Getein Biotech, Inc.
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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

Digitally signed by Goreacii Vitalie
Date: 2023.08.24 09:52:29 EEST
Reason: MoldSign Signature
Location: Moldova

基蛋生物科技股份有限公司
GETEIN BIOTECH, INC.

Steven Zhou

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

Declaration of Conformity

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

Maker (Name, Address)	**Getein Biotech, Inc.** No. 9 Bofu Road, Luhe District, Nanjing, 211505, China		
Authorized Representative (Name, Address)	**Lotus NL B.V.** Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.		
Medical device	Description	:	FIA8000 Quantitative Immunoassay Analyzer FIA8600 Quantitative Immunoassay Analyzer Cardiac Troponin I Fast Test Kit One Step Test for cTnI (Colloidal Gold) cTnI Rapid Test (Colloidal Gold Assay) One Step Test for NT-proBNP (Colloidal Gold) One Step Test for NT-proBNP/cTnI (Colloidal Gold) One Step Test for CK-MB/cTnI/Myo (Colloidal Gold) One Step Test for hs-CRP+CRP (Colloidal Gold) One Step Test for D-Dimer (Colloidal Gold) One Step Test for PCT (Colloidal Gold) One Step Test for β2-MG (Colloidal Gold) One Step Test for mAlb (Colloidal Gold) One Step Test for NGAL (Colloidal Gold) One Step Test for CysC (Colloidal Gold) One Step Test for HCG+β (Colloidal Gold) One Step Test for HbA1c (Colloidal Gold) One Step Test for PCT/CRP (Colloidal Gold) One Step Test for CK-MB/cTnI/H-FABP (Colloidal Gold) One Step Test for H-FABP (Colloidal Gold) One Step Test for CK-MB/cTnI (Colloidal Gold) One Step Test for CK-MB (Colloidal Gold) One Step Test for TSH (Colloidal Gold) One Step Test for T4/T3 (Colloidal Gold) One Step Test for T3 (Colloidal Gold) One Step Test for T4 (Colloidal Gold) One Step Test for 25-OH-VD (Colloidal Gold) One Step Test for FOB (Colloidal Gold) One Step Test for *H. pylori* (Colloidal Gold) One Step Test for SAA (Colloidal Gold) Getein1100 Immunofluorescence Quantitative Analyzer Getein1600 Immunofluorescence Quantitative Analyzer Getein1180 Immunofluorescence Quantitative Analyzer Getein1200 Immunofluorescence Quantitative Analyzer Cardiac Troponin I Fast Test Kit (Immunofluorescence Assay) NT-proBNP Fast Test Kit (Immunofluorescence Assay) hs-CRP+CRP Fast Test Kit (Immunofluorescence Assay) NT-proBNP/cTnI Fast Test Kit (Immunofluorescence Assay) CK-MB/cTnI/Myo Fast Test Kit (Immunofluorescence Assay) D-Dimer Fast Test Kit (Immunofluorescence Assay)

			PCT Fast Test Kit (Immunofluorescence Assay) β2-MG Fast Test Kit (Immunofluorescence Assay) mAlb Fast Test Kit (Immunofluorescence Assay) NGAL Fast Test Kit (Immunofluorescence Assay) CysC Fast Test Kit (Immunofluorescence Assay) CK-MB Fast Test Kit (Immunofluorescence Assay) CK-MB/cTnI Fast Test Kit (Immunofluorescence Assay) HCG+β Fast Test Kit (Immunofluorescence Assay) HbA1c Fast Test Kit (Immunofluorescence Assay) PCT/CRP Fast Test Kit (Immunofluorescence Assay) CK-MB/cTnI/H-FABP Fast Test Kit (Immunofluorescence Assay) H-FABP Fast Test Kit (Immunofluorescence Assay) 25-OH-VD Fast Test Kit (Immunofluorescence Assay) TSH Fast Test Kit (Immunofluorescence Assay) T3 Fast Test Kit (Immunofluorescence Assay) T4 Fast Test Kit (Immunofluorescence Assay 25-OH-VD Fast Test Kit (Immunofluorescence Assay) FOB Fast Test Kit (Immunofluorescence Assay) *H. pylori* Fast Test Kit (Immunofluorescence Assay) SAA Fast Test Kit (Immunofluorescence Assay) LH Fast Test Kit (Immunofluorescence Assay) FSH Fast Test Kit (Immunofluorescence Assay) AMH Fast Test Kit (Immunofluorescence Assay) PRL Fast Test Kit (Immunofluorescence Assay) CK-MB Control cTnI Control Myo Control NT-proBNP Control D-Dimer Control CRP Control PCT Control β2-MG Control mAlb Control NGAL Control CysC Control H-FABP Control HbA1c Control HCG+β Control CK-MB/cTnI/Myo Control CK-MB/cTnI Control NT-proBNP/cTnI Control TSH Control T4/T3 Control T3 Control T4 Control
	Classification of products according to directive	:	Others
	Batch/serial No. Type, production term (if applicable)	:	

Applicable coordination standards:	EN ISO 14971:2012 EN 13612:2002 EN 1041:2008 IEC 61010-1:2010 IEC 61326-1:2013	EN ISO 23640:2015 EN ISO15223-1:2012 EN ISO 18113-1:2011 IEC 61010-2-081:2015 IEC 61326-2-2:2013	EN ISO 13485:2016 EN ISO 18113-2:2011 EN ISO 18113-3:2011 IEC 61010-2-101:2015

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 III. 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 TÜV Rheinland (Shanghai) Co., Ltd.

General Manager: Enben Su

Nanjing, 20th, Jul, 2019

(place and date of issue)

(name and signature or equivalent marking of authorized person)

EC Declaration of Conformity

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

Ref. No.:20220513-A05

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	Getein 1100 Immunofluorescence Quantitative Analyzer
2	Cardiac Troponin I Fast Test Kit (Immunofluorescence Assay)
3	NT-proBNP Fast Test Kit (Immunofluorescence Assay)
4	hs-CRP+CRP Fast Test Kit (Immunofluorescence Assay)
5	NT-proBNP/cTnI Fast Test Kit (Immunofluorescence Assay)
6	CK-MB/cTnI/Myo Fast Test Kit (Immunofluorescence Assay)
7	D-Dimer Fast Test Kit (Immunofluorescence Assay)
8	PCT Fast Test Kit (Immunofluorescence Assay)
9	CysC Fast Test Kit (Immunofluorescence Assay)
10	mAlb Fast Test Kit (Immunofluorescence Assay)
11	NGAL Fast Test Kit (Immunofluorescence Assay)
12	β2-MG Fast Test Kit (Immunofluorescence Assay)
13	CK-MB/cTnI Fast Test Kit (Immunofluorescence Assay)
14	HCG+β Fast Test Kit (Immunofluorescence Assay)
15	H-FABP Fast Test Kit (Immunofluorescence Assay)
16	PCT/CRP Fast Test Kit (Immunofluorescence Assay)
17	CK-MB/cTnI/H-FABP Fast Test Kit (Immunofluorescence Assay)
18	HbA1c Fast Test Kit (Immunofluorescence Assay)
19	NT-proBNP/NGAL Fast Test Kit (Immunofluorescence Assay)
20	CK-MB Fast Test Kit (Immunofluorescence Assay)
21	hs-cTnI Fast Test Kit (Immunofluorescence Assay)
22	T3 Fast Test Kit (Immunofluorescence Assay)
23	T4 Fast Test Kit (Immunofluorescence Assay)
24	TSH Fast Test Kit (Immunofluorescence Assay)
25	Scr Fast Test Kit (Immunofluorescence Assay)
26	PLGF Fast Test Kit (Immunofluorescence Assay)

27	HCY Fast Test Kit (Immunofluorescence Assay)
28	Anti-CCP Fast Test Kit (Immunofluorescence Assay)
29	25-OH-VD Fast Test Kit (Immunofluorescence Assay)
30	Lp-PLA2 Fast Test Kit (Immunofluorescence Assay)
31	FOB Fast Test Kit (Immunofluorescence Assay)
32	SAA Fast Test Kit (Immunofluorescence Assay)
33	H. pylori Fast Test Kit (Immunofluorescence Assay)
34	PRL Fast Test Kit (Immunofluorescence Assay)
35	Transferrin Fast Test Kit (Immunofluorescence Assay)
36	Insulin Fast Test Kit (Immunofluorescence Assay)
37	PG Ⅰ /PG Ⅱ Fast Test Kit (Immunofluorescence Assay)
38	LH Fast Test Kit (Immunofluorescence Assay)
39	FSH Fast Test Kit (Immunofluorescence Assay)
40	Anti-TP Fast Test Kit (Immunofluorescence Assay)
41	AFP/CEA Fast Test Kit (Immunofluorescence Assay)
42	AMH Fast Test Kit (Immunofluorescence Assay)
43	fT3 Fast Test Kit (Immunofluorescence Assay)
44	fT4 Fast Test Kit (Immunofluorescence Assay)
45	Total IgE Fast Test Kit (Immunofluorescence Assay)
46	Vit-B12 Fast Test Kit (Immunofluorescence Assay)
47	Prog Fast Test Kit (Immunofluorescence Assay)
48	Testosterone Fast Test Kit (Immunofluorescence Assay)
49	E2 Fast Test Kit (Immunofluorescence Assay)
50	RF Fast Test Kit (Immunofluorescence Assay)
51	ASO Fast Test Kit (Immunofluorescence Assay)
52	Ferritin Fast Test Kit (Immunofluorescence Assay)
53	ST2 Fast Test Kit (Immunofluorescence Assay)
54	CA125 Fast Test Kit (Immunofluorescence Assay)
55	CA19-9 Fast Test Kit (Immunofluorescence Assay)
56	CA15-3 Fast Test Kit (Immunofluorescence Assay)
57	RSV/Influenza A/B Fast Test Kit (Immunofluorescence Assay)
58	Influenza A/B Fast Test Kit (Immunofluorescence Assay)
59	RSV Fast Test Kit (Immunofluorescence Assay)
60	IL-6 Fast Test Kit (Immunofluorescence Assay)
61	BNP Fast Test Kit (Immunofluorescence Assay)
62	SAA/CRP Fast Test Kit (Immunofluorescence Assay)
63	Folate acid Fast Test Kit (Immunofluorescence Assay)
64	hs-CRP Fast Test Kit (Immunofluorescence Assay)
65	TnT Fast Test Kit (Immunofluorescence Assay)
66	PCT/IL-6 Fast Test Kit (Immunofluorescence Assay)

67	HBP Fast Test Kit (Immunofluorescence Assay)
68	S100-β Fast Test Kit (Immunofluorescence Assay)
69	CK-MB/hs-cTnI/Myo Fast Test Kit (Immunofluorescence Assay)
70	Cortisol Fast Test Kit (Immunofluorescence Assay)
71	CEA Fast Test Kit (Immunofluorescence Assay)
72	AFP/CEA Fast Test Kit (Immunofluorescence Assay)

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

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

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基蛋生物 GeteinBiotech Getein Biotech,Inc.
No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel: +86-25-68569084 Fax: +86-25-68568500 E-mail: overseas@ getein.com.cn

Exclusive Distributor Agreement

This agreement is made and entered into by and between the parties concerned on 1th Jan, 2022 in Nanjing, China on the basis of equality and mutual benefit to develop business on terms and conditions mutually agreed upon as follows:

1. The Parties Concerned

Party A: Getein Biotech,Inc.
Add: No.9 Bofu Road, Luhe District, Nanjing (211505) China.
Tel: 86-25-68568519
Fax: 86-25-68568500

Party B: Sanmedico SRL
Add: Republic of Moldova, Chisinau, MD-2059, Petricani street, 88/1, office 10
Tel: 373 22 62 30 32

2. Appointment

Party A hereby appoints Party B as its exclusive distributor in the Republic of Moldova for the promotion, sales, and after-sale services etc. of products (Refer to Item3) from Party A and Party B accepts and assumes such appointment.

3. Products List A

One Step Test for CK-MB/cTnI/Myo (Colloidal Gold)(Quantitative)
Cardiac Troponin I Fast Test Kit(Colloidal Gold)(Quantitative)
One Step Test for CK-MB (Colloidal Gold)(Quantitative)
One Step Test for CK-MB/cTnI (Colloidal Gold)(Quantitative)
One Step Test for H-FABP(Colloidal Gold)(Quantitative)
One Step Test for NT-proBNP/cTnI(Colloidal Gold)(Quantitative)
One Step Test for hs-CRP(Colloidal Gold)(Quantitative)
One Step Test for D-Dimer(Colloidal Gold)(Quantitative)
One Step Test for NT-proBNP(Colloidal Gold)(Quantitative)
One Step Test for HbA1c(Colloidal Gold)(Quantitative)
One Step Test for PCT(Colloidal Gold)(Quantitative)
One Step Test for HCG(Colloidal Gold)(Quantitative)
One Step Test for mAlb(Colloidal Gold)(Quantitative)
One Step Test for β2-MG(Colloidal Gold)(Quantitative)
One Step Test for CysC(Colloidal Gold)(Quantitative)
One Step Test for NAGL(Colloidal Gold)(Quantitative)
One Step Test for TSH(Colloidal Gold)(Quantitative)

No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel: +86-25-68569084 Fax: +86-25-68568500 E-mail: overseas@ getein.com.cn

CK-MB/cTnI/Myo Fast Test Kit(Immunofluorescence Assay)
Cardiac Troponin I Fast Test Kit(Immunofluorescence Assay)
NT-proBNP/cTnI Fast Test Kit(Immunofluorescence Assay)
hs-CRP Fast Test Kit(Immunofluorescence Assay)
D-Dimer Fast Test Kit(Immunofluorescence Assay)
NT-proBNP Fast Test Kit(Immunofluorescence Assay)
PCT Fast Test Kit(Immunofluorescence Assay)
mAlb Fast Test Kit(Immunofluorescence Assay)
B2-MG Fast Test Kit(Immunofluorescence Assay)
CysC Fast Test Kit(Immunofluorescence Assay)
NAGL Fast Test Kit(Immunofluorescence Assay)
HbA1c Fast Test Kit(Immunofluorescence Assay)
TSH Fast Test Kit(Immunofluorescence Assay)
T3 Fast Test Kit(Immunofluorescence Assay)
T4 Fast Test Kit(Immunofluorescence Assay)
PRL Fast Test Kit(Immunofluorescence Assay)
LH Fast Test Kit(Immunofluorescence Assay)
FSH Fast Test Kit(Immunofluorescence Assay)
AMH Fast Test Kit(Immunofluorescence Assay)
tPSA Fast Test Kit(Immunofluorescence Assay)
25-OH-VD Fast Test Kit(Immunofluorescence Assay)
Getein 1100 Immunofluorescence Quantitative Analyzer
Getein 1600 Immunofluorescence Quantitative Analyzer

4. Territory:

In Republic of Moldova only.

Meanwhile Party B will not distribute for competitive firms identical or similar products, nor will associate directly or indirectly with the competitive firms in the field of products covered by this agreement; otherwise, party A has the right to decide whether to terminate the contract immediately or not.

5. Prices

Prices are stable for 12 months from the start of this agreement. Party A will not increase the prices subjectively, unless the raw material suppliers increase their prices. In case price increases have to be announced, Party B has to be informed at least one month (30 days) in advance.

This agreement shall come into force from Jan 1st,2022to Jan 1st,2024,is valid for 24 months.

6.Delivery

No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel: +86-25-68569084 Fax: +86-25-68568500 E-mail: overseas@ getein.com.cn

Party A shall establish a delivery term for each Party B's order, which shall not exceed 4 weeks after the payment is received. Party A will advise Party B about the day of dispatching, with all requested information concerning the dispatched products.

7. FORCE MAJEURE

If the performance of any part of this agreement interfered with new laws or governmental restrictions, war, civil commotions, riots, strike lockout, acts of God such as flood, fire or any other similar causes which are beyond the control of the parties, no party shall be responsible for delay or failure of performance of this agreement for such length of time and to the extent performance is made impossible. In this case, the parties shall immediately negotiate to what extent deliveries that could not be executed can be carried out executed.

8.Payment Term

Every order Party B shall pay 50% by TT in advance, the rest of 50% will be paid within 30-60 days after the goods arrives. Due to financial audition, all the credit payment should be cleared by December 31th, 2022.

If Party B is unable to pay, Party B will agree to use fixed assets or real estate to offset the loan. Party A has the right to bring a lawsuit against Party B in China according to relevant Chinese laws.

9. Sales target

Yearly sales volume is 200,000 USD, which include both analyzers and strips. Party B agrees and accepts the sales volume...

10. Governing Law

The agreement is subject to the International Trade Law. Any dispute concerning this agreement shall be settled in accordance with the International Trade Law either through negotiation or through legal proceedings if negotiation has failed.

11.Declaration of Conformity.

Getein Biotech,Inc. declares herein the above mentioned device (Refer to Item3) meets the basic requirements of the European Parliament and the Council's in vitro diagnostic medical devices directive: 98/79/EC Annex III.

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 TÜV Rheinland （Shanghai）Co., Ltd.

12. Intellectual Property Agreement

Party A reserves the right of goods design, drawing, plane graph specification, technology, data and information, technological process, the marketing plan of intellectual property rights which included the

No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel: +86-25-68569084 Fax: +86-25-68568500 E-mail: overseas@ getein.com.cn

Party A provide technical services to the Party B in the process of producing intellectual achievements . Without the Party A 's written consent, the Party B shall not disassemble the goods and the accompanying software, decoding, encoding, or any other reverse engineering by themselves or other third party.

13. Final Provisions

Attachments are an integral part of this contract, have the same legal effect with this contract; This contract was made in English with two originals, each party holds one, it is effective at the same time, and have the same legal effect.

Any change, modification, cancellation of this contract, to be replaced shall be made after agreed by both parties in writing.

Party A: Getein Biotech,Inc.	Party B: Sanmedico SRL
Date:	Date:
Represented by: Steven Zhou	Represented by: Vitalie Goreacii
Regional Sales Manager	Director

基蛋生物科技股份有限公司
GETEIN BIOTECH, INC.

CE IVD

One Step Test for D-Dimer

(Colloidal Gold)

User Manual Cat.# CG1006

IINTENDED USE

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

SUMMARY

Deep-vein thrombosis is a common condition, with a lifetime cumulative incidence of 2 to 5 percent. Untreated deep-vein thrombosis can result in pulmonary embolism, a potentially fatal outcome. Anticoagulant therapy reduces both morbidity and mortality from venous thromboembolism, and early diagnosis is therefore important. Accurate diagnosis of deep-vein thrombosis minimizes the risk of thromboembolic complications and averts the exposure of patients without thrombosis to the risks of anticoagulant therapy.
D-Dimer is a marker of endogenous fibrinolysis and should therefore be detectable in patients with deep-vein thrombosis. In recent years, an increasing number of studies have shown the D-Dimer assay has a high negative predictive value and D-Dimer is a sensitive but nonspecific marker of deep-vein thrombosis. Negative D-Dimer can exclude deep-vein thrombosis and pulmonary embolism.

PRINCIPLE

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

CONTENTS

A kit contains:

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

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

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

APPLICABLE DEVICE

FIA8000 Quantitative Immunoassay Analyzer

STORAGE AND STABILITY

Store the test card at 4~30℃ 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 user manual to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for ***plasma and whole blood samples. Sodium citrate*** should be used as the anticoagulant for plasma and whole blood. Samples should be free of hemolysis.
2. Suggest using plasma for better results.
3. If testing will be delayed, plasma sample may be stored up to 3 days at 2~8℃ 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 user manual.

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

Notes:

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

TEST RESULTS

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

EXPECTED VALUE

The expected normal value for D-Dimer was determined by testing samples from 500 apparently healthy individuals. The 95th percentile of the concentration for D-Dimer is 0.5 mg/L. (The probability that value of a normal person below 0.5 mg/L is 95%.)
It is recommended that each laboratory establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

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

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

LIMITATIONS

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

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

REFERENCES

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

DESCRIPTION OF SYMBOLS USED

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

Key to symbols used			
	Manufacturer		Expiration date
	Do not reuse		Date of manufacture
	Consult instructions for use	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 D-Dimer (Colloidal Gold). Please read this user manual carefully before operating to ensure proper use.

Version: WCG05-DL-S-01

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Website: www.bio-GP.com.cn

By Royal Charter

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:

Design & Development, Manufacture and Distribution of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay). 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).
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。
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）试剂配套使用的分析仪。

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2020-05-29
Latest Revision Date: 2020-07-22

Effective Date: 2020-07-26
Expiry Date: 2023-07-25

...making excellence a habit.™

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.

Getein Biotech, Inc.

Stock Code: 603387

OPTIMIZED POINT-OF-CARE SOLUTION

MAKING TEST EASY

Getein1100

Immunofluorescence Quantitative Analyzer

Cardiac Markers

Coagulation Markers

Diabetes Mellitus

Inflammation

Thyroid Function

Metabolic Marker

Renal Function

Tumor Markers

Reproduction /Fertility

Infectious Disease

Getein1100

Immunofluorescence Quantitative Analyzer

HIGHLY EFFICIENT & ACCURATE

Advanced fluorescence immunoassay

Multiple quality control

REAL-TIME AND RAPID TEST

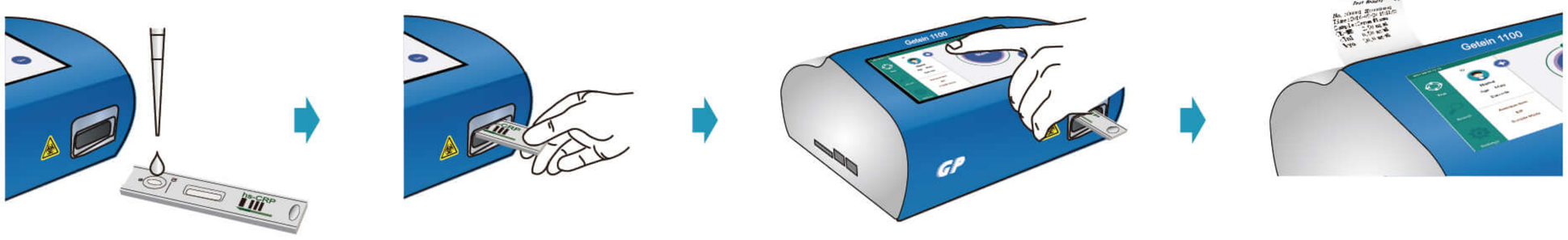
One-step test

3-15 min/test

5 sec/test for multiple tests

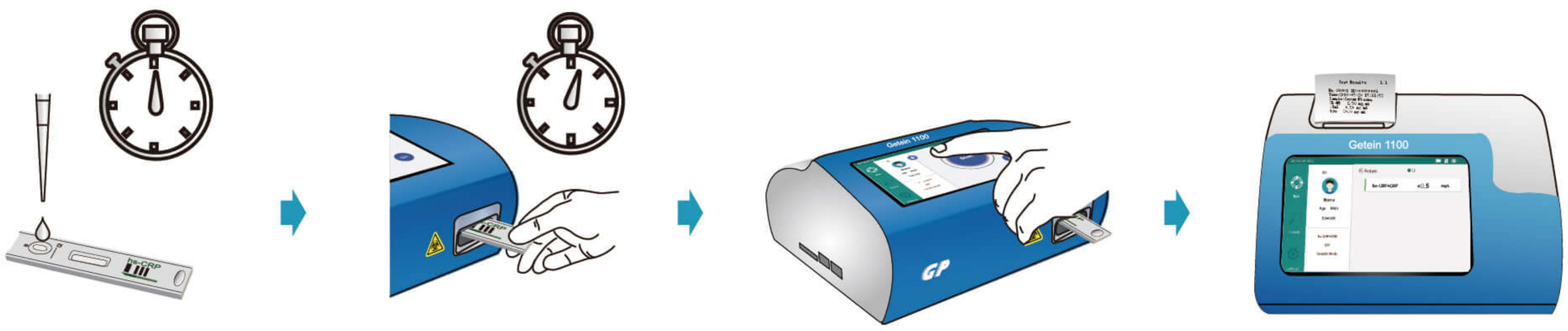
OPERATION MODES

Inside Mode (single sample rapid test mode)



Sample Dispense → Test Card Insert → Click “Start” Icon → Result Show and Print

Quick mode (mass samples rapid test mode)



Sample Dispense → Timing the Reaction Manually → Click “Start” Icon → Result Show and Print

CONVENIENT OPERATION

RFID card calibration

Keyboard and mouse connectivity through USB port

Handwriting input available

Continuous test for 3 hours with lithium battery

USER-FRIENDLY INTERFACE

Android system

7 inch touch screen

FRONT VIEW

PORTABLE DESIGN

Small in size: 261 ×241 ×115 mm

Light in weight: 2.0 kg

LARGE MEMORY

Up to 10,000 results storage capacity

TECHNICAL PARAMETERS

Methodology	Immunofluorescence
Result	Quantitative
Sample Type	WB, plasma, serum, urine, Stool, Nasal swab, Saliva, Capillary blood
Storage Capacity	10000 data
Language	English/Chinese/Spanish/Portuguese
Screen	7 inch touch screen
Power Supply	100-240 V~50 Hz/60 Hz, 60 VA
Working Environment	Tempreture: 10-35℃ Relative humidity ≤70% Air pressure 70.0~106.0 kpa
Dimension	261 mm×241 mm×115 mm (D×W×H)
Weight	2.0 kg

TEST ITEMS

Cat. #	TEST ITEMS	DISEASES	CUT-OFF VALUE	SAMPLE TYPES	MEASURING RANGE	SAMPLE VOLUME	REACTION TIME	QUALIFICATION
Cardiac Markers								
IF1001	cTnI	Myocardial infarction	0.1 ng/mL	S/P/WB	0.1-50.0 ng/mL	100 µL	10 min	NMPA CE
IF1089	BNP	Heart failure	100.0 pg/mL	P/WB	5.0-5000.0 pg/mL	100 µL	10 min	NMPA CE
IF1002	NT-proBNP	Heart failure	300 pg/mL	S/P/WB	100-35000 pg/mL	100 µL	10 min	NMPA CE
IF1005	CK-MB/cTnI/Myo	Myocardial damage /infarction	CK-MB: 5.0 ng/mL cTnI: 0.1 ng/mL Myo: 70 ng/mL	S/P/WB	2.5-80.0 ng/mL 0.1-50.0 ng/mL 30.0-600.0 ng/mL	100 µL	10 min	NMPA CE
IF1012	CK-MB/cTnI	Myocardial damage /infarction	CK-MB: 5.0 ng/mL cTnI: 0.1 ng/mL	S/P/WB	2.5-80.0 ng/mL 0.1-50.0 ng/mL	100 µL	10 min	CE
IF1014	H-FABP	Myocardial damage	6.36 ng/mL	S/P/WB	1.0-120.0 ng/mL	100 µL	3 min	NMPA CE
IF1016	CK-MB/cTnI/H-FABP	Myocardial damage /infarction	CK-MB: 5.0 ng/mL cTnI: 0.1 ng/mL H-FABP: 6.36 ng/mL	S/P/WB	2.5-80.0 ng/mL 0.1-50.0 ng/mL 2.0-100.0 ng/mL	100 µL	10 min	NMPA CE
IF1018	CK-MB	Myocardial injury	5.0 ng/mL	S/P/WB	2.5-80.0 ng/mL	100 µL	10 min	CE
NEW IF1078	ST2	Heart failure	35.0 ng/mL	S/P/WB	3.1-200.0 ng/mL	100 µL	10 min	CE
Coagulation Markers								
IF1006	D-Dimer	Venous thromboembolism	0.5 mg/L	P/WB	0.1-10.0 mg/L	100 µL	10 min	NMPA CE
Inflammation								
IF1003	hs-CRP+CRP	Cardiovascular inflammation /normal inflammation	3 mg/L 10 mg/L	S/P/WB/ Fingertip blood	0.5-200 mg/L	10 µL	3 min	NMPA CE
IF1007	PCT	Sepsis, bacterial infection	0.1 ng/mL	S/P/WB	0.1-50.0 ng/mL	100 µL	15 min	NMPA CE
IF1015	PCT/CRP	Sepsis, bacterial infection	PCT: 0.1 ng/mL CRP: 3.0 mg/L	S/P/WB	0.1-50.0 ng/mL 0.5-200.0 mg/L	100 µL	15 min	NMPA CE
IF1044	SAA	Bacterial/Virus infection	10.0 mg/L	S/P/WB/ Fingertip blood	5.0-200.0 mg/L	10 µL	5 min	NMPA CE
IF1090	SAA/CRP	Neonatal sepsis, Bacterial/virus infection	SAA: 10.0 mg/L CRP: 10.0 mg/L	S/P/WB/ Capillary blood	5.0-200.0 mg/L 0.5-200.0 mg/L	10 µL	5 min	NMPA CE
IF1088	IL-6	Acute inflammation	7.0 pg/mL	S/P/WB/ Peripheral blood	1.5-4000.0 pg/mL	100 µL	15 min	CE
Renal Function								
IF1008	CysC	Acute and chronic renal diseases	0.51-1.09 mg/L	S/P/WB	0.5-10.0 mg/L	10 µL	3 min	NMPA CE
IF1009	mAlb	Diabetic nephropathy, hypertensive nephropathy	20.0 mg/L	Urine	10.0-200.0 mg/L	100 µL	3 min	NMPA CE
IF1010	NGAL	Acute kidney injury	Serum: 200 ng/mL Urine: 100 ng/mL	S/Urine	50-5000 ng/mL	10 µL	10 min	NMPA CE
IF1011	β_2-MG	Acute and chronic kidney diseases/tumours	0.8-3.0 mg/L	S/P/WB	0.5-20.0 mg/L	10 µL	3 min	NMPA CE
Diabetes Mellitus								
IF1017	HbA1c	Diabetes mellitus	3.8%-5.8%	WB	2%-14%	10 µL	5 min	NGSP NMPA IFCC CE
Metabolic Marker								
IF1031	25-OH-VD	Osteomalacia, osteoporosis	30.0-50.0 ng/mL	S/P	8.0-70.0 ng/mL	40 µL	15 min	NMPA CE
Thyroid Function								
IF1024	TSH	Thyroid malfunction	0.27-4.20 µIU/mL	S/P	0.10-50.00 µIU/mL	100 µL	15 min	NMPA CE
IF1022	T3	Hyperthyroidism, hypothyroidism	1.30-3.10 nmol/L	S/P	0.30-10.00 nmol/L	40 µL	15 min	CE
IF1023	T4	Hyperthyroidism, hypothyroidism	59.0-154.0 nmol/L	S/P	5.4-320.0 nmol/L	40 µL	15 min	CE
IF1067	fT3	Hyperthyroidism, hypothyroidism	3.1-6.8 pmol/L	S/P	0.4-50.0 pmol/L	100 µL	15 min	CE
IF1068	fT4	Hyperthyroidism, hypothyroidism	12.0-22.0 pmol/L	S/P	0.3-100.0 pmol/L	100 µL	15 min	CE

Cat. #	TEST ITEMS	DISEASES	CUT-OFF VALUE	SAMPLE TYPES	MEASURING RANGE	SAMPLE VOLUME	REACTION TIME	QUALIFICATION
Reproduction/Fertility								
IF1013	HCG+β	Fertility	5.1 mIU/mL	S/P	5-100000 mIU/mL	100 μL	10 min	NMPA CE
IF1055	LH	Homeostasis fertility regualtion	Refer to User Manual	S/P	0.2-150.0 mIU/mL	100 μL	15 min	CE
IF1056	FSH	PCOS, infertility evaluation and pituitary disorders	Refer to User Manual	S/P	0.2-150.0 mIU/mL	100 μL	15 min	CE
IF1066	AMH	Fertility, PCOS, gonadal function, precocious/late puberty	Refer to User Manual	S/P	0.10-20.00 ng/mL	200 μL	15 min	CE
IF1048	PRL	Infertility, gonadal disorders	Refer to User Manual	S/P	0.50-200.0 ng/mL	100 μL	15 min	CE
IF1071	Prog	Infertility, evaluation of ovulation	Refer to User Manual	S/P	0.10-40.00 ng/mL	100 μL	15 min	CE
Tumor Markers								
IF1053	tPSA	Prostate cancer	4.0 ng/mL	S/P	0.50-100.00 ng/mL	100 μL	15 min	
IF1072	fPSA	Prostate cancer	1.0 ng/mL	S/P	0.10-30.00 ng/ml	100 μL	10 min	
IF1050	AFP	Liver cancer, cancer of ovaries or testicles, etc.	7.0 ng/mL	S/P	2.0-500.0 ng/mL	100 μL	15 min	CE
IF1051	CEA	Cancer marker: colon cancer etc.	4.7 ng/mL	S/P/WB	2.0-500.0 ng/mL	100 μL	15 min	CE
Infectious Disease								
IF1057	Anti-HCV	Hepatitis C	1 S/CO	S/P	1.00-20.00 S/CO	100 μL	15 min	
IF1058	Anti-TP	Syphilis	1 S/CO	S/P	1.00-50.00 S/CO	100 μL	15 min	CE
IF1059	Anti-HIV	AIDS	1 S/CO	S/P	1.00-1000.00 S/CO	100 μL	15 min	
IF1064	HBsAg	Hepatitis B	1 IU/mL	S/P	1.00-100.00 IU/mL	100 μL	15 min	
NEW IF1063	Anti-HBs	Hepatitis B	10.00 mIU/mL	S/P/WB	10.00-1000.00 mIU/mL	100 μL	15 min	
IF1084	2019-nCoV IgM/IgG	COVID-19	1 COI	S/P/WB		100 μL	10 min	CE
NEW IF1091	SARS-CoV-2 Antigen	COVID-19	1 COI	Nasal swab/Saliva		100 μL	15 min	CE
NEW IF1092	SARS-CoV-2 Total Antibody/ Neutralizing Antibody	COVID-19	Refer to User Manual	S/P/WB		100 μL	10 min	CE
NEW IF1095	SARS-CoV-2 Neutralizing Antibody	COVID-19	Refer to User Manual	S/P/WB		100 μL	10 min	
IF1047	*H. pylori*	*H. pylori* infection	5 ng/mL	Stool	1-200 ng/mL	150 mg	10 min	CE
Others								
NEW IF1077	Ferritin	Anemia/tumors	Male: 30-400 ng/mL Female: 13-150 ng/mL	S/P	0.50-2000.00 ng/mL	100 μL	15 min	CE
NEW IF1069	Total IgE	Allergic disorders	Refer to User Manual	S/P/WB	1.00-2000.00 IU/mL	100 μL	15 min	CE

Coming Soon: FOB, ASO, RF, anti-CCP, Folate…

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Web: en.bio-gp.com.cn

ISO13485 FSC CE NMPA NGSP IFCC IVD

CE IVD

Cardiac Troponin I Fast Test Kit

User Manual Cat.# CG2001

INTENDED USE

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

SUMMARY

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

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

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

PRINCIPLE

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

CONTENTS

A kit contains:

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

A test card consists of:

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

Whole blood buffer composition:

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

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

STORAGE AND STABILITY

Store the test card at 4~30℃ 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 or whole blood samples. Heparin,EDTA or sodium citrate*** should be used as the anticoagulant for plasma and whole blood. Samples should be free of hemolysis.
2. Suggest using serum or plasma for better results.
3. Serum or plasma can be used directly. For whole blood sample, whole blood buffer must be added before testing.
4. If testing will be delayed, serum and plasma samples may be stored up to 7 days at 2~8℃ 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: ***80 µl***.

TEST PROCEDURE

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

TEST RESULTS

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

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

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

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

EXPECTED VALUE

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

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

LIMITATIONS

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

REFERENCES

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

DESCRIPTION OF SYMBOLS USED

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

Key to symbols used			
	Manufacturer		Expiration date
	Do not reuse		Date of manufacture
	Consult instructions for use	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 Cardiac Troponin I Fast Test Kit. Please read this user manual carefully before operating to ensure proper use.

Version: WCG01A-DX-S-02

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Website: www.bio-gp.com.cn

Atlas Medical

Date: 05/Jan/2023

STATEMENT

We, Atlas Medical having a registered office at Ludwig-Erhard-Ring 3, 15827 Blankenfelde-Mahlow, Berlin, Germany assign SRL Sanmedico having a registered office at A. Corobceanu Street 7A, apt.9, Chisinau MD-2012, Moldova, as authorized representative in correspondence with the conditions of directive 98/79/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

On Behalf of Manufacturer:

General Manager

Haya Amawi

Signature: _____

Date: 05.01.2023

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CERTIFICAT
CERTIFICATE OF REGISTRATION
N° 36655 rev.1

GMED certifie que le système de management de la qualité développé par

GMED certifies that the quality management system developed by

ATLAS MEDICAL GmbH
Ludwig-Erhard-Ring 3
15827 Blankenfelde-Mahlow GERMANY

pour les activités
for the activities

Conception et développement, fabrication et vente de dispositifs médicaux de diagnostic in vitro .

Design and Development, Manufacturing and Sales of in vitro diagnostic medical devices.

réalisées sur le(s) site(s) de
performed on the location(s) of

Voir addendum

See addendum

est conforme aux exigences des normes internationales
complies with the requirements of the international standards

ISO 13485: 2016

Début de validité */ Effective date* **October 9th, 2020 (included)**
Valable jusqu'au */ Expiry date :* **October 8th, 2023 (included)**
Etabli le */ Issued on :* **October 8th, 2020**

DocuSigned by:
Beatrice Lys
EE33BDA9BAA04A3...

GMED SAS GMED SAS GMED GROUPE LNE

On behalf of the President
Béatrice LYS
Technical Director

cofrac
CERTIFICATION DE SYSTEMES DE MANAGEMENT
Accréditation n°4-0608
Liste des sites accrédités et portée disponible sur www.cofrac.fr

GMED N° 36655–1
Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

Renouvelle le certificat 36655-0

GMED_SQ_plus3sites-F-V0-07-2018

Addendum au certificat n° 36655 rev. 1 page 1/1
Addendum of the certificate n° 36655 rev. 1
Dossier / *File* N°P601408

Ce certificat couvre les activités et les sites suivants :
This certificate covers the following activities and sites:

French version :
Conception et développement, fabrication et vente de dispositifs médicaux de diagnostic *in vitro* à usage professionnel et/ ou d'autodiagnostic, dans les domaines du groupage sanguin, de la microbiologie, de la biochimie, de la toxicologie, de l'oncologie, de la cardiologie, de l'histologie, de l'endocrinologie et des maladies infectieuses, dans les techniques d'Agglutination/ ELISA/ Tests rapides/ Colorimétrie/ Disques antibiotiques.

English version:
Design and Development, Manufacturing and Sales of in vitro diagnostic medical devices for professional use and/or for self-testing, in the field of Immunohematology, Microbiology, Biochemistry, Toxicology, Oncology, Cardiology, Histology, Endocrinology Biosensors and Infectious diseases, in techniques of Agglutination/ ELISA/ Rapid tests/ Colorimetry/Antibiotic disks.

ATLAS MEDICAL GmbH
Ludwig-Erhard-Ring 3
15827 Blankenfelde-Mahlow
GERMANY

French version:
Siège social, responsable de la mise sur le marché
English version:
Headquarter, legal manufacturer

****

Sahab Industrial Zone Area
King Abdullah II Industrial City
Amman 11512
JORDAN

French version:
Conception, fabrication et contrôle final
English version:
Design, manufacture and final control

****

William James House
Cowley Road,
Cambridge, CB OWX
United Kingdom

French version:
Contact réglementaire
English version:
Regulatory Administration

****

3 sites / 3 *sites*

DocuSigned by:
Beatrice Lys
EF33BDA9BAA04A3...

On behalf of the President
Béatrice LYS
Technical Director

Certificate of Analysis for RPR Kit

1- Product Identification:

Lot No	22111005
Product Name	RPR Syphilis kit
QC Method No	F30D
Batch Size	70
EXP. Date	11.2024
Mfg. Date (if applicable)	N.A

2- Physical Inspection:

Inspection level	AQL	Sample size code letter	Inspected quantity	Accepted	Rejected
S-1	1.0	B	3	0	1

Applicable test type	Inspected item / criteria	Inspection results
➢ Kit Assembly:	All components of the kit are present according to the outer label	■ Pass □ Fail
➢ Item Color & Status:	RPR carbon Ag/reagent: Black – Liquid	■ Pass □ Fail
	Positive control: Colorless /Yellowish – Liquid	■ Pass □ Fail
	Negative control: Colorless /Yellowish – Liquid	■ Pass □ Fail
➢ Item Size/ Reagent Size is compatible with that requested in Item Dispense:	RPR carbon Ag/reagent :10 ml	■ Pass □ Fail
	Positive control : 2 ml	■ Pass □ Fail
	Negative control : 2 ml	■ Pass □ Fail
➢ Labels:	Correct label orientation	■ Pass □ Fail
	Correct label position	■ Pass □ Fail
	Clear printing	■ Pass □ Fail
➢ Package Insert:	Clear printing and correct folding	■ Pass □ Fail
	Correct code, version and brand as mentioned in Item Dispense	■ Pass □ Fail
	Address as mentioned on box design	■ Pass □ Fail
➢ Closing Cap:	No leakage and closed well	■ Pass □ Fail
➢ Stirring Sticks:	No breaking sticks and clean	□ Pass □ Fail
➢ Paper Card:	No scratch in test circles or edges and clean	□ Pass □ Fail
➢ Quantity/Kit:	Compatible with the quantity mentioned in the outer label. • Record the QTY/Kit: 5/1	■ Pass □ Fail
➢ Final Result:	■ Pass □ Fail, justify: …….	

Done by (Signature): Abdullah… Date: 20.11.2022 Time: 11:00

QC Officer/Supervisor

3- Biochemical Inspection:

	RN No./Lot No.	Agglutination time	Agglutination Intensity	Result (Agg./No Agg.)	Result (Pass / Fail)
RPR Antigen (if requested)	22111005	8 min	+2/-ve	Agg./No Agg.	■ Pass ☐ Fail
Positive Control Check	22111005	8 min	+2	Agg.	■ Pass ☐ Fail
Negative Control Check	22111005	8 min	-ve	No Agg.	■ Pass ☐ Fail
➢ Final Result:	■ Pass ☐ Fail, justify: …….				
Done by (Signature): Abdullah…. Date: 20.11.2022 Time: 11:30 QC Officer/Supervisor					

Final Conclusion: ■ **Pass** ☐ **Fail**	
Final QC Manager Approval (Signature): Tasneem	**Date:** 20.11.2022

QC Release Stamp:

Atlas Medical

Declaration Ref No: DC21-0193

CE Declaration of Conformity

We,

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Email: info@atlas-medical.com

Declare our responsibility that the following product:

Product Code	Product Name	Class	GMDN code
8.00.18.0.0005	RPR Carbon Antigen Reagent, 5 ml/vial	General-IVD	32450
8.00.18.2.1000	RPR Carbon Antigen 1000ml/bottle	General-IVD	32450
8.00.18.0.0050	RPR Carbon Antigen Kit, 50 Tests	General-IVD	32450
8.00.18.1.0050	RPR Carbon Antigen Kit, 50 Tests, White Glass Slide.	General-IVD	32450
8.00.18.2.0500	RPR Carbon Antigen Kit, 500 Tests (2ml latex, 2x0.5 ml control) Without card.	General-IVD	32450
8.00.18.3.0500	RPR Carbon Antigen Kit, 500 Tests (10ml latex, 2x0.5 ml control) Without card, stirring sticks.	General-IVD	32450
8.00.18.0.0100	RPR Carbon Antigen Kit, 100 Tests (2ml latex, 2x0.5 ml control)	General-IVD	32450
8.00.18.2.0100	RPR Carbon Antigen Kit, 100 Tests (2ml latex, 2x0.5 ml control +White Glass slide stirring sticks)	General-IVD	32450
8.00.18.0.0025	RPR Carbon Antigen Kit, 25 Tests (0.5ml latex, 2x0.5 ml control)	General-IVD	32450
8.00.18.0.0150	RPR Carbon Antigen Kit, 150 Tests	General-IVD	32450
8.00.18.0.0200	RPR Carbon Antigen Kit, 200 Tests	General-IVD	32450
8.00.18.0.0250	RPR Carbon Antigen Kit, 250 Tests	General-IVD	32450

Atlas Medical Quality Products

Atlas Medical	First issue date	Date of review	Management approval	MRXDO10F.10 08.02.2011
	September.2021	06.09.2021		

Amin Al-Habashneh
RA Manager

Atlas Medical

Declaration Ref No: DC21-0193

8.00.18.0.0500	RPR Carbon Antigen Kit,500 Tests	General-IVD	32450
8.00.18.0.1000	RPR Carbon Antigen Kit, 1000 Tests	General-IVD	32450
8.00.18.4.0500	RPR Carbon Antigen Kit,500 Tests (3x3.4ml reagent,2x1 controls)	General-IVD	32450
8.00.18.5.0500	RPR Carbon Antigen Kit, 500 Tests, (3x3.4ml reagent,2x1 controls)	General-IVD	32450
8.00.18.8.0500	RPR Carbon Antigen 500 Test (10ml reagent) without Control's.	General-IVD	32450
8.00.18.9.0050	RPR Carbon Antigen Kit, (5x10ml Reagent,2x2ml Control) , white glass Slide, Stirring Stick.	General-IVD	32450
8.33.04.0.0001	RPR Positive control	General-IVD	32450
8.33.04.1.0001	RPR Positive control ,Bulk	General-IVD	32450
8.33.04.0.0100	RPR Positive control(100ml/vial)	General-IVD	32450
8.33.04.0.0500	RPR Positive control(500ml/bottle)	General-IVD	32450
8.33.08.0.0001	RPR Negative control	General-IVD	32450

Is produced under Atlas quality system (ISO13485: 2016) supported by GMED certificate:

Certificate N^{0}.: 36655 rev 1

Expiry Date: October 8 th.2023

and complies with the essential requirements of

In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex I

And

EN ISO 18113-1, -2 :2011, EN ISO 15223:2016

EN ISO 14971:2019, EN ISO 23640 :2015 , ISO 2859 :2017,

EN 13612:2002, EN 13641:2002 , EN 13975:2003, ISO 13485:2016

And

Intended for In-Vitro Professional use only.

This Declaration includes the batches produced beyond this day according to the product Lot Log.

Manufacturer
Atlas Medical GmbH
Ludwig-Erhard-Ring 3
15827 Blankenefelde-Mahlow Germany.

Atlas Medical
Quality Diagnostic Products

Atlas Medical

RPR SYPHILIS CARD TEST
A qualitative and Semi- quantitative rapid card test for the detection of Non-Treponema (reagin) in serum or plasma

For *In-Vitro* and professional use only
Store at 2 to 8 C

INTENDED USE
For the qualitative and quantitative detection of Non-Treponema in serum or plasma.

INTRODUCTION & PRINCIPLE
Besides other antibodies, *Treponema Pallidium* produces non-Treponemal antibodies (reagin) in syphilitic persons. These antibodies can be detected by RPR antigen. ATLAS RPR card test is a macroscopic screening test for the qualitative and Semi-quantitative detection of reagin antibodies in serum or plasma. The kit contains RPR antigen which is based on the easy to use VDRL carbon antigens. In the presence of the reagin, the antigen causes flocculation of the carbon particles, which appears as black clumps. The charcoal particles contained in the antigen suspension enhances the visual appearance of the coagglutination in positive samples.

MATERIALS
MATERIALS PROVIDED
- RPR carbon antigen reagent.
- Positive and negative controls.
- RPR test cards.
- Plastic sticks.
- Dispensing Dropper.

MATERIALS NEEDED BUT NOT PROVIDED
- Saline 0.9%.
- Rotator (100rpm).
- Accurate pipette to deliver 50 µl and.
- Timer.

PRECAUTIONS
- Always use a fresh pipette tip for every test.

STORAGE AND STABILITY
- The reagents in this kit should be stored in an upright position and refrigerated between 2 to 8°C . Never Freeze. Test cards need not to be refrigerated and can be kept at room temperature.
- Reagents should be brought to room temperature and mixed well to obtain a uniform suspension of carbon particles.

PREPARING THE SPECIMEN
- ATLAS RPR kit can be used with either unheated plasma or heated serum samples.
- Serum samples can stay stable for up to 5 days if stored at 2 to 8 °C.
- Plasma samples collected with EDTA can stay stable up to 24 hours if stored at 2 to 8 °C.

PROCEDURES
QUALITATIVE PROCEDURE
1. Bring reagents to room temperature.
2. Dispense 50µl of sample onto a single circle on the test card.
3. Repeat step 2 for the positive and negative controls.
4. Spread the sample of each test specimen over the entire test circle.
5. Mix the carbon antigen suspension well.
6. Dispense one drop (20 µl) of the carbon antigen onto each test circle containing specimen. Do not mix the antigen with the sample.
7. Using the rotator, rotate the card at 100rpm for 8 minutes.
8. Read the results in good light immediately after 8 minutes.
9. Don't read the results after more than 8 minutes.

READING THE QUALITATIVE RESULTS
POSITIVE
- If large aggregates appear in the centre or the periphery of the test circle containing the sample,then the test should be read as positive (reactive)
- If the aggregates are visible, but weak or small, then the test should be read as weak positive (weakly reactive).
- If test is positive, then results should be confirmed by the quantitative procedure mentioned below.

NEGATIVE
If no aggregates appear and the specimen has smooth grey appearance (non-reactive)

SEMI-QUANTITATIVE PROCEDURE
1. Dispense 50µl of 0.9% saline to test circles numbered 2 to 5. Saline should not be spread. Dispense 50 µl of specimen onto test circle 1.
2. Dispense 50 µl of specimen onto test circle 2. Prepare serial two-fold dilutions by drawing the mixture up and down the pipette 5-6 times (avoid any bubble formation. Transfer 50 µl from circle 2 to 3, to 4 and to 5. Dispose 50 µl from circle 5 after mixing.
3. Starting from circle 5 and onto 4,3,2 and 1, mix and spread the serum over the entire area of each test circle.
4. Continue with steps 6-9 of the qualitative procedure.

READING THE SEMI-QUANTITATIVE RESULTS
The dilution of the circles are as follows:

Circle	1	2	3	4	5
Dilution	-	1:2	1:4	1:8	1:16

The titer of the sample is read as follows (P:Positive, N:Negative)

Positive 1:2	P	P	N	N	N

Positive 1:4	P	P	P	N	N
Positive 1:8	P	P	P	P	N
Positive 1:16	P	P	P	P	P

Positive and negative results are read as in the reading qualitative results procedure.

If the result in circle 5 is positive, then further dilution to 1:32, 1:64, 1:128 and 1:256 is required. Use steps 3 in semi-quantitative procedure and steps 6-9 in qualitative procedure to obtain the required dilutions.

**The titer , in the semi- quantitative method , is defined as the highest dilution showing a positive results.

LIMITATION

- This test provides a presumptive diagnosis of syphilis. Physicians should evaluate all clinical and laboratory findings before making a definitive diagnosis.
- In positive specimens, it is recommended to confirm the result by another serological test such as the TPHA.

REFERENCES

1. Falcone V.H., Stout G.W. and Moore M.B. Jr., PHR 79: 491-495, 1964.
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