotic use vs a standard approach for acute respiratory tract infections in primary care. Arch Intern Med. Oct 13 2008;168(18):2000-7; discussion 2007-8.
- American College of Chest Physicians/Society of Critical Care Medicine: Definitions for sepsis and organ failure and guidelines for the use of innovative therapies in sepsis. Crit Care Med 1992, 20:864-874.

5. EN ISO 18113-1:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.

6. EN ISO 18113-2:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: *In vitro* diagnostic reagents for professional use (ISO 18113-2:2009).

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on One Step Test for PCT (Colloidal Gold) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN 980:2008 and International Standard ISO 15223-1:2007.

Key to symbols used			
	Manufacturer		Expiration date
	Do not reuse		Date of manufacture
	Consult instructions for use		Batch code
	Temperature limitation		<i>In vitro</i> diagnostic medical device
	Sufficient for		Authorized representative in the European Community
	CE mark		Do not use if package is damaged

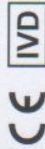
Thank you for purchasing One Step Test for PCT (Colloidal Gold). Please read this user manual carefully before operating to ensure proper use.

Version: WCG06-DL-S-01



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Cardiac Troponin I Fast Test Kit

User Manual

Cat.# CG2001

INTENDED USE

Cardiac Troponin I Fast Test Kit is intended for *in vitro* qualitative and semi-quantitative determination of cardiac Troponin I (cTnI) in serum, plasma or whole blood. This test is used as an aid in the diagnosis of myocardial injury such as Acute Myocardial Infarction (AMI), Unstable Angina, Acute Myocarditis and Acute Coronary Syndrome (ACS).

SUMMARY

Troponin, a molecular complex that is bound to the thin filament (actin) of striated muscle fibers, acts with intracellular calcium to control the interaction of the thin filament with the thick filament (myosin), thus regulating muscle contraction. Troponin consists of three subunits: T, which connects the troponin complex and tropomyosin (another cardiac muscle regulatory protein); I, which prevents muscle contraction in the absence of calcium; and C, which binds calcium. Cardiac Troponin I (MW 22.5 kDa) and the two skeletal muscle isoforms of Troponin I have considerable amino acid sequence homology, but cTnI contains an additional N-terminal sequence and is highly specific for myocardium.

Clinical studies have demonstrated the release of cTnI into the blood stream within hours following acute myocardial infarctions (AMI) or ischemic damage. Elevated levels of cTnI are detectable in blood within 4 to 6 hours after the onset of chest pain, reaching peak concentrations in approximately 8 to 28 hours, and remain elevated for 3 to 10 days following AMI. Due to the high myocardial specificity and the long duration of elevation, cTnI has become an important marker in the diagnosis and

evaluation of patients suspected of having an AMI.

The current guideline of The Joint European Society of Cardiology/American College of Cardiology Committee support the use of cTnI as a preferred marker of myocardial injury. Several major studies have shown that cTnI is also a predictor of cardiac risk in patients with unstable angina. The American College of Cardiology and the American Heart Association's current guidelines recommend using troponin results when making treatment decisions regarding unstable angina and non-ST segment elevation MI (NSTEMI).

PRINCIPLE

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

CONTENTS

A kit contains:

1. Getein cTnI test card in a sealed pouch with desiccant 25
2. Disposable pipet 25
3. User manual 1
4. Standard colorimetric card 1
5. Whole blood buffer 1

A test card consists of:

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

Whole blood buffer composition:

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

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

STORAGE AND STABILITY

Store the test card at 4-30°C with a valid period of 24 months. Use the test card within 1 hour once the foil pouch is opened. Store the whole blood buffer at 0-30°C with a valid period of 24 months.

Store the whole blood buffer at 2-8°C for better results.

PRECAUTIONS

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

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for serum, plasma or whole blood samples. Heparin, EDTA or sodium citrate should be used as the anticoagulant for plasma and whole blood. Samples should be free of hemolysis.
2. Suggest using serum or plasma for better results.
3. Serum or plasma can be used directly. For whole blood sample, whole blood buffer must be added before testing.
4. If testing will be delayed, serum and plasma samples may be stored up to 7 days at 2-8°C or stored at -20°C for 6 months before testing (whole blood sample may be stored up to 3 days at 2-8°C).



5. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
6. Do not use heat-inactivated samples.
7. SAMPLE VOLUME: 80 µl.

TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, sample and reagent should be brought to room temperature before testing.
3. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
4. Put the test card on a clean table, horizontally placed.
5. Using sample transfer pipette, deliver 80 µl of sample (or 3 drops of sample when using disposable pipet) into the sample port on the test card (for whole blood sample, one drop of whole blood buffer must be added after loading 80 µl sample on the test card).
6. Read the results visually in 15 minutes. For semi-quantitative interpretation of results, please refer to the standard colorimetric card.

TEST RESULTS

Negative: A single purplish red band appears at the control area (C) without any other band at test line is a valid negative result, indicating the concentration of cTnI in the sample is below the cut-off value.

Positive: A single purplish red band appears at the control area (C) and a purplish red colored band appears in test line is a valid positive result. The intensity of the purplish red color in the test line helps to read the semi-quantitative result visually according to the standard colorimetric card:

Color intensity	Reference Concentration (ng/ml)
—	<0.3
+	0.3~1
++	1~5
+++	5~15
++++	15~30
+++++	30~50
+++++	>50

Invalid: If no colored band appears in the control area (C) in 15 minutes, the test result is invalid. The test should be repeated and if the same situation happened again, please stop using this batch of products and contact your supplier.

EXPECTED VALUE

The expected normal value for Troponin I was determined by testing samples from 500 apparently healthy individuals. The 99th percentile of the concentration for cTnI is 0.3 ng/ml. (The probability that value of a normal person below 0.3 ng/ml is 99%). cTnI concentration less than 0.3 ng/ml can be estimated as normal.

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

LIMITATIONS

As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.

REFERENCES

1. Mauro Pantaghini; Undefined International Federation of Clinical Chemistry and Laboratory Medicine (IFCC). Scientific Division Committee on Standardization of Markers of Cardiac Damage. Clin Chem Lab Med, 1998, 36:887~893.
2. Antman EM, Anbe DT, Armstrong PW, et al. ACC/AHA guidelines for the management of patients with ST-elevation myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1999 Guidelines for the Manage 2004).
3. EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
4. EN ISO 18113-2:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO18113-2:2011).

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on Cardiac Troponin I Fast Test Kit are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN 980:2008 and International Standard ISO 15223 - 1: 2012.

Key to symbols used			
	Manufacturer		Expiration date
	Do not reuse		Date of manufacture
	Consult instructions for use		Batch code
	Temperature limitation		In vitro diagnostic medical device
	Sufficient for		Authorized representative in the European Community
	CE mark		Do not use if package is damaged

Thank you for purchasing Cardiac Troponin I Fast Test Kit. Please read this user manual carefully before operating to ensure proper use.

Version: WCG01A-DX-S-02



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cTnI Control

Cat.# QC 001

User Manual

PRODUCT NAME

cTnI Control

PRODUCT SPECIFICATION

cTnI Control - Level 1/2/3

Level 1	1 x 1 ml
Level 2	1 x 1 ml
Level 3	1 x 1 ml

INTENDED USE

This product is intended for *in vitro* diagnostic use in the quality control of Cardiac Troponin I (cTnI) on the Getein Platforms.

PRINCIPLE

The lyophilized cTnI control is prepared from dissolving stable and high quality recombinant cTnI antigen into calf serum. With matching equipments and reagents, it can fulfill value transfer work. As different equipments and reagents have uncertainty to some extent, different control results may appear.

CONTENTS

The kit contains:

1. cTnI Control –Level 1 1 x 1 ml
2. cTnI Control –Level 2 1 x 1 ml
3. cTnI Control –Level 3 1 x 1 ml
4. User manual 1
5. Target value sheet 1

MATCHING EQUIPMENTS

FIA8000 Quantitative Immunoassay Analyzer

Getein1100/1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

UNOPENED: The product is stable for 18 months when stored at -20°C and is stable for 7 days at 2-8°C avoid light.

OPENED: The product is stable for 7 days at 2-8°C if kept capped in original container and free from contamination. Only the required amount of product should be removed. After use, any residual product should NOT BE RETURNED to the original vial. The residual product is recommended to be dispensed into smaller vials and they are stable for 18 months when stored at -20 to -70°C.

MATERIALS REQUIRED BUT NOT PROVIDED

1. 1 ml pipette
2. Distilled water
3. Getein test kit
4. Getein instrument

TEST PROCEDURE

1. The product should be brought to room temperature (15-30°C) prior to use.
2. Open the vial carefully in case of loss of content.
3. Reconstitute each vial with 1 ml of distilled water.



- Gently mix until all material has dissolved. Avoid violent shaking.
- Keep it at room temperature for 5-10 minutes before use.
- Treat the control in the same manner as patient specimen in the assay procedure. Follow the directions of test kit and the instrument application instruction.

ASSIGNED VALUES

Refer to values listed on the target value sheet.

If the result is beyond the range, it indicates the existence of some unreliable factors in the testing system. Referring to the control graph helps judge the accuracy and stability of the testing system.

The expected range of the mean is provided to aid laboratory until it has established its own mean and SD for its methods.

PERFORMANCE CHARACTERISTICS

- Homogeneity: $\leq 15\%$
- Accuracy range: Target value $\pm 40\%$

LIMITATIONS

- This product can only be used on the Getein Platforms.
- Variation exists between different equipments developed by different methods even using the same control product.
- This product is not intended to be used as standard material.

NOTES

- For *in vitro* diagnostic use only.
- Do not use the product beyond the expiration date.
- Avoid multiple freeze-thaw cycles.
- Do not use the product if it is contaminated with bacteria.
- Proper handling and disposal methods should be followed in accordance with local regulations.



DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on cTnI control are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN 980:2008 and International Standard ISO 15223-1:2007.

Key to symbols used			
	Manufacturer		Expiration date
	Do not reuse		Date of manufacture
	Consult instructions for use		Batch code
	Temperature limitation		<i>In vitro</i> diagnostic medical device
	Sufficient for		Authorized representative in the European Community
	CE mark		Do not use if package is damaged

Thank you for purchasing cTnI Control.

Please read this user manual carefully before operating to ensure proper use.

Version: WZK01-S-01



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Please contact Getein Biotech Company if you have any questions.



D-Dimer Control

Cat.# QC 006

User Manual

PRODUCT NAME

D-Dimer Control

PRODUCT SPECIFICATION

D-Dimer Control - Level 1/2/3

Level 1	1 x 1 ml
Level 2	1 x 1 ml
Level 3	1 x 1 ml

INTENDED USE

This product is intended for *in vitro* diagnostic use in the quality control of D-Dimer on the Getein Platforms.

PRINCIPLE

The lyophilized D-Dimer control is prepared from dissolving stable and high quality recombinant D-Dimer antigen into calf serum. With matching equipments and reagents, it can fulfill value transfer work. As different equipments and reagents have uncertainty to some extent, different control results may appear.

CONTENTS

The kit contains:

1. D-Dimer Control –Level 1 1 x 1 ml
2. D-Dimer Control –Level 2 1 x 1 ml
3. D-Dimer Control –Level 3 1 x 1 ml
4. User manual 1
5. Target value sheet 1

MATCHING EQUIPMENTS

FIA8000 Quantitative Immunoassay Analyzer
Getein1100/1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

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Thank you for purchasing D-Dimer Control.

Please read this user manual carefully before operating to ensure proper use.

Version: WZK04-S-01



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