Getein Biotech, Inc.
Add: No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel: 86-25-68568508 Email: overseas@geteincom.cn Web: www.bio-GP.com.cn

Document No.: GP-GMSQ-2024121101

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 Jan 1, 2025and will be valid to December 31 2025.

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

Getein Biotech, Inc.

Name: Steven Zhou
Position: Overseas Sales Director

基蛋生物科技股份有限公司
GETEIN BIOTECH, INC.

Digitally signed by Dolgopol Iulian
Date: 2026.02.24 12:07:51 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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

...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。

Original Registration Date: 2020-05-29
Latest Revision Date: 2023-04-26

Effective Date: 2023-07-26
Expiry Date: 2026-07-25

Certificate No: **MD 728432**

Location	Registered Activities
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	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 Jiangbei New District Nanjing Jiangsu 211505 China 基蛋生物科技股份有限公司 中国 江苏省 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。

Original Registration Date: 2020-05-29

Effective Date: 2023-07-26

Latest Revision Date: 2023-04-26

Expiry Date: 2026-07-25

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 Nº 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 β_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+β (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
13th, May, 2022

(place and date of issue)

Enben Su

(name and signature or equivalent marking of authorized person)

CE

Cat. #	TEST ITEMS	DISEASES	MEASURING RANGE	SAMPLE TYPES	SAMPLE VOLUME	REACTION TIME	QUALIFICATION	
CARDIAC MARKERS								
CG1001	cTnI	Myocardial infarction	0.50-50.00ng/mL	S/P/WB	120μL	15min	CE	NMPA
CG1002	NT-proBNP	Heart failure	100-35000pg/mL	S/P/WB	120μL	15min	CE	NMPA
CG1004	NT-proBNP /cTnI	Heart failure, acute coronary syndrome	100-12000pg/mL 0.50-50.00ng/mL	S/P/WB	120μL	18min	CE	NMPA
CG1005	CK-MB /cTnI/Myo	Myocardial injury	2.50-80.00ng/mL 0.50-50.00ng/mL 30.00-1000.00ng/mL	S/P/WB	120μL	15min	CE	NMPA
CG1006	D-Dimer	Venous thromboembolism	0.10-10.00mg/L	P/WB	120μL	7min	CE	NMPA
CG1012	CK-MB/cTnI	Myocardial damage/infarction	2.50-80.00ng/mL 0.50-50.00ng/mL	S/P/WB	120μL	15min	CE	
CG1018	CK-MB	Myocardial injury	2.50-80.00ng/mL	S/P/WB	120μL	15min	CE	
Diabetes Mellitus								
CG1017	HbA1c	Diabetes mellitus	2.00%-14.00%	WB	10μL	3min	CE NGSP	NMPA IFCC
Inflammation								
CG1003	hs-CRP+CRP	Cardiovascular inflammation, normal inflammation	0.5-200.0mg/L	S/P/WB Fingertip Blood	10μL	90s	CE	NMPA
CG1007	PCT	Sepsis, bacterial infection	0.10-50.00ng/mL	S/P/WB	120μL	15min	CE	NMPA
Renal Function								
CG1008	CysC	Acute and chronic renal diseases	0.50-10.00mg/L	S/P/WB	10μL	3min	CE	NMPA
CG1009	mAlb	Diabetic nephropathy, hypertensive nephropathy	10.0-200.0mg/L	Urine	120μL	3min	CE	NMPA
CG1010	NGAL	Acute kidney injury	50.0-5000.0ng/mL	S/Urine	10μL	3min	CE	NMPA
CG1011	β_2-MG	Acute and chronic kidney diseases/tumours	0.50-20.00mg/L	S/P/WB	10μL	3min	CE	NMPA
Fertility								
CG1013	HCG+β	Fertility	5.0-100000.0mIU/mL	S/P	100μL	10min	CE	NMPA
Hormone								
CG1024	TSH	Thyroid malfunction	0.10-50.00μIU/mL	S/P	100μL	15min	CE	
Others								
CG1047	*H. Pylori*	*H. Pylori* infection	5-200ng/mL	Stool	100μL	10min	CE	
CG1042	FOB	Gastrointestinal diseases	100-2000ng/mL	Stool	100μL	10min	CE	

Getein Biotech, Inc.
Add: No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel: +86-25-68568508/68568594
Fax: +86-25-68568500
E-mail: sales@getein.com.cn; overseas@getein.com.cn
Web: www.bio-GP.com.cn

FSC CE NMPA NGSP IFCC IVD

WPT2-80-05

Getein Biotech, Inc. | Stock Code 603387

FIA8000

Quantitative Immunoassay Analyzer

MAKE TEST SIMPLE

Optimized solution for point-of-care test.

FIA8000

Quantitative Immunoassay Analyzer

USER-FRIENDLY INTERFACE

- 5.6 Inch touch screen
- PC, LIS, HIS connectivity

SIMPLIFIED OPERATION

- One-step test
- Item auto-recognition
- Optional barcode scanner

RELIABLE AND ADVANCED SYSTEM

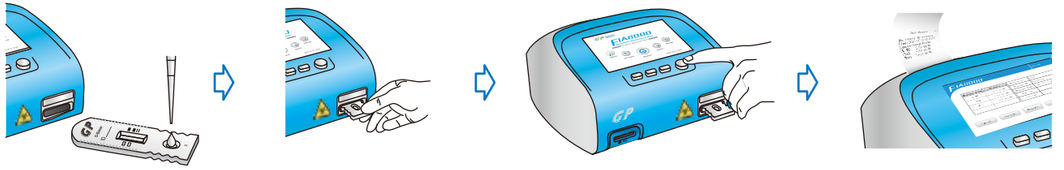
- Up to 10000 data storage
- Multiple quality control
- 5 seconds/test for multiple samples

WIDESPREAD APPLICATION

- Cardiac
- Inflammation
- Diabetes mellitus
- Renal function
- Thyroid malfunction
- Fertility

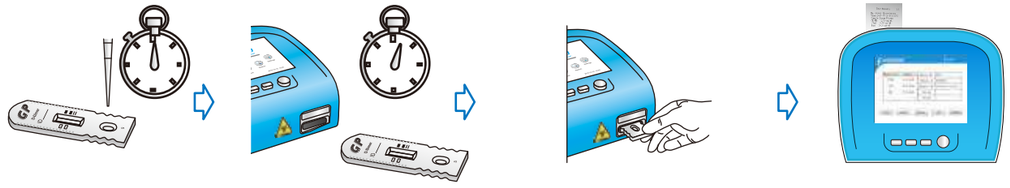
Operation Modes

Inside Mode



Add sample → Insert test kit → Press ‘ENT’ button or Click ‘Measure’ icon → Result printed automatically

Outside Mode



Add sample → Timing manually → Insert test kit → Result printed automatically

TECHNICAL PARAMETERS+

Methodology	Quantitative Immunoassay
Result	Quantitative
Sample Type	WB, plasma, serum, urine
Storage Capacity	10000 data
Language	English/Chinese/Spanish
Screen	5.6 inch touch screen
Power Supply	100-240V~50Hz/60Hz, 60VA
Working Environment	Tempreture: -15~+40℃ Relative humidity ≤93% Air pressure: 50.0~106.0kpa
Dimension	250mm×250mm×120mm (D×W×H)
Weight	1.8 kg

CE IVD

One Step Test for CK-MB/cTnI/Myo

(Colloidal Gold)

User Manual

REF CG1005 for FIA8000
CG3005 for FIA8600

INTENDED USE

One Step Test for CK-MB/cTnI/Myo (Colloidal Gold) is intended for *in vitro* quantitative determination of CK-MB/cTnI/Myo in serum, plasma or whole blood. This test is used as an aid in the clinical diagnosis, prognosis and evaluation of myocardial injury such as Acute Myocardial Infarction (AMI), Unstable Angina, Acute Myocarditis and Acute Coronary Syndrome (ACS).

SUMMARY

Creatine kinases are dimer isozymes composed of two monomer subunits, CK-M (for skeletal muscle derived) and CK-B (for brain derived), which can form all three combinations of monomers: CK-BB, CK-MM, and CK-MB. BB is found primarily in the brain. Skeletal muscles primarily contain the MM isoform, with trace amount of MB (around 1-4% of total CK activity). Cardiac muscles also contain the MM isoform, but higher amount of MB, typically around 20% of total CK activity. CK-MB is a more sensitive marker of myocardial injury than total CK activity, because it has a lower basal level and a much narrower normal range. Medical literatures commonly state that CK-MB levels are elevated in 4 to 6 hours, peak at 10 to 24 hours, and return to normal within 3 to 4 days after an acute myocardial infarction. Classically, an increase of the myocardial-specific enzyme CK-MB is considered as the hallmark of acute myocardial infarction, and increased levels are frequently interpreted by the clinician as objective evidence of myocardial cell damage.

Troponin complex 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; 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 myocardia.

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.

Myoglobin is a small monomeric protein which serves as an intracellular oxygen storage site. It is found in abundance in the muscle and can get through into the blood circulation directly when myocardial cell is damaged mildly. Therefore, myoglobin has been advocated as a sensitive marker for early acute myocardial injury by American College of Cardiology Committee.

PRINCIPLE

Mixed monoclonal antibodies against human CK-MB, cTnI and Myo were conjugated with colloidal gold and another set of anti-human CK-MB/cTnI/Myo monoclonal antibodies were coated on different test lines respectively. After the sample has been applied to the test strip, the gold-labelled anti-human CK-MB, cTnI and Myo monoclonal antibodies will bind with the CK-MB, cTnI and Myo in sample respectively and form marked antigen-antibody complexes. These complexes move to the test card detection zone by capillary action. Then marked antigen-antibody complexes will be captured on different test lines by another set of monoclonal antibody against human CK-MB, cTnI or Myo respectively resulting in purplish red streaks appear on the test lines. The color intensity of each test line increases in proportion to the amount of CK-MB, cTnI or Myo in sample.

Then insert test card into FIA8000/FIA8600 Quantitative Immuno-assay Analyzer (hereinafter referred to as FIA8000 and FIA8600), the concentrations of CK-MB, cTnI and Myo in sample will be determined and displayed on the screen. The value will be stored in FIA8000/FIA8600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

1. A kit for FIA8000/FIA8600 contains:

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

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

2. A test card consists of:

A plastic shell and a reagent strip which is composed of a sample pad, a colloidal gold pad (coated with gold-labeled anti-human CK-MB, cTnI and Myo monoclonal antibodies), nitrocellulose membrane with 3 test lines (these three lines are coated with another anti-human CK-MB, another anti-human cTnI and another anti-human Myo monoclonal antibody, respectively, and the control line C is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

3. Whole blood buffer composition:

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

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

APPLICABLE DEVICE

FIA8000 Quantitative Immunoassay Analyzer
FIA8600 Quantitative Immunoassay Analyzer

STORAGE AND STABILITY

Store the test kit at 4~30°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. Do not use the kit beyond the expiration date.
3. Do not use the test card if the foil pouch is damaged.
4. Do not open pouches until ready to perform the test.
5. Do not reuse the test card.
6. Do not reuse the pipet.
7. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
8. Carefully read and follow user manual to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for ***serum, plasma and whole blood samples. Heparin and sodium citrate*** can be used as the anticoagulant for plasma and whole blood. Samples should be free of hemolysis.
2. Suggest using serum or plasma for better results.
3. Serum or plasma can be used directly. For whole blood sample, one drop of whole blood buffer must be added before testing.
4. If testing is delayed, serum and plasma samples may be stored up to 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 according with test kit lot No.. Perform calibration when necessary (Details refer to FIA8000/8600 User Manual).
4. On the main interface of FIA8000/FIA8600, press "ENT" button (FIA8000) or click on “Measure” icon (FIA8000/8600) to enter testing interface.
5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
6. Put the test card on a clean table, horizontally placed.
7. Using sample transfer pipette, deliver ***120 μL*** of sample into the sample well on the test card (for whole blood sample, one drop of whole blood buffer must be added after loading 120 μL sample on the test card).
8. ***Reaction time: 15 minutes.*** Insert the test card into FIA8000/FIA8600, press "ENT" button (FIA8000) or click on “Measure” icon (FIA8000/FIA8600) after reaction time is elapsed. The result will be shown on the screen and printed automatically.

Notes:

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

TEST RESULTS

Valid: When a purplish-red band appears at the control area (C), use FIA8000/FIA8600 to analyze the test card and get the result.
Invalid: If no colored band appears in the control area (C), the test result is invalid. The test should be repeated and if the same situation happened again, please stop using this batch of products and contact your supplier.
Others: Dilute the sample which concentration is higher than the upper limit with calf serum, the dilution ratio should be less than 5 times.

EXPECTED VALUE

The expected normal value for CK-MB was determined by testing samples from 500 apparently healthy individuals. The 99th percentile of the concentration for CK-MB is 5.00 ng/ml. (The probability that value of a normal person below 5.00 ng/ml is 99%.) 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 0.50 ng/ml. (The probability that value of a normal person below 0.50 ng/ml is 99%.) The expected normal value for Myo was determined by testing samples from 500 apparently healthy individuals. The 95th percentile of the concentration for Myo is 50.0 ng/ml. The 97.5th percentile of the concentration for Myo is 70.0 ng/ml. (According to different Statistics methods, the probability that value of a normal person below 50 ng/ml is 95% or below 70 ng/ml is 97.5%.)
It is recommended that each laboratory establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

	CK-MB	cTnI	Myo
Measuring Range	2.50~80.00 ng/ml	0.50~50.00 ng/ml	30.0~1000.0 ng/ml
Lower Detection Limit	≤ 2.50 ng/ml	≤ 0.50 ng/ml	≤ 30.0 ng/ml
Recovery	96%(mean)	95%(mean)	95%(mean)
Within-Run Precision	≤10%		
Between-Run Precision	≤15%		

LIMITATIONS

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

Interferent	Hemoglobin	Triglyceride	Bilirubin
Concentration (Max)	10 g/L	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 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
4. EN ISO 18113-2:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use .

DESCRIPTION OF SYMBOLS USED

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

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

Thank you for purchasing One Step Test for CK-MB/cTnI/Myo (Colloidal Gold). Please read this user manual carefully before operating to ensure proper use.

Version: WCG09-DL-S-08

Getein Biotech, Inc.
Add.: No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel: +86-25-68568508
Fax: +86-25-68568500
E-mail: tech@getein.com.cn,
overseas@getein.com.cn
Website: www.getein.com

EC REP CMC Medical Devices & Drugs S.L.
Add.: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain
Tel: +34951214054

CE IVD

Cardiac Troponin I Fast Test Kit

User Manual

REF CG1001 for FIA8000
CG3001 for FIA8600

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

CONTENTS

1. A kit for FIA8000/FIA8600 contains:

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

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

2. A test card consists of:

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

3. Whole blood buffer composition:

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

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

APPLICABLE DEVICE

FIA8000 Quantitative Immunoassay Analyzer
FIA8600 Quantitative Immunoassay Analyzer

STORAGE AND STABILITY

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

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. 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 is delayed, serum and plasma samples may be stored up to 7 days at 2~8℃ or stored at -20℃ for 6 months before testing (whole blood sample may be stored up to 3 days at 2~8℃).
5. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
6. Do not use heat-inactivated samples.
7. SAMPLE VOLUME: ***120 μL***.

TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, sample and reagent should be brought to room temperature before testing.
3. Confirm SD card lot No. in according with test kit lot No.. Perform calibration when necessary (Details refer to FIA8000/ 8600 User Manual).
4. On the main interface of FIA8000/FIA8600, press "ENT" button (FIA8000) or click on “Measure” icon (FIA8000/8600) to enter testing interface.
5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
6. Put the test card on a clean table, horizontally placed.
7. Using sample transfer pipette, deliver ***120 μL*** of sample into the sample well on the test card (for whole blood sample, one drop of whole blood buffer must be added after loading 120 μL sample on the test card).
8. ***Reaction time: 15 minutes.*** Insert the test card into FIA8000 /FIA8600, press "ENT" button (FIA8000) or click on “Measure” icon (FIA8000/FIA8600) after reaction time is elapsed. The result will be shown on the screen and printed automatically.

Notes:

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

TEST RESULTS

Valid: When a purplish-red band appears at the control area (C), use FIA8000/FIA8600 to analyze the test card and get the result.
Invalid: If no colored band appears in the control area (C), the test result is invalid. The test should be repeated and if the same situation happened again, please stop using this batch of products and contact your supplier.
Others: Dilute the sample which concentration is higher than the upper limit with calf serum, the dilution ratio should be less than 5 times.

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 0.50 ng/ml. (The probability that value of a normal person below 0.50 ng/ml is 99%.) It is recommended that each laboratory establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range	0.50~50.00 ng/ml
Lower Detection Limit	≤ 0.50 ng/ml
Within-Run Precision (n=10)	≤10%
Between-Run Precision	≤15%
Recovery	95% (mean)

LIMITATIONS

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

Interferent	Hemoglobin	Triglyceride	Bilirubin
Concentration (Max)	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 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
4. EN ISO 18113-2:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on 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 ISO 15223-1:2021.

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

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

Version: WCG02-DL-S-09

Getein Biotech, Inc.
Add.: No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel: +86-25-68568508
Fax: +86-25-68568500
E-mail: tech@getein.com.cn,
overseas@getein.com.cn
Website: www.getein.com

EC REP CMC Medical Devices & Drugs S.L.
Add.: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain
Tel: +34951214054

CE IVD

One Step Test for D-Dimer

(Colloidal Gold)

Instructions for Use REF CG1006 for FIA8000 CG3006 for FIA8600

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

CONTENTS

1. A kit for FIA8000/FIA8600 contains:
Package specifications: 25 tests/box, 10 tests/box
1) Getein D-Dimer test card in a sealed pouch with desiccant
2) Disposable pipet
3) Sample diluent
4) Instructions for use: 1 piece/box
5) SD card: 1 piece/box

2. A test card consists of:
A plastic shell and a reagent strip which is composed of a sample pad, a colloidal gold pad (coated with 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.

3. 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
FIA8600 Quantitative Immunoassay Analyzer

STORAGE AND STABILITY

Store the test card at 4~30℃ 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℃ with a valid period of 24 months.
Store the sample diluent at 2~8℃ 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 instructions for use 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 is delayed, plasma sample may be stored up to 3 days at 2~8℃ or stored at -20℃ for 1 months before testing (whole blood sample may be stored up to 3 days at 2~8℃).
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 instructions for use.
2. Test card, sample and reagent should be brought to room temperature before testing.
3. Confirm SD card lot No. in according with test kit lot No..Perform calibration when necessary (Details refer to FIA8000/8600 instructions for use).
4. On the main interface of FIA8000/FIA8600, press "ENT" button (FIA8000) or click on “Measure” icon (FIA8000/8600) to enter testing interface.
5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
6. Put the test card on a clean table, horizontally placed.

7. Using sample transfer pipette, deliver ***120 µl*** of sample into one tube of sample diluent, mix gently and thoroughly. Then drop ***120 µl*** of sample mixture into the sample port on the test card.
8. ***Reaction time: 7 minutes.*** Insert the test card into FIA8000 /FIA8600, press "ENT" button (FIA8000) or click on "Measure" icon (FIA8000/FIA8600) after reaction time is elapsed. The result will be shown on the screen and printed automatically.

Notes:

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

TEST RESULTS

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

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

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

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 0.50 mg/L. (The probability that value of a normal person below 0.50 mg/L is 95%.)

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

PERFORMANCE CHARACTERISTICS

Measuring Range	0.10~10.00 mg/L
Lower Detection Limit	≤0.10 mg/L
Within-Run Precision (n=10)	≤10%
Between-Run Precision	≤15%
Recovery	99%

Method Comparison:

The assay was compared with Sysmex CA7000 and Siemens D-Dimer PLUS assay with 200 blood 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, Klil-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, Muiña 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, 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.
3. EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
4. EN ISO 18113-2:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on One Step Test for 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 ISO 15223-1:2021.

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

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

Version: WCG05-DL-S-09

Getein Biotech, Inc.
Add: No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel: +86-25-68568508
Fax: +86-25-68568500
E-mail: tech@getein.com.cn
overseas@getein.com.cn
Website: www.getein.com

EC REP CMC Medical Devices & Drugs S.L.
Add.: C/ Horacio Lengo N° 18, CP 29006, Málaga, Spain
Tel: +34951214054

CE IVD

One Step Test for HbA1c

(Colloidal Gold)

Instructions for Use REF CG1017 for FIA 8000 CG3017 for FIA 8600

INTENDED USE

One Step Test for HbA1c (Colloidal Gold) 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.
For professional and laboratory use only.

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 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. Then marked antigen-antibody complex is captured on the test line by the anti-human HbA1c. The color intensity of the test line increases in proportion to the amount of HbA1c in sample.

CONTENTS

Materials provided	Main Contents	10 T/kit	25 T/kit
HbA1c test card	Gold-labelled anti-human Hb monoclonal antibody, anti-human HbA1c monoclonal antibody and polyclonal IgG antibody.	10 pcs	25 pcs
Disposable pipet	/	10 pcs	25 pcs
Sample diluent	Phosphate buffer matrix, surfactant, preservative	10 tubes	25 tubes
Instructions for use	/	1 pc	1 pc
SD card	/	1 pc	1 pc

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

APPLICABLE DEVICE

FIA 8000 Quantitative Immunoassay Analyzer
FIA 8600 Quantitative Immunoassay Analyzer

STORAGE AND STABILITY

Store the test kit at 4~30°C with a valid period of 24 months. The test kits are stable until the expiry date printed on the labels.
Use the test card within 1 hour once the foil pouch is opened.

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. For professional and laboratory use only, not for near-patient test and self-testing.
3. Do not use the test card if the foil pouch is damaged.
4. Do not open pouches until performing the test.
5. Handle all specimens as potentially infectious. The foil bag is nondegradable. Proper handling and disposal methods should be followed in accordance with local regulations.
6. It is recommended that operators take necessary self-protection measures (work clothes, goggles and disposable gloves, etc) when touching kits or samples.

SPECIMEN COLLECTION AND PREPARATION

1. Whole blood can be used as samples in the assay.
2. EDTA can be used as the anticoagulant for whole blood.
3. Whole blood is stable for 4 hours at room temperature (15~30°C), 3 days at 2-8°C and avoid cryopreservation.
4. Specimens must be recovered to room temperature before testing and mix the blood sample thoroughly before testing.
5. SAMPLE VOLUME: ***10 µl.***

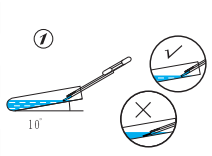
TEST PROCEDURE

1. User must carefully read and operate in strict accordance with the instructions for use before testing, otherwise reliable results cannot be guaranteed.
2. Test kit and sample should be brought to room temperature before testing.
3. Confirm SD card lot No. in according with test kit lot No.. Perform calibration when necessary (Details refer to FIA 8000/ 8600 User Manual).
4. On the main interface of FIA 8000/FIA 8600, press "ENT" button (FIA 8000) or click on “Measure” icon (FIA 8000/8600) to enter testing interface.
5. Select the corresponding “Sample” on the analyzer according to the sample type (Details refer to FIA 8000/ 8600 User Manual).
6. Remove the test card from the sealed pouch immediately before use. Put the test card on a clean table, horizontally placed.
7. Deliver ***10 µL*** of sample into one tube of sample diluent using disposable pipet or pipette, mix gently and thoroughly. Then drop ***100 µL*** of sample mixture into the sample well on the test card.
8. ***Reaction time: 3 minutes.*** Insert the test card into FIA 8000/ FIA 8600, press "ENT" button (FIA 8000) or click on “Measure”icon (FIA 8000/FIA 8600) after reaction time is elapsed. The result will be shown on the screen and printed automatically.

Notes:
1. It is required to perform calibration when using a new batch of kits.
2. Make sure the test card insertion is correct and complete.

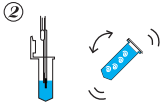
3. The directions for using disposable pipet are as follows:

Directions to use disposable pipet

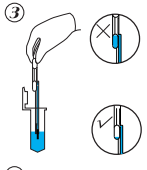


Insert the disposable pipet into the sample tube, gently touch the liquid surface with the capillary tip, and draw the sample.

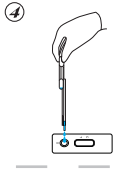
Note: Do not immerse the exhaust pipe below the liquid level.



Insert the disposable pipet (including the exhaust tube) into the dilution liquid, gently squeeze the suction bulb to perform 2-3 aspiration washing cycles, then mix the dilution manually.



Insert the disposable pipet (including the exhaust tube) into the dilution liquid, firmly squeeze the suction bulb to aspirate the mixed sample.



Squeeze the suction bulb and drop the mixed sample vertically into the sample well on the test card.

TEST RESULTS

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

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

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:

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

EXPECTED VALUE

The expected normal value for HbA1c was determined by testing samples from 345 healthy, non-pregnant individuals. The normal value for HbA1c is 3.80%-5.80%.
It is recommended that each laboratory establish its expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range	2.00%-14.00%
Limit of Detection	≤2.00%
Within-Run Precision	≤10%
Between-Lot Precision	≤15%

Method Comparison:
The assay was compared with Roche P800 Automatic Biochemistry Analyzer and Sichuan Maccura HbA1c assay with 200 blood samples. The correlation coefficient (r) is for HbA1c 0.956.

REFERENCES

1. Cagliero E, Levina E V, Nathan D M. Immediate feedback of HbA1c levels improves glycemic control in type 1 and insulin-treated type 2 diabetic patients[J]. Diabetes care, 1999, 22 (11):1785-1789.
2. Özdamar Ö, Gün i, Keskin U, et al. The role of maternal serumbeta-HbA1c and PAPP-A levels at gestational weeks 10 to 14 in the prediction of pre-eclampsia[J]. 2014.
3. EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
4. EN ISO 18113-2:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer(labelling) - Part 2:

In vitro diagnostic reagents for professional use.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on One Step Test for HbA1c (Colloidal Gold) are the most common ones appearing on medical devices and their packaging. They are explained in more detail in the European Standard EN ISO 15223-1:2021.

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

Thank you for purchasing One Step Test for HbA1c (Colloidal Gold). Please read the instructions for use carefully before operating to ensure proper use.

Version: WCG22-DL-S-11

Getein Biotech, Inc.
Add: No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel: +86-25-68568508
Fax: +86-25-68568500
E-mail: tech@getein.com.cn
overseas@getein.com.cn
Website: www.getein.com

EC REP CMC Medical Devices & Drugs S.L.
Add.: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain
Tel: +34951214054

CE IVD

One Step Test for NT-proBNP

(Colloidal Gold)

User Manual

REF CG1002 for FIA8000
CG3002 for FIA8600

INTENDED USE

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

SUMMARY

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

PRINCIPLE

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

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

CONTENTS

1. A kit for FIA8000/FIA8600 contains:

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

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

2. A test card consists of:

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

3. Whole blood buffer composition:

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

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

APPLICABLE DEVICE

FIA8000 Quantitative Immunoassay Analyzer
FIA8600 Quantitative Immunoassay Analyzer

STORAGE AND STABILITY

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

PRECAUTIONS

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

SPECIMEN COLLECTION AND PREPARATION

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

TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, sample and reagent should be brought to room temperature before testing.
3. Confirm SD card lot No. in according with test kit lot No..Perform calibration when necessary (Details refer to FIA8000/8600 User Manual).
4. On the main interface of FIA8000/FIA8600, press "ENT" button (FIA8000) or click on “Measure” icon (FIA8000/8600) to enter testing interface.
5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
6. Put the test card on a clean table, horizontally placed.
7. Using sample transfer pipette, deliver ***120 μL*** of sample into

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

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

Notes:

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

TEST RESULTS

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

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

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

EXPECTED VALUE

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

Table 1 NT-proBNP reference value

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

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

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

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

PERFORMANCE CHARACTERISTICS

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

LIMITATIONS

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

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

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4. EN ISO 18113-2:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use .

DESCRIPTION OF SYMBOLS USED

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

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

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

Version: WCG03-DL-S-08

Getein Biotech, Inc.
Add.: No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel: +86-25-68568508
Fax: +86-25-68568500
E-mail: tech@getein.com.cn, overseas@getein.com.cn
Website: www.getein.com

EC REP CMC Medical Devices & Drugs S.L.
Add.: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain
Tel: +34951214054

CE IVD

One Step Test for PCT

(Colloidal Gold)

User Manual

REF CG1007 for FIA8000
CG3007 for FIA8600

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

CONTENTS

1. A kit for FIA8000/FIA8600 contains:

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

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

2. A test card consists of:

A plastic shell and a reagent strip which is composed of a sample pad, a colloidal gold pad, 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.

3. Whole blood buffer composition:

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

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

APPLICABLE DEVICE

FIA8000 Quantitative Immunoassay Analyzer
FIA8600 Quantitative Immunoassay Analyzer

STORAGE AND STABILITY

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

PRECAUTIONS

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

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for ***serum, plasma and whole blood samples. Heparin and sodium citrate*** can be used as the anticoagulant for plasma and whole blood. Samples should be free of hemolysis.
2. Suggest using serum or plasma for better results.
3. Serum or plasma can be used directly. For whole blood sample, one drop of whole blood buffer must be added before testing.
4. If testing is delayed, serum and plasma samples may be stored up to 7 days at 2~8℃ or stored at -20℃ for 6 months before testing (whole blood sample may be stored up to 3 days at 2~8℃).
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 according with test kit lot No.. Perform calibration when necessary (Details refer to FIA8000/8600 User Manual).
4. On the main interface of FIA8000/FIA8600, press "ENT" button (FIA8000) or click on “Measure” icon (FIA8000/8600) to enter testing interface.
5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
6. Put the test card on a clean table, horizontally placed.
7. Using sample transfer pipette, deliver ***120 μL*** of sample into

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

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

Notes:

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

TEST RESULTS

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

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

Others: Dilute the sample which concentration is higher than the upper limit with calf serum or negative samples, the dilution ratio should be less than 5 times.

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 0.10 ng/ml. (The probability that value of a normal person below 0.10 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
< 0.50 ng/ml	Local bacterial infection is possible, systemic infection (sepsis) is not likely.
≥ 0.50 and < 2.00 ng/ml	Systemic infection (sepsis) is possible, a moderate risk of severe sepsis and/or septic shock.
≥ 2.00 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	0.10~50.00 ng/ml
Lower Detection Limit	≤0.10 ng/ml
Within-Run Precision	≤10%
Between-Run Precision	≤15%
Recovery	98%

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

1. Balcl 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.
2. Schuetz P, Christ-Crain M, Thomann R, et al. Effect of procalcitonin-based guidelines vs standard guidelines on antibiotic use in lower respiratory tract infections: the ProHOSP randomized controlled trial. JAMA. Sep 9 2009; 302(10):1059-66.
3. EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
4. EN ISO 18113-2:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on One Step Test for 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 ISO 15223-1:2021.

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

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

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Getein Biotech, Inc.
Add.: No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel: +86-25-68568508
Fax: +86-25-68568500
E-mail: tech@getein.com.cn,
overseas@getein.com.cn
Website: www.getein.com

EC REP CMC Medical Devices & Drugs S.L.
Add.: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain
Tel: +34951214054