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-2022-110

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. as our official distributor for registering, promoting, selling, distributing, taking part in tenders, maintaining & after sale technical services of under-mentioned product in the territory of Moldova:

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 to, otherwise, the risks and losses arising therefrom shall be undertaken by Sanmedico SRL

This authorization starts from Jan 1, 2022 and will be valid to December 31 2023

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 Monastîrschii Viorica
Date: 2023.12.11 14:25:27 EET
Reason: MoldSign Signature
Location: Moldova

Steven Zhou

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

EC Declaration of Conformity

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

Ref. No.:20220513-F02

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	Myo Control
2	CK-MB Control
3	NT-proBNP Control
4	D-Dimer Control
5	PCT Control
6	CRP Control
7	cTnI Control
8	H-FABP Control
9	mAlb Control
10	NGAL Control
11	β_2-MG Control
12	CysC Control
13	CK-MB/cTnI/Myo Control
14	CK-MB/cTnI Control
15	NT-proBNP/cTnI Control
16	HCG+β Control
17	HbA1c Control
18	TSH Control
19	T4 /T3 Control
20	T3 Control
21	T4 Control

22	FOB Control
23	H. pylori Control
24	SAA Control
25	LH Control
26	FSH Control
27	25-OH-VD Control
28	fT3 Control
29	fT4 Control
30	PRL Control
31	SARS-CoV-2 Control
32	Prog Control
33	IL-6 Control
34	Fer Control
35	cTnT Control
36	BNP Control
37	IGE Control
38	AMH Control
39	TPO Control
40	TG-Ab Control
41	T Control
42	E2 Control
43	E3 Control
44	HCG+β Control
45	CA50 Control
46	CA125 Control
47	CA15-3 Control
48	CA19-9 Control
49	CA242 Control
50	CA72-4 Control
51	CY21-1 Control
52	NSE Control

53	AFP Control
54	CEA Control
55	Fer Control
56	HE4 Control
57	cTnT Control
58	INS Control
59	C-P Control
60	PTH Control
61	BGP Control
62	IAA Control
63	IgE Control
64	GH Control
65	Cor Control
66	TP Control
67	PGI Control
68	PGII Control
69	G17 Control
70	Pro-GRP Control
71	SCC Control
72	ST2 Control
73	PLA2 Control
74	CG Control
70	HA Control
71	LN Control
72	III Control
73	CIV Control
74	SHBG Control
75	Renin Control
76	TG Control
77	PVK Control
78	HBP Control

79	PIIIP N-P Control
80	CIV Control
81	CRP Calibrator
82	β2-MG Calibrator
83	C3 Calibrator
84	C4 Calibrator
85	IgA Calibrator
86	CysC Calibrator
87	IgG Calibrator
88	IgM Calibrator
89	PA Calibrator
90	ApoA1 Calibrator
91	ApoB Calibrator

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

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

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

Reference Code：GP-DT-018-07-19 Issued by 07/26/2019

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.

Getein
Biotech, Inc.

GP CE IVD

CK-MB/cTnI/Myo Control

REF QC016

User Manual

PRODUCT NAME

CK-MB/cTnI/Myo Control

PRODUCT SPECIFICATION

Package: 3(Level)*2(Vial)*1(ml), 3(Level)*1(Vial)*1(ml)
CK-MB/cTnI/Myo Control - Level 1/2/3

INTENDED USE

This product is intended for *in vitro* diagnostic use in the quality control of CK-MB/cTnI/Myo on the Getein Platforms.

PRINCIPLE

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

CONTENTS

The kit for FIA8000/FIA8600/Getein1100 contains:

1. CK-MB/cTnI/Myo Control - Level 1
   CK-MB/cTnI/Myo Control - Level 2
   CK-MB/cTnI/Myo Control - Level 3
2. User manual: 1 piece/box
3. Target value sheet: 1 piece/box

The kit for Getein1600 contains:

1. CK-MB/cTnI/Myo Control - Level 1
   CK-MB/cTnI/Myo Control - Level 2
   CK-MB/cTnI/Myo Control - Level 3
2. User manual: 1 piece/box
3. Quality control holder - Level 1
   Quality control holder - Level 2
   Quality control holder - Level 3

Note: Each quality control holder is labelled with barcode which contains target value and level of different items.

MATCHING EQUIPMENTS

FIA8000/8600 Quantitative Immunoassay Analyzer
Getein1100/1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

UNOPENED: The product is stable for 18 months at -20℃ and for 30 days at 2 ~ 8℃ to avoid light.
OPENED: The product is stable for 7 days at 2 ~ 8℃ if kept capped in orginal container and free from contamination. Only the required amount of product should be removed. Any residual product should NOT BE RETURNED to the original vial after using. It is recommended to be dispensed into smaller vials after dilution and stable for 30 days at -20 ~ -70℃.

MATERIALS REQUIRED BUT NOT PROVIDED

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

TEST PROCEDURE

1. The product should be brought to room temperature (15 ~ 30℃) prior to use.
2. Open the vial carefully in case of the loss of content.

3. Dissolve each control material with 1 ml distilled water.
4. Gently mix until all material has dissolved. Avoid violent shaking.
5. Keep it at room temperature for 5 ~ 10 minutes before use.

For FIA8000/FIA8600/Getein1100:

6. Treat the control in the same manner as patient specimen in the assay procedure. Follow the directions of test kit and the instrument application instruction.

For Getein1600:

7. Match each vial with corresponding quality control holder.
8. Insert quality control holder into sample holder.
9. Insert sample holder with a constant speed and barcode facing the scanner, refer to the User Manual of Getein1600 to start QC testing.

ASSIGNED VALUES

Refer to values listed on the target value sheet.
If the result is beyond the range, it indicates the existence of some unreliable factors in the testing system. Referring to the control graph helps judge the accuracy and stability of the testing system.
The expected range of the mean is provided to aid laboratory until it has established its own mean and SD for its methods.

PERFORMANCE CHARACTERISTICS

1. Homogeneity: ≤ 15%
2. Accuracy range: Refer to the target value sheet

LIMITATIONS

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

NOTES

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

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on CK-MB/cTnI/Myo control are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN 980:2008 and EN ISO15223-1:2016.

Key to symbols used			
	Manufacturer		Expiration date
REF	Catalogue number		Date of manufacture
	Consult instructions for use	LOT	Batch code
	Temperature limitation	IVD	*In vitro* diagnostic medical device
	Sufficient for		Biological risk
CE	CE mark	EC REP	Authorized representative in the European Community

Thank you for purchasing CK-MB/cTnI/Myo Control.
Please read this user manual carefully before operating to ensure proper use.

Version: WZK15-S-02

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.bio-GP.com.cn

Please contact Getein if you have any questions.

CE IVD

One Step Test for CK-MB/cTnI/Myo

(Colloidal Gold)

User Manual Cat.# CG1005

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 Quantitative Immunoassay Analyzer (hereinafter referred to as FIA8000), 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 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

A kit contains:

1. Getein CK-MB/cTnI/Myo 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-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.

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℃ 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℃ with a valid period of 24 months.
Store the whole blood buffer 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 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℃ 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 accordance with test kit lot No.. Perform "QC (SD)" calibration when necessary (Details refer to 8.2.1 of FIA8000 User Manual).
4. On the main interface of FIA8000, press "ENT" button to enter testing interface.
5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
6. Put the test card on a clean table, horizontally placed.
7. Using sample transfer pipette, deliver ***120 µl*** of sample (or 4 drops of sample when using disposable pipet) into the sample port on the test card (for whole blood sample, one drop of whole blood buffer must be added after loading 120 µl sample on the test card).
8. ***Reaction time: 15 minutes.*** Insert the test card into FIA8000 and press "ENT" button after reaction time is elapsed. The result will be shown on the screen and printed automatically.

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

TEST RESULTS

Valid: When a purplish-red band appears at the control area (C), use FIA8000 to analyze the test card and get the result.
Invalid: If no colored band appears in the control area (C), the test result is invalid. The test should be repeated and if the same situation happened again, please stop using this batch of products and contact your supplier.

EXPECTED VALUE

The expected normal value for CK-MB was determined by testing samples from 500 apparently healthy individuals. The 99th percentile of the concentration for CK-MB is 5.0 ng/ml. (The probability that value of a normal person below 5.0 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 0.5 ng/ml. (The probability that value of a normal person below 0.5 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 ng/ml. The 97.5th percentile of the concentration for Myo is 70 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	2.5~80.0 ng/ml	0.5~50.0 ng/ml	30.0~1000.0 ng/ml
Lower Detection Limit	≤ 2.5 ng/ml	≤ 0.5 ng/ml	≤ 30.0 ng/ml
Recovery	96%(mean)	95%(mean)	95%(mean)
Within-Run Precision	≤10%		
Between-Run Precision	≤15%		

Method Comparison:
The assay was compared with HITACHI 7600/OLYMPUS AU5400 and its matching CK-MB test kits, SIEMENS IMMULITE 1000/2000 and its matching cTnI and Myo test kits with 200 serum samples (60 positive samples and 140 negative samples). The correlation coefficient (r) for CK-MB is 0.928, the correlation coefficient (r) for cTnI is 0.952, the correlation coefficient (r) for Myo is 0.938.

LIMITATIONS

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

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

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on 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 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	LOT	Batch code
	Temperature limitation	IVD	*In vitro* diagnostic medical device
	Sufficient for	EC REP	Authorized representative in the European Community
CE	CE mark		Do not use if package is damaged

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-01

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.bio-GP.com.cn

cTnI Control

REF QC001

User Manual

PRODUCT NAME

cTnI Control

PRODUCT SPECIFICATION

Package: 3(Level)*2(Vial)*1(ml), 3(Level)*1(Vial)*1(ml)
cTnI Control - Level 1/2/3

INTENDED USE

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

PRINCIPLE

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

CONTENTS

The kit for FIA8000/FIA8600/Getein1100 contains:

1. cTnI Control - Level 1
   cTnI Control - Level 2
   cTnI Control - Level 3
2. User manual: 1 piece/box
3. Target value sheet: 1 piece/box

The kit for Getein1600 contains:

1. cTnI Control - Level 1
   cTnI Control - Level 2
   cTnI Control - Level 3
2. User manual: 1 piece/box
3. Target value sheet: 1 piece/box
4. Quality control holder - Level 1
   Quality control holder - Level 2
   Quality control holder - Level 3

Note: Each quality control holder is labelled with barcode which contains target value and level of different items.

MATCHING EQUIPMENTS

FIA8000/8600 Quantitative Immunoassay Analyzer
Getein1100/1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

UNOPENED: The product is stable for 18 months at -20℃ and for 30 days at 2 ~ 8℃ to avoid light.
OPENED: The product is stable for 1 day at 2 ~ 8℃ if kept capped in orginal container and free from contamination. Only the required amount of product should be removed. Any residual product should NOT BE RETURNED to the original vial after using. It is recommended to be dispensed into smaller vials after dilution and stable for 30 days at -20 ~ -70℃.

MATERIALS REQUIRED BUT NOT PROVIDED

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

TEST PROCEDURE

1. The product should be brought to room temperature (15 ~ 30℃) prior to use.
2. Open the vial carefully in case of the loss of content.
3. Dissolve each control material with 1 ml distilled water.

4. Close the vial and mix gently until all contents are dissolved completely. Avoid violent shaking or foam formation.
5. Keep it at room temperature for 5 ~ 10 minutes before use.

For FIA8000/FIA8600/Getein1100:

6. Treat the control in the same manner as patient specimen in the assay procedure. Follow the directions of test kit and the instrument application instruction.

For Getein1600:

7. Insert quality control holder into sample holder.
8. Insert sample holder with a constant speed and barcode facing the scanner, refer to the User Manual of Getein1600 to start QC testing.

ASSIGNED VALUES

Refer to values listed on the target value sheet.
If the result is beyond the range, it indicates the existence of some unreliable factors in the testing system. Referring to the control graph helps judge the accuracy and stability of the testing system.
The expected range of the mean is provided to aid laboratory until it has established its own mean and SD for its methods.

PERFORMANCE CHARACTERISTICS

1. Homogeneity: ≤ 15%
2. Accuracy range: Refer to the target value sheet

LIMITATIONS

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

NOTES

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

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on cTnI control are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN 980:2008 and EN ISO15223-1:2016.

Key to symbols used			
	Manufacturer		Expiration date
REF	Catalogue number		Date of manufacture
	Consult instructions for use	LOT	Batch code
	Temperature limitation	IVD	*In vitro* diagnostic medical device
	Sufficient for		Biological risk
CE	CE mark	EC REP	Authorized representative in the European Community

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

Version: WZK01-S-04

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.bio-GP.com.cn

Please contact Getein if you have any questions.

CE IVD

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℃ 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℃ with a valid period of 24 months.
Store the whole blood buffer 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 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℃ 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 accordance with test kit lot No.. Perform "QC (SD)" calibration when necessary (Details refer to 8.2.1 of FIA8000 User Manual).
4. On the main interface of FIA8000, press "ENT" button to enter testing interface.
5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
6. Put the test card on a clean table, horizontally placed.
7. Using sample transfer pipette, deliver ***120 µl*** of sample (or 4 drops of sample when using disposable pipet) into the sample port on the test card (for whole blood sample, one drop of whole blood buffer must be added after loading 120 µl sample on the test card).
8. ***Reaction time: 15 minutes.*** Insert the test card into FIA8000 and press "ENT" button after reaction time is elapsed. The result will be shown on the screen and printed automatically.

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

TEST RESULTS

Valid: When a purplish-red band appears at the control area (C), use FIA8000 to analyze the test card and get the result.
Invalid: If no colored band appears in the control area (C), the test result is invalid. The test should be repeated and if the same situation happened again, please stop using this batch of products and contact your supplier.

EXPECTED VALUE

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

PERFORMANCE CHARACTERISTICS

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

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

LIMITATIONS

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

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

REFERENCES

1. Mauro Pantaghini; Undefined International Federation of Clinical Chemistry and Laboratory Medicine (IFCC).Scientific Division Committee on Standardization of Markers of Cardiac Damage. Clin Chem Lab Med, 1998, 36:887~893.
2. Antman EM, Anbe DT, Armstrong PW, et al. ACC/AHA guidelines for the management of patients with ST-elevation myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1999 Guidelines for the Manage 2004).
3. EN ISO 18113-1:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
4. EN ISO 18113-2:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: *In vitro* diagnostic reagents for professional use (ISO 18113-2:2009).

DESCRIPTION OF SYMBOLS USED

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

Key to symbols used			
	Manufacturer		Expiration date
	Do not reuse		Date of manufacture
	Consult instructions for use	LOT	Batch code
	Temperature limitation	IVD	*In vitro* diagnostic medical device
Σ	Sufficient for	EC REP	Authorized representative in the European Community
CE	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

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.bio-GP.com.cn

NT-proBNP Control

REF QC007

User Manual

PRODUCT NAME

NT-proBNP Control

PRODUCT SPECIFICATION

Package: 3(Level)*2(Vial)*1(ml), 3(Level)*1(Vial)*1(ml)
NT-proBNP Control - Level 1/2/3

INTENDED USE

This product is intended for *in vitro* diagnostic use in the quality control of N-terminal B-type natriuretic peptide precursor (NT-proBNP) on the Getein Platforms.

PRINCIPLE

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

CONTENTS

The kit for FIA8000/FIA8600/Getein1100 contains:

1. NT-proBNP Control - Level 1
   NT-proBNP Control - Level 2
   NT-proBNP Control - Level 3
2. User manual: 1 piece/box
3. Target value sheet: 1 piece/box

The kit for Getein1600 contains:

1. NT-proBNP Control - Level 1
   NT-proBNP Control - Level 2
   NT-proBNP Control - Level 3
2. User manual: 1 piece/box
3. Target value sheet: 1 piece/box
4. Quality control holder - Level 1
   Quality control holder - Level 2
   Quality control holder - Level 3

Note: Each quality control holder is labelled with barcode which contains target value and level of different items.

MATCHING EQUIPMENTS

FIA8000/8600 Quantitative Immunoassay Analyzer
Getein1100/1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

UNOPENED: The product is stable for 18 months at -20℃ and for 30 days at 2 ~ 8℃ to avoid light.
OPENED: The product is stable for 1 day at 2 ~ 8℃ if kept capped in orginal container and free from contamination. Only the required amount of product should be removed. Any residual product should NOT BE RETURNED to the original vial after using. It is recommended to be dispensed into smaller vials after dilution and stable for 30 days at -20 ~ -70℃.

MATERIALS REQUIRED BUT NOT PROVIDED

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

TEST PROCEDURE

1. The product should be brought to room temperature (15 ~ 30℃) prior to use.
2. Open the vial carefully in case of the loss of content.
3. Dissolve each control material with 1 ml distilled water.
4. Close the vial and mix gently until all contents are dissolved

completely. Avoid violent shaking or foam formation.

5. Keep it at room temperature for 5 ~ 10 minutes before use.

For FIA8000/FIA8600/Getein1100:

6. Treat the control in the same manner as patient specimen in the assay procedure. Follow the directions of test kit and the instrument application instruction.

For Getein1600:

7. Insert quality control holder into sample holder.
8. Insert sample holder with a constant speed and barcode facing the scanner, refer to the User Manual of Getein1600 to start QC testing.

ASSIGNED VALUES

Refer to values listed on the target value sheet.

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

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

PERFORMANCE CHARACTERISTICS

1. Homogeneity: ≤ 15%
2. Accuracy range: Refer to the target value sheet

LIMITATIONS

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

NOTES

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

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on NT-proBNP control are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN 980:2008 and EN ISO15223-1:2016.

Key to symbols used			
	Manufacturer		Expiration date
	Catalogue number		Date of manufacture
	Consult instructions for use		Batch code
	Temperature limitation		*In vitro* diagnostic medical device
	Sufficient for		Biological risk
	CE mark		Authorized representative in the European Community

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

Version: WZK02-S-04

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.bio-GP.com.cn

Please contact Getein if you have any questions.

CE IVD

One Step Test for NT-proBNP

(Colloidal Gold)

User Manual Cat.# CG1002

INTENDED USE

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

SUMMARY

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

PRINCIPLE

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

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

CONTENTS

A kit contains:

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

A test card consists of:

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

Whole blood buffer composition:

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

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

APPLICABLE DEVICE

FIA8000 Quantitative Immunoassay Analyzer

STORAGE AND STABILITY

Store the test card at 4~30℃ 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℃ with a valid period of 24 months.
Store the whole blood buffer 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 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℃ 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 accordance with test kit lot No.. Perform “QC (SD)” calibration when necessary (Details refer to 8.2.1 of FIA8000 User Manual).
4. On the main interface of FIA8000, press "ENT" button to enter testing interface.
5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control

identification.

6. Put the test card on a clean table, horizontally placed.
7. Using sample transfer pipette, deliver ***120 µl*** of sample (or 4 drops of sample when using disposable pipet) into the sample port on the test card (for whole blood sample, one drop of whole blood buffer must be added after loading 120 µl sample on the test card).
8. ***Reaction time: 15 minutes.*** Insert the test card into FIA8000 and press "ENT" button after reaction time is elapsed. The result will be shown on the screen and printed automatically.

Notes:

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

TEST RESULTS

Valid: When a purplish-red band appears at the control area (C), use FIA8000 to analyze the test card and get the result.
Invalid: If no colored band appears in the control area (C), the test result is invalid. The test should be repeated and if the same situation happened again, please stop using this batch of products and contact your supplier.

EXPECTED VALUE

The expected normal value for 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	230	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

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

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

REFERENCES

1. de Lemos JA, McGuire DK, Drazner MH. B-type natriuretic peptide in cardiovascular disease. Lancet 2003; 362:316~322.
2. Pfister R, Scholz M, Wielckens K, Erdmann E, Schneider CA. The value of natriuretic peptides NT-pro-BNP and BNP for the assessment of left-ventricular volume and function. A prospective study of 150 patients. Deutsche medizinische Wochenschrift (1946) 2002; 127(49):2605.
3. EN ISO 18113-1:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
4. EN ISO 18113-2:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: *In vitro* diagnostic reagents for professional use (ISO 18113-2:2009).

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on 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	LOT	Batch code
	Temperature limitation	IVD	*In vitro* diagnostic medical device
	Sufficient for	EC REP	Authorized representative in the European Community
CE	CE mark		Do not use if package is damaged

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

Version: WCG03-DL-S-01

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.bio-GP.com.cn

GP CE IVD

PCT Control

Cat.# QC 004

User Manual

PRODUCT NAME

PCT Control

PRODUCT SPECIFICATION

PCT Control - Level 1/2/3

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

INTENDED USE

This product is intended for *in vitro* diagnostic use in the quality control of Procalcitonin (PCT) on the Getein Platforms.

PRINCIPLE

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

CONTENTS

The kit contains:

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

MATCHING EQUIPMENTS

FIA8000 Quantitative Immunoassay Analyzer
Getein1100/1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

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

MATERIALS REQUIRED BUT NOT PROVIDED

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

TEST PROCEDURE

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

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

ASSIGNED VALUES

Refer to values listed on the target value sheet.
If the result is beyond the range, it indicates the existence of some unreliable factors in the testing system. Referring to the control graph helps judge the accuracy and stability of the testing system.
The expected range of the mean is provided to aid laboratory until it has established its own mean and SD for its methods.

PERFORMANCE CHARACTERISTICS

1. Homogeneity: ≤ 15%
2. Accuracy range: Target value ± 40%

LIMITATIONS

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

NOTES

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

DESCRIPTION OF SYMBOLS USED

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

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

Thank you for purchasing PCT Control.
Please read this user manual carefully before operating to ensure proper use.

Version: WZK05-S-01

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: http://www.bio-GP.com.cn

Please contact Getein Biotech Company if you have any questions.

CE IVD

One Step Test for PCT

(Colloidal Gold)

User Manual Cat.# CG1007

INTENDED USE

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

SUMMARY

PCT is a peptide precursor of the hormone calcitonin, the latter being involved with calcium homeostasis. It is composed of 116 amino acids and is produced by parafollicular cells (C cells) of the thyroid and by the neuroendocrine cells of the lung and the intestine.
Measurement of PCT can be used as a marker of severe sepsis and generally grades well with the degree of sepsis, although levels of PCT in the blood are very low. PCT has the greatest sensitivity and specificity for differentiating patients with systemic inflammatory response syndrome (SIRS) from those with sepsis.
PCT levels may be useful to distinguish bacterial infections from nonbacterial infections. It has shown that PCT may help guide therapy and reduce antibiotic use, which can help save on cost of antibiotic prescriptions and drug resistance.

PRINCIPLE

The test uses an anti-human PCT monoclonal antibody conjugated with colloidal gold. For PCT product, test line 1 was coated with anti-human PCT polyclonal antibody and test line 2 was coated with another anti-human PCT monoclonal antibody. After the sample has been applied to the test strip, the gold-labelled anti-human PCT monoclonal antibody or polyclonal antibody binds with the PCT in sample and forms a marked antigen antibody complex. This complex moves to the test card detection zone by capillary action. Then marked antigen antibody complex is captured on the test line by the other anti-human PCT monoclonal antibody or the polyclonal antibody. The color intensity of the test line increases in proportion to the amount of PCT in sample.
Then insert test card into FIA8000 Quantitative Immunoassay Analyzer (hereinafter referred to as FIA8000), the concentration of PCT in sample will be measured and displayed on the screen. The value will be stored in FIA8000 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

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

A test card consists of:
A plastic shell and a reagent strip which is composed of a sample pad, a colloidal gold pad, nitrocellulose membrane (coated with a gold-labelled anti-human PCT monoclonal antibody), nitrocellulose membrane (the test lines are coated with another anti-human PCT monoclonal antibody and polyclonal antibody, and the control line is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.
Whole blood buffer composition:
Phosphate buffered saline, proteins, detergent, preservative, stabilizer.

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

APPLICABLE DEVICE

FIA8000 Quantitative Immunoassay Analyzer

STORAGE AND STABILITY

Store the test card at 4~30℃ 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℃ with a valid period of 24 months.
Store the whole blood buffer 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 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℃ 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 accordance with test kit lot No.. Perform “QC (SD)” calibration when necessary (Details refer to 8.2.1 of FIA8000 User Manual).
4. On the main interface of FIA8000, press "ENT" button to enter testing interface.
5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control

identification.
6. Put the test card on a clean table, horizontally placed.
7. Using sample transfer pipette, deliver ***120 µl*** of sample (or 4 drops of sample when using disposable pipet) into the sample port on the test card (for whole blood sample, one drop of whole blood buffer must be added after loading 120 µl sample on the test card).
8. ***Reaction time: 15 minutes.*** Insert the test card into FIA8000 and press "ENT" button after reaction time is elapsed. The result will be shown on the screen and printed automatically.

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

TEST RESULTS

Valid: When a purplish-red band appears at the control area (C), use FIA8000 to analyze the test card and get the result.
Invalid: If no colored band appears in the control area (C), the test result is invalid. The test should be repeated and if the same situation happened again, please stop using this batch of products and contact your supplier.

EXPECTED VALUE

The expected normal value for PCT was determined by testing samples from 500 apparently healthy individuals. The 99th percentile of the concentration for PCT is 0.1 ng/ml. (The probability that value of a normal person below 0.1 ng/ml is 99%.)
The table below comes from the research of ACCP/SCCM (American College of Chest Physicians/Society of Critical Care Medicine), showing the PCT value and its clinical meaning [4]:

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

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

PERFORMANCE CHARACTERISTICS

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

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

LIMITATIONS

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

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

REFERENCES

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.
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DESCRIPTION OF SYMBOLS USED

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

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

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

Version: WCG06-DL-S-01

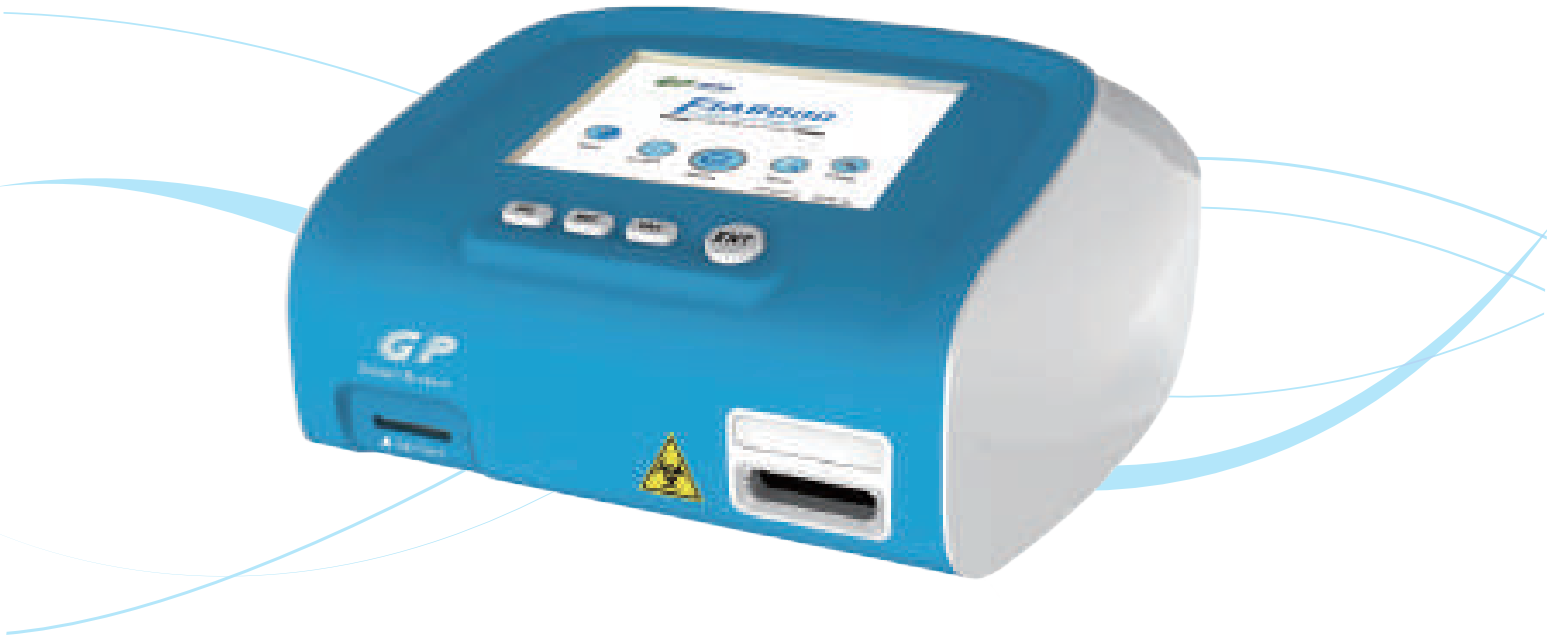
Getein Biotech, Inc.
Add: No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel: +86-25-68568508
Fax: +86-25-68568500
E-mail: tech@getein.com.cn
overseas@getein.com.cn
Website: www.bio-GP.com.cn

IVD Industry
POCT Leading Brand

FIA8000

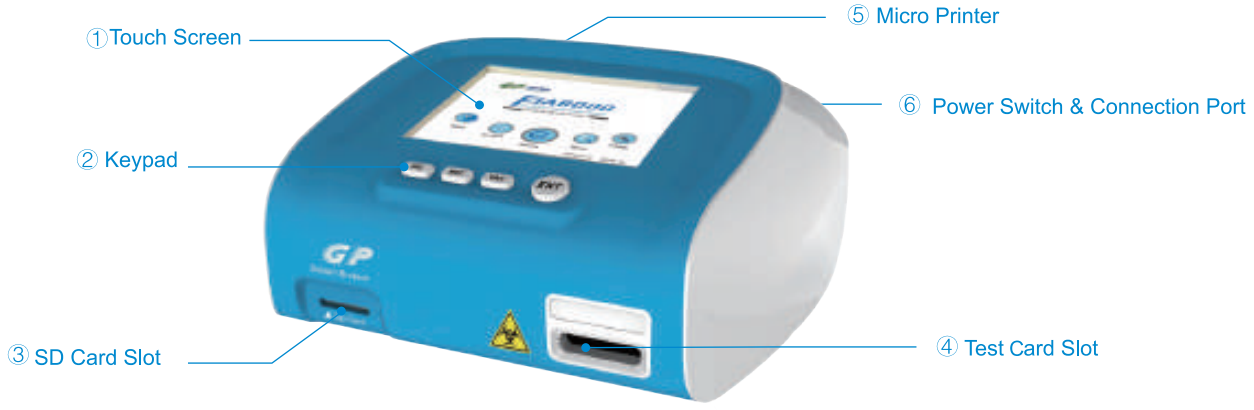
Quantitative Immunoassay Analyzer

PREMIUM POINT OF CARE SOLUTION



Getein Biotech, Inc.

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$\leqslant$1%; r$\geqslant$0.990
- **LIS and HIS Connectivity**

Test Items

CARDIAC	cTnI	NT-proBNP	NT-proBNP/cTnI	CK-MB/cTnI/Myo
	H-FABP	CK-MB/cTnI/H-FABP		
VENOUS THROMBOEMBOLISM	D-Dimer			
INFLAMMATION MONITORING	hs-CRP	PCT		
DIABETES CARE	HbA1c			
FERTILITY	HCG+β			
RENAL FUNCTION	β_2-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℃ - 35℃
	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	15 min
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	β_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+β	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.

Add: No.9 Bofu Road, Luhe District, Nanjing, 211505, China

Tel:+86-25-68569011;68568508;68588528

Fax:+86-25-68568500

Email:sales@getein.com.cn;tech@getein.com.cn

Http:www.bio-GP.com.cn