

## Letter of Authorization

To whom it may concern,

We, **Getein Biotech, Inc.** (No.9 Bofu Road, Luhe District, Nanjing, 211505, China), hereby authorize Sanmedico SRL (Address: Republic of Moldova, Chisinau, MD-2059, Petricani street, 88/1, office 10 ) as our official and non-exclusive distributor for registration, promoting, selling, distributing and providing after-sale services of under-mentioned product in the territory of Moldova only:

FIA8000 Quantitative Immunoassay Analyzer and Reagents

Getein1100 Immunofluorescence Quantitative Analyzer and Reagents

Getein1160 Immunofluorescence Quantitative Analyzer and Reagents

Getein 1600 Immunofluorescence Quantitative Analyzer and Reagents

Sanmedico SRL will comply with the laws and regulations of the countries and regions where they are located in and where they are selling mentioned product.

Sanmedico SRL will carry out marketing efforts to fulfill service and maintenance for above mentioned products and will provide with users benefits of having a local stock of above mentioned products and on-time delivery with every order, supported by a local service in local language.

This authorization starts from **1<sup>st</sup> Jan, 2024** and will be valid to **31th, December, 2024** .

Getein Biotech, Inc. has the right to terminate the authorization before validity and will inform Sanmedico SRL with 10 days in advance.

  
基蛋生物科技股份有限公司  
**Getein Biotech, Inc.**  
**GETEIN BIOTECH, INC.**  
Seal & Signature

Authority Person Name: **Steven Zhou**

Authority Person Position: **Regional Manager**

Date: **2023.12.13**

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: **Getein Biotech, Inc.**  
No.9 Bofu Road  
Luhe District  
Nanjing  
Jiangsu  
211505  
China

基蛋生物科技股份有限公司  
中国  
江苏省  
南京市  
六合区  
沿江工业开发区  
博富路9号  
邮编: 211505

Holds Certificate No: **MD 728432**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Please see scope page.

For and on behalf of BSI:

**Graeme Tunbridge, Senior Vice President Medical Devices**

Original Registration Date: 2020-05-29

Latest Revision Date: 2023-04-26

Effective Date: 2023-07-26

Expiry Date: 2026-07-25

Page: 1 of 3



...making excellence a habit.™

Certificate No: **MD 728432**

## Registered Scope:

Design & Development, Manufacture and Distribution of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay), PCR Assay and Colloidal Gold self-testing Assay to detect infectious disease. Design & Development, Manufacture and Distribution of Analyzers in use of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay), PCR Assay to detect infectious disease, Immunofluorescence self-testing Assay to detect dyslipidemia disease, Blood Coagulation Assay to detect thrombotic disease.

研发，生产和销售化学发光法试剂，生化试剂，即时诊断（包括胶体金法，免疫荧光法，干式化学法）试剂，传染病相关PCR分子诊断试剂和胶体金自测试剂。研发，生产和销售用于化学发光法试剂，生化试剂，即时诊断（包括胶体金法，免疫荧光法，干式化学法）试剂，传染病相关PCR分子诊断试剂，血脂异常疾病相关免疫荧光自测试剂，血栓疾病相关血凝试剂配套使用的分析仪。



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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

An electronic certificate can be authenticated [online](#).

Printed copies can be validated at [www.bsi-global.com/ClientDirectory](http://www.bsi-global.com/ClientDirectory) or telephone +86 10 8507 3000.

Information and Contact: BSI, John M. Keynesplein 9, 1066 EP Amsterdam The Netherlands. Tel: +31 (0) 20 3460 780

BSI Group The Netherlands B.V., registered in the Netherlands under number 33264284, at John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands

A Member of the BSI Group of Companies.

Certificate No: **MD 728432**

Location

Getein Biotech, Inc.  
No.9 Bofu Road  
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211505  
China  
基蛋生物科技股份有限公司  
中国  
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Registered Activities

Design & Development, Manufacture and Distribution of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay), PCR Assay and Colloidal Gold self-testing Assay to detect infectious disease. Design & Development, Manufacture and Distribution of Analyzers in use of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay), PCR Assay to detect infectious disease, Immunofluorescence self-testing Assay to detect dyslipidemia disease, Blood Coagulation Assay to detect thrombotic disease.  
研发, 生产和销售化学发光法试剂, 生化试剂, 即时诊断 (包括胶体金法, 免疫荧光法, 干式化学法) 试剂, 传染病相关PCR分子诊断试剂和胶体金自测试剂。 研发, 生产和销售用于化学发光法试剂, 生化试剂, 即时诊断 (包括胶体金法, 免疫荧光法, 干式化学法) 试剂, 传染病相关PCR分子诊断试剂, 血脂异常疾病相关免疫荧光自测试剂, 血栓疾病相关血凝试剂配套使用的分析仪。

Getein Biotech, Inc.  
No. 6 KeFeng Road  
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基蛋生物科技股份有限公司  
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南京  
江北新区  
科丰路6号  
邮编: 211505

Manufacture of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay), Colloidal Gold self-testing Assay to detect infectious disease. Manufacture of Analyzers in use of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay), PCR Assay to detect infectious disease, Immunofluorescence self-testing Assay to detect dyslipidemia disease, Blood Coagulation Assay to detect thrombotic disease.  
生产化学发光法试剂, 生化试剂, 即时诊断 (包括胶体金法, 免疫荧光法, 干式化学法) 试剂和传染病相关胶体金自测试剂。 生产用于化学发光法试剂, 生化试剂, 即时诊断 (包括胶体金法, 免疫荧光法, 干式化学法) 试剂, 传染病相关PCR分子诊断试剂, 血脂异常疾病相关免疫荧光自测试剂, 血栓疾病相关血凝试剂配套使用的分析仪。

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# EC Declaration of Conformity

according to Directive 98/79/EC, on in vitro diagnostic medical devices

Ref. No.:20220513-B03

**Manufacturer**  
(Name, Address)

**Getein Biotech, Inc.**  
No. 9 Bofu Road, Luhe District, Nanjing, 211505, China

**Authorized Representative**  
(Name, Address)

**CMC Medical Devices & Drugs S.L.**  
Add: C/ Horacio Lengo N° 18, CP 29006, Málaga, Spain

**Medical device**

No.	Product Name
1	FIA 8000 Quantitative Immunoassay Analyzer
2	Cardiac Troponin I Fast Test Kit
3	One Step Test for cTnI (Colloidal Gold)
4	One Step Test for NT-proBNP (Colloidal Gold)
5	One Step Test for hs-CRP+CRP (Colloidal Gold)
6	One Step Test for NT-proBNP/cTnI (Colloidal Gold)
7	One Step Test for CK-MB/cTnI/Myo (Colloidal Gold)
8	One Step Test for D-Dimer (Colloidal Gold)
9	One Step Test for PCT (Colloidal Gold)
10	One Step Test for CysC (Colloidal Gold)
11	One Step Test for mAlb (Colloidal Gold)
12	One Step Test for NGAL (Colloidal Gold)
13	One Step Test for $\beta_2$ -MG (Colloidal Gold)
14	One Step Test for HbA1c (Colloidal Gold)
15	One Step Test for H-FABP (Colloidal Gold)
16	One Step Test for PCT/CRP (Colloidal Gold)
17	One Step Test for CK-MB/cTnI/H-FABP (Colloidal Gold)
18	One Step Test for HCG+ $\beta$ (Colloidal Gold)
19	One Step Test for CK-MB (Colloidal Gold)
20	One Step Test for CK-MB/cTnI (Colloidal Gold)
21	One Step Test for T3 (Colloidal Gold)
22	One Step Test for T4 (Colloidal Gold)
23	One Step Test for TSH (Colloidal Gold)
24	One Step Test for Scr (Colloidal Gold)
25	One Step Test for PLGF (Colloidal Gold)
26	One Step Test for HCY (Colloidal Gold)



- 27 One Step Test for Anti-CCP (Colloidal Gold)
- 28 One Step Test for 25-OH-VD (Colloidal Gold)
- 29 One Step Test for Lp-PLA2 (Colloidal Gold)
- 30 One Step Test for FOB (Colloidal Gold)
- 31 One Step Test for *H. pylori* /FOB (Colloidal Gold)
- 32 One Step Test for SAA (Colloidal Gold)
- 33 One Step Test for *H. pylori* (Colloidal Gold)
- 34 One Step Test for PRL (Colloidal Gold)
- 35 One Step Test for AFP (Colloidal Gold)
- 36 One Step Test for CEA (Colloidal Gold)
- 37 Cardiac Troponin I Fast Test Kit Qualitative
- 38 cTnI Rapid Test (Colloidal Gold Assay)
- 39 Dengue NS1 Ag Rapid Test (Colloidal Gold Assay)
- 40 Dengue IgG/IgM Combo Rapid Test (Colloidal Gold Assay)
- 41 Dengue NS1 Ag-IgG/IgM Combo Rapid Test (Colloidal Gold Assay)
- 42 Malaria P.f/P.v Ag Rapid Test (Colloidal Gold Assay)
- 43 Malaria P.f/Pan Ag Rapid Test (Colloidal Gold Assay)
- 44 Malaria P.f Ag Rapid Test (Colloidal Gold Assay)
- 45 HSV-I IgG/IgM Rapid Test (Colloidal Gold Assay)
- 46 HSV-II IgG/IgM Rapid Test (Colloidal Gold Assay)
- 47 Influenza A/B Rapid Test (Colloidal Gold Assay)
- 48 Strep A Rapid Test (Colloidal Gold Assay)
- 49 Strep B Rapid Test (Colloidal Gold Assay)
- 50 RSV/Influenza A/B Combo Rapid Test (Colloidal Gold Assay)
- 51 RSV Rapid Test (Colloidal Gold Assay)
- 52 Dengue IgG/IgM Rapid Test
- 53 Dengue NS1 Ag-IgG/IgM Rapid Test
- 54 Dengue NS1 Ag Rapid Test
- 55 Influenza A/B Rapid Test
- 56 HSV-I IgG/IgM Rapid Test
- 57 HSV-II IgG/IgM Rapid Test
- 58 Malaria P.f Ag Rapid Test
- 59 Malaria P.f/P.v Ag Rapid Test
- 60 Malaria P.f/Pan Ag Rapid Test
- 61 RSV/Influenza A/B Rapid Test
- 62 RSV Rapid Test
- 63 Strep A Rapid Test
- 64 Strep B Rapid Test

**Classification**

Other device (according to Annex II of the directive 98/79/EC)

**Conformity  
assessment route**

Annex III of the 98/79/EC

**Applicable  
coordination  
standards**

EN 13612:2002	EN ISO 14971:2019	EN ISO15223-1:2016
EN ISO 18113-1:2011	EN ISO 18113-2:2011	EN ISO 18113-3:2011
EN ISO 23640:2015	EN ISO 13485:2016	ISO 780:2015
EN 61326-2-6:2006	IEC 61326-1:2013	
EN 61010-2-101:2002	IEC 61010-1:2010	

Signatory representative declares herein the above-mentioned device meets the basic requirements of the European Parliament and the Council's in vitro diagnostic medical devices directive: 98/79/EC Annex I.

This declaration of conformity is based on European Parliament and the Council's 98/79/EC directive Annex III. The compiled technical file and quality system document according to 98/79/EC directive Annex III are testified and the quality system certificate has issued by BSI Group The Netherlands B. V. The manufacturer is exclusively responsible for the declaration of conformity.

**General Manager** Enben Su

*Nanjing*

*13<sup>th</sup>, May, 2022*

(place and date of issue)



(name and signature or equivalent  
marking of authorized person)

CE

# CERTIFICATE

*Getein Biotech*

hereby certifies

**Mr. Vitalie Goreacii**

**from Sanmedico SRL.**

Completion of Getein Products Technical and Operational Training  
& Qualification of After-sales Service

基蛋生物科技股份有限公司  
GETEIN BIOTECH, INC.





IVD Industry  
POCT Leading Brand

# FIA8000

*Quantitative Immunoassay Analyzer*

PREMIUM POINT OF CARE SOLUTION



# FIA8000 *Quantitative Immunoassay Analyzer*



## ►► Highlights

- ◆ **Portable Design**      Small in size (250 x 250 x 120mm); Light in weight (1.8kg)
- ◆ **Multiplex Test Items**      Cardiac; Inflammation monitoring; Diabetes mellitus; Fertility; Renal function etc.
- ◆ **Easy to Use**      Ready-to-use cassette, one-step test, automatic print, quantitative result
- ◆ **Reliable Performance**       $CV \leq 1\%$ ;  $r \geq 0.990$
- ◆ **LIS and HIS Connectivity**

## ►► Test Items

<b>CARDIAC</b>	cTnI	NT-proBNP	NT-proBNP/cTnI	CK-MB/cTnI/Myo
	H-FABP	CK-MB/cTnI/H-FABP		
<b>VENOUS THROMBOEMBOLISM</b>		D-Dimer		
<b>INFLAMMATION MONITORING</b>		hs-CRP	PCT	
<b>DIABETES CARE</b>		HbA1c		
<b>FERTILITY</b>		HCG+β		
<b>RENAL FUNCTION</b>		β <sub>2</sub> -MG	mAlb	CysC      NGAL

## ►► Application Department

The analyzer can be widely applied to clinical departments including Cardiology Dept., Clinical Laboratory, Emergency Dept., ICU, Oncology Dept., Nephrology Dept., Pediatrics Dept., Endocrinology Dept., Gynecology Dept., Respiratory Dept., Gastroenterology Dept., Urology Dept. etc.

## Flexible Operation Modes

### Inside Mode (Automatic Timing)



Sample dispense



Test card insert



Press "ENT" button



Result printed automatically after reaction

### Outside Mode (Manual Timing)



Sample dispense



Timing the reaction manually



Test card insert



Result printed automatically in 5-8s

## Technical Data

Assay Method	Lateral Flow Chromatography (Colloidal Gold)	
Test Result	Quantitative	
Language	Chinese/English/German/Spanish/Serbian (French,Russian,Arabic,Vietnamese etc. are under developing)	
Display	5.6 Inch Touch Screen; Resolution 640×480	
Printer	Internal Thermal Printer	
Working Environment	Temperature	+15 °C - 35 °C
	Relative humidity	10% - 85%
	Air pressure	70.0kPa - 106.0kPa
Power Supply	AC 100~240V, 50~60 Hz	
Data Storage	10,000 results can be saved	
Dimensions	Height	120mm
	Width	250mm
	Length	250mm
Weight	1.8kg	

# FIA8000 Parameters

Cat.#	Test Item	Disease	Measuring Range	Sample	Cut-off Value	Reaction Time
CG 1001	cTnI	Myocardial infarction	0.5~50.0ng/ml	S/P/W.B	0.5ng/ml	15min
CG 1002	NT-proBNP	Heart failure	100~35000pg/ml	S/P/W.B	300pg/ml	15min
CG 1003	hs-CRP	Cardiovascular inflammatory diseases; Inflammatory disorders	0.5~200mg/L	S/P/W.B/ Fingertip blood	3mg/L 10mg/L	90s
CG 1004	NT-proBNP /cTnI	Heart failure; Acute coronary syndrome	100~12000pg/ml 0.5~50.0ng/ml	S/P/W.B	300pg/ml 0.5ng/ml	18min
CG 1005	CK-MB /cTnI /Myo	Myocardial injury	2.5~80.0ng/ml 0.5~50.0ng/ml 30~1000ng/ml	S/P/W.B	5ng/ml 0.5ng/ml 70ng/ml	15min
CG 1006	D-Dimer	Venous thromboembolism; Pulmonary embolism	0.1~10.0mg/L	P/W.B	0.5mg/L	7min
CG 1007	PCT	Sepsis; Septic shock	0.1~50ng/ml	S/P/W.B	0.1ng/ml	15min
CG 1008	CysC	Early diagnosis of kidney disease; Detection of kidney damage for surgery patients	0.5~10.0mg/L	S/P/W.B	0.51~1.09 mg/L	3min
CG 1009	mAlb	Early diagnosis and evaluation of diabetic nephropathy	10~200mg/L	Urine	20mg/L	3min
CG 1010	NGAL	The best indicator of early renal injury	50~5000ng/ml	S/Urine	Serum:200ng/ml Urine:100ng/ml	3min
CG 1011	$\beta_2$ -MG	Kidney damage for diabetic & hypertensive patients	0.5~20.0mg/L	S/P/W.B	0.8~3.0 mg/L	3min
CG 1012	CK-MB /cTnI	Myocardial injury	2.5~80.0ng/ml 0.5~50.0ng/ml	S/P/W.B	5ng/ml 0.5ng/ml	15min
CG 1013	HCG+ $\beta$	Pregnancy early test	5~10000mIU/ml	S/P/W.B	5.1mIU/ml	10min
CG 1017	HbA1c	Diabetes mellitus	2%~14%	W.B	3.8%~5.8%	3min
CG 1018	CK-MB	Myocardial injury	2.5~80.0ng/ml	S/P/W.B	5ng/ml	15min

 **Getein Biotech, Inc.**

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CE

IVD

 TUV Rheinland





# 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 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.**

## 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).

- Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
- Do not use heat-inactivated samples.
- SAMPLE VOLUME: **120 µl**.

## TEST PROCEDURE

- Collect specimens according to user manual.
- Test card, sample and reagent should be brought to room temperature before testing.
- 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).
- On the main interface of FIA8000, press "ENT" button to enter testing interface.
- 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).
- 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 cTnI was determined by testing samples from 500 apparently healthy individuals. The 99<sup>th</sup> 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

- 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 interferences may influence the results. The table below listed the maximum allowance of these potential interferences.

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

## REFERENCES













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

Version: WCG02-DL-S-01



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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.**

## 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 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 95<sup>th</sup> 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 interferences 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 interferences.

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

## REFERENCES













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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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# One Step Test for HbA1c

(Colloidal Gold)

User Manual

Cat.# CG1017

## INTENDED USE

One Step Test for HbA1c is intended for the quantitative measurement of HbA1c in whole blood. This test is used as an aid for monitoring glycemic control in diabetics. In addition, it can identify people at risk of developing the disease and ongoing monitoring.

## SUMMARY

Hemoglobin is the protein molecule in red blood cells with the main function transport oxygen and carbon dioxide in blood. HbA1c belongs to the glycated, a fraction formed by the attachment of various sugars to the Hb molecule and is proportional to average blood glucose concentration over the previous four weeks to three months. One advantage of using HbA1c for diagnosis is that the test does not require a fasting blood sample. Although HbA1c testing is mainly used for monitoring blood sugar control in patients with diabetes, the World Health Organization (WHO) now recommends that HbA1c can be used as a diagnostic test for diabetes, provided that stringent quality assurance tests are in place and assays are standardised to criteria aligned to the international reference values.

## PRINCIPLE

The test uses an anti-human Hb monoclonal antibody conjugated with colloidal gold and an anti-human HbA1c monoclonal antibody coated on the test line. After the sample

has been applied to the test strip, the gold-labelled anti-human Hb monoclonal antibody binds with the HbA1c and Hb in sample proportionally and forms marked antigen-antibody complex. The complex moves to the detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by the anti-human HbA1c monoclonal antibody. The color intensity of the test line increases in proportion to the amount of HbA1c in sample.

Then insert test card into the FIA8000 Quantitative Immunoassay Analyzer (hereinafter referred to as FIA8000), the concentration of HbA1c is measured and displayed on the screen. The HbA1c concentration is stored in the FIA8000 and is available on demand. The result can be transmitted to the lab or hospital information system, if it is connected to FIA8000.

## CONTENTS

### A kit contains:

1. Getein HbA1c 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, nitrocellulose membrane (the colloidal gold is coated with gold-labelled anti-human HbA1c monoclonal antibody, the test line is coated with an anti-human HbA1c polyclonal 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.**

## 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 bag 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 **whole blood samples**. **Heparin, sodium citrate and EDTA** can be used as the anticoagulant under aseptic conditions.
2. The test is for human blood, other specimens or bodily fluids may not get accurate results.
3. The test should be performed within 4 hours after whole blood collection.
4. Samples could be kept for 7 days at 2~8°C and avoid cryopreservation.
5. Samples must be recovered to room temperature before testing.
6. SAMPLE VOLUME: **10 µl**.

## TEST PROCEDURE

1. Collect specimens 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 **10 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 mixture 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 test card can be detected and the result will be printed 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.
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 RANGE OF VALUE

HbA1c concentration is determined using samples obtained from 345 apparently healthy individuals. The normal value for HbA1c is 3.8%-5.8%.

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

## PERFORMANCE CHARACTERISTICS

Measuring Range	2%-14%
Lower Detection Limit	≤2%
Within-Run Precision (n=10)	≤10%
Between-Run Precision	≤15%

Accuracy: verify with comparison experiments, the correlation coefficient  $r \geq 0.990$ , the relative error  $\leq 20\%$ .

## LIMITATIONS

1. The result of the test should be evaluated in the context of all the clinical and laboratory data available. In those instances where the laboratory results do not agree with the clinical evaluation, additional tests should be performed accordingly.
2. Some substances in blood as listed below may interfere with the test and cause erroneous results. The maximum allowance concentration of them is as follows:

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













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10 to 14 in the prediction of pre-eclampsia[J]. 2014.

## DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on One Step Test For HbA1c (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 HbA1c (Colloidal Gold). Please read this user manual carefully before operating to ensure proper use.

Version: WCG22-DL-S-02



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# 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).
- 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 95<sup>th</sup> percentile of the concentration for NT-proBNP is 185 pg/ml and the 97.5<sup>th</sup> percentile of the concentration for NT-proBNP is 300 pg/ml. Because of the apparent difference of the concentration of NT-proBNP among different age groups, the reference values of the NT-proBNP are reported in groups. Details refer to Table 1. Clinical diagnosis value: refer to Roche criterion, details see Table 2.

Table 1 NT-proBNP reference value

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

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

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

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

#### PERFORMANCE CHARACTERISTICS

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

Recovery:

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

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 interferences may influence the results. The table below listed the maximum allowance of these potential interferences.

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

#### REFERENCES

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- 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		<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 NT-proBNP (Colloidal Gold). Please read this user manual carefully before operating to ensure proper use.

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# 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).
- 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 99<sup>th</sup> 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<sup>[4]</sup>:

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

- 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 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













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- 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).

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