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

Document No.: GP-GMSQ-2024121101

Letter of Authorization

To whom it may concern,

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

FIA8000 Quantitative Immunoassay Analyzer and Reagents

Getein1100 Immunofluorescence Quantitative Analyzer and Reagents

Getein1160 Immunofluorescence Quantitative Analyzer and Reagents

Getein 1600 Immunofluorescence Quantitative Analyzer and Reagents

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

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

This authorization starts from Jan 1, 2025and will be valid to December 31 2025.

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

Getein Biotech, Inc.

基蛋生物科技股份有限公司
GETEIN BIOTECH, INC.

Name: Steven Zhou
Position: Overseas Sales Director

Steven Zhou

Digitally signed by Dolgopol Iulian
Date: 2025.03.28 11:33:06 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

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

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

Holds Certificate No: **MD 728432**

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

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

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

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

...making excellence a habit.™

Certificate No: **MD 728432**

Registered Scope:

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

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

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

Certificate No: **MD 728432**

Location	Registered Activities
Getein Biotech, Inc. No.9 Bofu Road Luhe District Nanjing Jiangsu 211505 China 基蛋生物科技股份有限公司 中国 江苏省 南京市 六合区 沿江工业开发区 博富路9号 邮编：211505	Design & Development, Manufacture and Distribution of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay), PCR Assay and Colloidal Gold self-testing Assay to detect infectious disease. Design & Development, Manufacture and Distribution of Analyzers in use of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay), PCR Assay to detect infectious disease, Immunofluorescence self-testing Assay to detect dyslipidemia disease, Blood Coagulation Assay to detect thrombotic disease. 研发，生产和销售化学发光法试剂，生化试剂，即时诊断（包括胶体金法，免疫荧光法，干式化学法）试剂，传染病相关PCR分子诊断试剂和胶体金自测试剂。 研发，生产和销售用于化学发光法试剂，生化试剂，即时诊断（包括胶体金法，免疫荧光法，干式化学法）试剂，传染病相关PCR分子诊断试剂，血脂异常疾病相关免疫荧光自测试剂，血栓疾病相关血凝试剂配套使用的分析仪。
Getein Biotech, Inc. No. 6 KeFeng Road Jiangbei New District Nanjing Jiangsu 211505 China 基蛋生物科技股份有限公司 中国 江苏省 南京 江北新区 科丰路6号 邮编：211505	Manufacture of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay), Colloidal Gold self-testing Assay to detect infectious disease. Manufacture of Analyzers in use of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay), PCR Assay to detect infectious disease, Immunofluorescence self-testing Assay to detect dyslipidemia disease, Blood Coagulation Assay to detect thrombotic disease. 生产化学发光法试剂，生化试剂，即时诊断（包括胶体金法，免疫荧光法，干式化学法）试剂和传染病相关胶体金自测试剂。 生产用于化学发光法试剂，生化试剂，即时诊断（包括胶体金法，免疫荧光法，干式化学法）试剂，传染病相关PCR分子诊断试剂，血脂异常疾病相关免疫荧光自测试剂，血栓疾病相关血凝试剂配套使用的分析仪。

Original Registration Date: 2020-05-29

Effective Date: 2023-07-26

Latest Revision Date: 2023-04-26

Expiry Date: 2026-07-25

EC Declaration of Conformity

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

Ref. No.:20220513-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

D-Dimer
Fast Test Kit
(Immunofluorescence Assay)

IF1006 for Getein1100
IF3006 for Getein1180
IF4006 for Getein1200
IF2006 for Getein1600
REF IF5006 for Getein1160
IF6006 for Getein208

User Manual

INTENDED USE

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

SUMMARY

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

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

PRINCIPLE

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

Then insert test card into Getein1100/Getein1160/Getein1180 Immunofluorescence Quantitative Analyzer/ Getein208 Hand-held Integrated System /automatically inserted by Getein1200/ Getein1600 Immunofluorescence Quantitative Analyzer (hereafter referred to as Getein1100, Getein1160, Getein1180, Getein208, Getein1200 and Getein1600), the concentrations of D-Dimer in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1160/ Getein1180/Getein208/Getein1200/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

1. A kit for Getein1100/Getein1160/Getein1180/Getein208 contains:
Package specifications: 25 tests/box, 10 tests/box
1) D-Dimer test card in a sealed pouch with desiccant
2) Disposable pipet
3) Sample diluent
4) User manual: 1 piece/box
5) SD card: 1 piece/box

2. A kit for Getein1200/Getein1600 contains:
Package specifications: 2×24 tests/kit, 2×48 tests/kit
1) Sealed cartridge with 24/48 Getein D-Dimer test cards
2) User manual: 1 piece/box
Materials required for Getein1200/Getein1600:
1) Sample diluent: 1 bottle/box
2) Box with pipette tips: 96 tips/box
3) Mixing plate: 1 piece/box

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

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

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

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1180 Immunofluorescence Quantitative Analyzer
Getein1200 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer
Getein1160 Immunofluorescence Quantitative Analyzer
Getein208 Hand-held Integrated System

STORAGE AND STABILITY

Store the test card at 4~30℃ with a valid period of 24 months. Use the test card for Getein1100/Getein1160/Getein1180/Getein-208 within 1 hour once the foil pouch is opened.

For test card of Getein1200/Getein1600: if the cartridge is opened, it could be stable within 24 hours once exposed to air. If the test cards can't be used up at a time, please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.

PRECAUTIONS

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

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for ***plasma and whole blood samples. Sodium citrate*** can be used as the anticoagulant for plasma and whole blood. Samples should be free of hemolysis.
2. Suggest using plasma for better results.
3. If testing is delayed, plasma sample may be stored up to 3 days at 2~8℃ or stored at -20℃ for 1 month 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 ***(for Getein1100/Getein1160/Getein1180): 100 µL.***

(for Getein208): 60 µL.

TEST PROCEDURE

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

For Getein1100:

3. Confirm SD card lot No. in accordance with test kit lot No.. Perform “SD card” calibration when necessary.
4. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
5. Put the test card on a clean table, horizontally placed.
6. Using sample transfer pipette, deliver ***100 µL*** of sample into one tube of sample diluent, mix gently and thoroughly. Then drop ***100 µL*** of sample mixture into the sample port on the test card.
7. ***Reaction time: 10 minutes.*** Insert the test card into Getein1100 and press "ENT" button or click on “Start” icon (for Android Getein1100) after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1160/Getein1180:

8. Confirm SD card lot No.in accordance with test kit lot No.. Perform “SD card”calibration when necessary.
9. Enter testing interface of Getein1160/Getein1180.
10. Remove the test card from the sealed pouch immediately before use.Label the test card with patient or control identification.
11. Put the test card on a clean table,horizontally placed.
12. Using sample transfer pipette,deliver ***100 µL*** of sample into one tube of sample diluent,mix gently and thoroughly.Then drop ***100 µL*** of sample mixture into the sample port on the test card.
13. ***Reaction time: 10 minutes.*** Insert the test card into Getein1160/Getein1180 immediately after sample loading. The analyzer will count down the reaction time and automatically test the card after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein208:

14. Long press the Power Button to start the analyzer
15. The system will enter (Test) menu.
16. Insert the MEMo memory chip which is with the same batch number as the test card.
17. Select (Test) menu, press (OK) to enter [Read Calibration Card] interface.
18. Press (OK) to automatically obtain the test item, batch number, serial number and sampling volume. Select the sample type by pressing＜or＞buttons.
19. Press (OK). The screen then prompts [Insert test card] and starts counting down from 60 sec. Insert test card within the 60 sec.

Note: Do not move the test card after it is inserted.

20. Add sample within 120 sec when the screen prompts [Wait for sample]. Then draw ***60 µL*** of sample and drop it into 1000 µL of sample diluent. Then drop ***60 µL*** of sample mixture into the sample port on the test card.
21. After sample adding, the system starts react-time countdown automatically.
22. After the countdown is over, the system starts testing automatically.

Please check and record test results then.

Note: Test results are saved automatically in the system.

23. Long Press (OK) to return to the main interface. Take out and discard the test card.

For Getein1200/Getein1600:

24. Each cartridge for Getein1200/Getein1600 contains a specific RFID card which can calibrate automatically.
25. Place the sample diluent at the correct position in Getein1200/Getein1600.
26. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1200/Getein1600 will do the testing and print the result automatically.

Notes:

1. It is required to perform “SD card” calibration when using a new batch of kits for Getein1100/Getein1160/Getein1180/Getein208.
2. It is suggested to calibrate once for one batch of kits for Getein1100/Getein1160/Getein1180/Getein208.
3. Make sure the test card and the sample insertion is correct and complete.

TEST RESULTS

Getein1100/Getein1160/Getein1180/Getein208/Getein1200/Getein1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein1100/Getein1160/Getein1180/Getein208/Getein1200/Getein1600.

EXPECTED VALUE

The expected normal value for D-Dimer was determined by testing samples from 500 apparently healthy individuals. The 95th percentile of the concentration for D-Dimer is 0.50 mg/L. (The probability that value of a normal person below 0.50 mg/L is 95%.)

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

PERFORMANCE CHARACTERISTICS

Measuring Range	0.10~10.00 mg/L
Lower Detection Limit	≤0.10 mg/L
Within-Run Precision	≤10%
Between-Run Precision	≤15%

LIMITATIONS

1. As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.
2. 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 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
5. EN ISO 18113-2:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on D-Dimer Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

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

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

Version: WIF05-S-13

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

EC REP Lotus NL B.V.
Add.: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
E-mail: peter@lotusnl.com
Tel: +31644168999

D-二聚体检测试剂盒（干式免疫荧光法）检验报告

Certificate of Analysis

产品名称 Product Name	D-二聚体检测试剂盒（干式免疫荧光法） D-Dimer Fast Test Kit (Immunofluorescence Assay)		
产品批号 Lot No.	Y066240040W	产品规格 Specifications	25 人份/盒
生产日期 Production Date	2025-01-06	失效日期 Valid till	2027-01-06
成品数量 Quantity	620 盒	检验数量 Sample Quantity	4 盒
主要仪器 Analyzer	☑Getein1100 □Getein1180 □Getein1150 □Getein1160 □Getein3200 □Getein3208 □Getein1600 □Getein1200 □Getein3600 □Getein3608 □Getein200 □Getein208		
检测依据 Contract No.	D-二聚体检测试剂盒（干式免疫荧光法）检验标准操作规程		

检验项目 Test Items		检验标准 Test Criteria	符合要求 Conformity
1 外观 Appearance		产品外包装盒和铝箔包装袋，其完整、无破损。 Package box and aluminum foil bag are intact and undamaged.	☑是 Yes □否 No
2 检测缓冲液（本条款仅适用配套 Getein1100/1180/1150/1160/200/208 分析仪的试剂盒） Sample Diluent (Only for Getein1100/1180/1150/1160/200/208 matching kits)	外观 Appearance	缓冲液应澄清透明，无悬浮物。管体密封好，无漏液现象。 The sample diluent should be clear and transparent, without suspended matter. The bottle should be closed tightly and no leakage.	☑是 Yes □否 No
	装量 Packing Volume	其净含量应在 1.00 g±0.05 g 之间。Net weight should be within 1.00±0.05 g.	☑是 Yes □否 No
	pH	pH 应在 7.2±0.2 之间。pH should be within 7.2±0.2.	☑是 Yes □否 No
3 试纸条 Test Strip	外观 Appearance	整洁平整、无毛刺、无破损、无污染；材料附着牢固。 The surface should be sleek, burr-free, undamaged and no pollution. The material is firmly attached.	☑是 Yes □否 No
	宽度 Width	试纸条的宽度不超过标称值±0.80 mm，标称值为 4.50 mm。 Average width value should be within 4.50±0.80 mm.	☑是 Yes □否 No
	移行速度 Capillary Flow Rate	液体移行速度不低于 10.0 mm/min。 Fluid capillary flow rate should not be less than 10.0 mm/min.	☑是 Yes □否 No
4 最低检出限 Limit of Detection		最低检出限不高于 0.1 mg/L。 The limit of detection should not be greater than 0.1 mg/L.	☑是 Yes □否 No
5 线性范围 Linear Range		在（0.1~10.0）mg/L 范围内，线性相关系数 r≥0.990。 In the range of 0.1~10.0 mg/L, the linear correlation coefficient r≥0.990.	☑是 Yes □否 No
6 准确度 Accuracy		相对偏差不大于 20%。Relative deviation should not be greater than 20%.	☑是 Yes □否 No
7 重复性 Repeatability		重复性（CV）应不大于 10%。Repeatability should not be greater than 10%.	☑是 Yes □否 No
结论 Conclusion：☑合格 Conformity □不合格 Inconformity			

基蛋生物科技股份有限公司 质检专用章

检验人 Inspector/日期 Date：2025.01.09　　复核人 Auditor/日期 Date：2025.01.09

Record No.：250113

STATEMENT

We, Zhejiang Orient Gene Biotech Co., Ltd , having a registered office at 3787#, East Yangguang Avenue, Dipu Street Anji 313300, Huzhou, Zhejiang, China assign SRL SANMEDICO having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova, as exclusive authorized representative for Orient Gene Brand product in correspondence with the conditions of directive 98/79/EEC in Moldova only. The detailed product list is in the Annex 1 in the following pages.

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.

This Statement letter will be valid from Mar.10th,2025to Mar.09th, 2027.

Zhejiang Orient Gene Biotech Co., Ltd

General Manager:

Date:2025/3/10

Annex 1

Numărul de catalog (referință)*	**Denumire generică (denumirea dispozitivului)**	**Denumire comercială (brand)***	**Modelul**
GCCOV-702a-H1	TEST RAPID	Orient Gene	Rapid COVID-19 Antigen Oral Fluid Self-Test
GCCOV-702a-H5	TEST RAPID	Orient Gene	Rapid COVID-19 Antigen Oral Fluid Self-Test
GCCOV-702a-H20	TEST RAPID	Orient Gene	Rapid COVID-19 Antigen Oral Fluid Self-Test
GCCOV-502a-H1OGE	TEST RAPID	Orient Gene	Rapid COVID-19 (Antigen) Self-test
GCCOV-502a-H5OGE	TEST RAPID	Orient Gene	Rapid COVID-19 (Antigen) Self-test
GCCOV-502a-H20OGE	TEST RAPID	Orient Gene	Rapid COVID-19 (Antigen) Self-test
GIHSA-102a	TEST RAPID	Orient Gene	One Step Microalbumin Test Cassette
GIHSA-101a	TEST RAPID	Orient Gene	One Step Microalbumin Test Strip (Urine)
GCROA-602a	TEST RAPID	Orient Gene	Rotavirus rapid test cassette (feces)
GCMAL(pf/pv)-402a	TEST RAPID	Orient Gene	Malaria P.f./P.v. Ag Rapid Test Cassette (Whole Blood)
GCROA/ADE-602a	TEST RAPID	Orient Gene	Rotavirus and Adenovirus Combo Rapid Test Cassette (Feces)
GASPE-902a	TEST RAPID	Orient Gene	Male Fertility Rapid Test Cassette (Semen)
GAFSH-101a	TEST RAPID	Orient Gene	One Step Menopause Test Strip (Urine)
GAFSH-102a	TEST RAPID	Orient Gene	One Step Menopause Test Cassette (Urine)
GAIGF1-502a	TEST RAPID	Orient Gene	iGFBP-1 Rapid test Cassette (Swab)

GAIGF1-501a	TEST RAPID	Orient Gene	iGFBP-1 Rapid Test Strip (Cervical Secretion)
GALH-101a	TEST RAPID	Orient Gene	One Step Ovulation Test Strip (Urine) (25mIU)
GALH-101b	TEST RAPID	Orient Gene	One Step Ovulation Test Strip (Urine) (40mIU)
GALH-102a	TEST RAPID	Orient Gene	One Step Ovulation Test Cassette (Urine) (25mIU)
GALH-102b	TEST RAPID	Orient Gene	One Step Ovulation Test Cassette (Urine) (40mIU)
GCTYP-302a	TEST RAPID	Orient Gene	Typhoid IgG/IgM Rapid Test Cassette (serum/plasma)
GCMAL(pf/pan)-402a	TEST RAPID	Orient Gene	Malaria P.f./Pan Ag Rapid Test Cassette (Whole Blood)
GCDEN-425a	TEST RAPID	Orient Gene	Dengue NS1+IgM/IgG Combo Rapid Test Cassette (Whole blood/serum/plasma)
GCDEN(NS)-402c	TEST RAPID	Orient Gene	Dengue NS1 Antigen Rapid Test Cassette (Whole blood/serum/plasma)
GCDEN(ab)-402c	TEST RAPID	Orient Gene	Dengue IgM/IgG Rapid Test Cassette (Whole blood/serum/plasma)
GCVCH(O1/O9)-602a	TEST RAPID	Orient Gene	V.cholerae O1/O139 Ag Combo Rapid Test Cassette (Feces)
GCMAL(pf)-402a	TEST RAPID	Orient Gene	Malaria Pf Ag Rapid Test Cassette (Whole blood)
GCSAL(ST)-602a	TEST RAPID	Orient Gene	S. typhi Ag Rapid Test Cassette (Serum/plasma/Feces)
GCCHK(IgM)-402a	TEST RAPID	Orient Gene	Chikungunya IgM Rapid Test Cassette (Whole blood/Serum/Plasma)
GCCOV-502a-NN	TEST RAPID	Orient Gene	Coronavirus Ag Rapid Test Cassette (Swab)
GCCOV (Nab)-402b	TEST RAPID	Orient Gene	SARS-CoV-2 Neutralizing Antibody Rapid Test Cassette (Whole blood/Serum/Plasma)
GCCOV-502a-NA	TEST RAPID	Orient Gene	Coronavirus Ag Rapid Tests Cassette (Swab)

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GCCOV (Ag)-PN10	TEST RAPID	Orient Gene	COVID-19 Antigen Control Kit
GCCOV (Ag)-PN20	TEST RAPID	Orient Gene	COVID-19 Antigen Control Kit
GCFCRA-545a	TEST RAPID	Orient Gene	Flu, COVID-19,RSV&Adeno Ag Combo Tests Cassette (Swab)
GCTV-502a	TEST RAPID	Orient Gene	Trichomonas Ag Rapid Test Cassette (Swab)
GCVCH(O1)-602a	TEST RAPID	Orient Gene	V.cholerae O1 Ag Rapid Test Cassette (Feces)
GCCHA-402a	TEST RAPID	Orient Gene	Chagas Ab Rapid Test Cassette (Whole blood/serum/plasma)
GCMAL(pf/pv Ab)-302a	TEST RAPID	Orient Gene	Malaria Pf/Pv Ab Rapid Test Cassette (Serum/plasma)
GCMAL(pf/pv Ab)-402a	TEST RAPID	Orient Gene	Malaria Pf/Pv Ab Rapid Test Cassette (Whole blood/Serum/plasma)
GCMKP-502b	TEST RAPID	Orient Gene	Monkeypox Ag Rapid Test Cassette (Swab)
GCCOV(Del)-T502a	TEST RAPID	Orient Gene	SARS-CoV-2 Delta-series Mutant Strain Ag Rapid Test cassette (Swab)
GCCOV-PN10	TEST RAPID	Orient Gene	COVID-19 IgG/IgM Control kit
GCCOV-PN20	TEST RAPID	Orient Gene	COVID-19 IgG/IgM Control kit
GCFCR-T525a	TEST RAPID	Orient Gene	COVID-19/Flu A&B/ RSV Ag Combo Rapid Test Cassette (Swab)
GCCOV(B117)-525a	TEST RAPID	Orient Gene	COVID-19 Ag&B.1.1.7 Mutant Strain Combo Test Cassette (Swab)
GCFCRA-T525a	TEST RAPID	Orient Gene	COVID-19/Flu A&B/ RSV/Adeno Ag Combo Rapid Test Cassette (Swab)
GCCOV-702a	TEST RAPID	Orient Gene	COVID-19 Ag Rapid Test Cassette (Oral fluid)
GCFC-T502a	TEST RAPID	Orient Gene	COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab)

GCMKP-402a	TEST RAPID	Orient Gene	Monkeypox IgG/IgM Rapid Test Cassette (Whole blood/serum/plasma)
GCKal-401a	TEST RAPID	Orient Gene	Leishmania Ab Rapid Test strip (Whole blood/serum/plasma)
GCKal-T402a	TEST RAPID	Orient Gene	Leishmania IgG/IgM Rapid test cassette (whole blood/serum/plasma)
GCCOV-503a	TEST RAPID	Orient Gene	Smart Rapid COVID-19 Ag Test Device
GCBRU-402a	TEST RAPID	Orient Gene	Brucella Antibody Rapid Test Cassette (Whole blood/serum/plasma)
GCCHA-302a	TEST RAPID	Orient Gene	Chagas Ab Rapid Test Cassette (Serum/plasma)
GCCHK(IgM)-302a	TEST RAPID	Orient Gene	Chikungunya IgM Rapid Test Cassette (Serum/Plasma)
GCCOV-501a	TEST RAPID	Orient Gene	Rapid COVID-19 Antigen Test Strip
GCMON-352a	TEST RAPID	Orient Gene	Mononucleosis IgG/IgM Rapid Test Cassette (Serum/plasma)
GCMON-402a	TEST RAPID	Orient Gene	Mononucleosis Rapid Test Cassette (Whole blood/Serum/plasma)
GCMON-425a	TEST RAPID	Orient Gene	Mononucleosis IgG/IgM Rapid Test Cassette (Whole blood/Serum/plasma)
GCEV71 (IgM)-302a	TEST RAPID	Orient Gene	EV71 IgM Rapid Test Cassette (Serum/plasma)
GCEV71 (IgM)-402a	TEST RAPID	Orient Gene	EV71 IgM Rapid Test Cassette (Whole blood/Serum/plasma)
GENMP22-102a	TEST RAPID	Orient Gene	One Step Nuclear Matrix Protein 22 Test Cassette (Urine)
GEFOB/TF-602a	TEST RAPID	Orient Gene	Fecal Occult Blood and Transferrin Combo Rapid Test Cassette (Feces)
GCHEV-302a	TEST RAPID	Orient Gene	HEV IgM Rapid Test Cassette (Serum/Plasma)
GCMP (IgM)-302a	TEST RAPID	Orient Gene	M.pneumonia IgM Rapid Test Cassette (Serum/plasma)

FCCOV-502a	TEST RAPID	Orient Gene	SARS-CoV-2 Ag Fluorescence Rapid Test Cassette (Swab)
GCCOV-402Ba	TEST RAPID	Orient Gene	COVID-19 IgG/IgM Rapid test cassette (whole blood/serum/plasma)
GCCOV-402a	TEST RAPID	Orient Gene	COVID-19 IgG/IgM Rapid test cassette (whole blood/serum/plasma)
GCCOV-502a	TEST RAPID	Orient Gene	Coronavirus Ag Rapid Test Cassette (Swab)
GCFC-T503a	TEST RAPID	Orient Gene	Smart Rapid COVID-19 &Flu A/B Ag Test Device
GAHCG-101a	TEST RAPID	Orient Gene	One step pregnancy test strip (urine)
GAHCG-101d	TEST RAPID	Orient Gene	One step pregnancy test strip (urine)
GAHCG-101b	TEST RAPID	Orient Gene	One step pregnancy test strip (urine)
GAHCG-102a	TEST RAPID	Orient Gene	One step pregnancy test cassette (urine)
GAHCG-102d	TEST RAPID	Orient Gene	One step pregnancy test cassette (urine)
GAHCG-102b	TEST RAPID	Orient Gene	One step pregnancy test cassette (urine)

GEFOB-602c	TEST RAPID	Orient Gene	Fecal Occult Blood Rapid Test Cassette (Feces)
GEFOB-602b	TEST RAPID	Orient Gene	Fecal Occult Blood Rapid Test Cassette (Feces)
GEFOB-601c	TEST RAPID	Orient Gene	Fecal Occult Blood Rapid Test Strip (Feces)
GEFOB-601b	TEST RAPID	Orient Gene	Fecal Occult Blood Rapid Test Strip (Feces)
GECEA-402a	TEST RAPID	Orient Gene	Carcinoembryonic Antigen Rapid Test Cassette (Whole blood/serum/plasma)

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GECEA-401a	TEST RAPID	Orient Gene	Carcinoembryonic Antigen Rapid Test Strip (Whole blood/serum/plasma)
GETF-602a	TEST RAPID	Orient Gene	Transferrin Rapid Test Cassette (Feces)
GETF-601a	TEST RAPID	Orient Gene	Transferrin Rapid Test Strip (Feces)
GEAFP-401a	TEST RAPID	Orient Gene	Alpha-Fetoprotein Rapid Test Strip (Whole blood/serum/plasma)
GEAFP-402a	TEST RAPID	Orient Gene	Alpha-Fetoprotein Rapid Test Cassette (Whole blood/serum/plasma)
GIHSA-101a	TEST RAPID	Orient Gene	One step microalbumin test strip (urine)
GIHSA-102a	TEST RAPID	Orient Gene	One step microalbumin test cassette (urine)
GDCAR-335a	TEST RAPID	Orient Gene	Myoglobin/CK-MB/Troponin I Combo Test Cassette (Serum/plasma)
GDCKM-302a	TEST RAPID	Orient Gene	One step CK-MB Test Cassette (Serum/Plasma)
GDCKM-402a	TEST RAPID	Orient Gene	CK-MB Rapid Test Cassette (Whole blood/serum/plasma)
GDCRP-402a	TEST RAPID	Orient Gene	C-Reactive Protein Semi-Quantitative Rapid Test Cassette (Whole Blood/serum/plasma)
GDTRO-302a	TEST RAPID	Orient Gene	Troponin I Rapid Test Cassette (Serum/Plasma)
GDTRO-402a	TEST RAPID	Orient Gene	Troponin I Rapid Test Cassette (Whole blood/Serum/Plasma) **(Except the tender No. ocds-b3wdp1-MD-1722410248839 din 05.09.2024, limited to the quantity 28060 pcs only, as per the tender)**
GDTRO-402b	TEST RAPID	Orient Gene	Troponin I Rapid Test Cassette (Whole blood/Serum/Plasma)

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GDMYO-402a	TEST RAPID	Orient Gene	Myoglobin Rapid Test Cassette (Whole blood/serum/plasma)
GDCAR-W435a	TEST RAPID	Orient Gene	Myoglobin/CK-MB/Troponin I Combo Rapid Test Cassette (whole blood/Serum/plasma)
GDPCT-402a	TEST RAPID	Orient Gene	Procalcitonin Rapid Test Cassette (Whole blood/serum/plasma)
GDPCT-T402a	TEST RAPID	Orient Gene	Procalcitonin Semi-Quantitative Rapid Test Cassette (Whole blood/serum/plasma)
GDPCT-T401a	TEST RAPID	Orient Gene	Procalcitonin Semi-Quantitative Rapid Test Strip (Whole blood/serum/plasma)
FDPCT -302a	TEST RAPID	Orient Gene	Procalcitonin Rapid Test Kit (serum/plasma)
GDDDI-402b	TEST RAPID	Orient Gene	D-Dimer Rapid Test Cassette (Whole blood/plasma)
FDCAR-T302a	TEST RAPID	Orient Gene	Troponin I/CK-MB/Myoglobin Fluorescence Combo Test Kit (Serum/plasma)
FDTRO-302a	TEST RAPID	Orient Gene	Troponin I Fluorescence Rapid Test Kit (Serum/plasma)
FDBNP-302a	TEST RAPID	Orient Gene	NT-ProBNP Fluorescence Rapid Test Kit (Serum/plasma)
FDCRP-402a	TEST RAPID	Orient Gene	C-Reactive Protein Rapid Test Kit (Whole blood/serum/plasma)
GDCKM-402a	TEST RAPID	Orient Gene	CK-MB Rapid Test Cassette (whole blood/serum/plasma)
GAHCG-201a	TEST RAPID	Orient Gene	One step pregnancy test strip (Urine/serum)
GAHCG-202a	TEST RAPID	Orient Gene	One step pregnancy test cassette (Urine/serum)
GAHCG-201b	TEST RAPID	Orient Gene	One step pregnancy test strip (Urine/serum)
GAHCG-202b	TEST RAPID	Orient Gene	One step pregnancy test cassette (Urine/serum)
GCHAV(IgM)-302Ba	TEST RAPID	Orient Gene	HAV IgM Rapid Test Cassette (Serum/plasma)
GCHAV-602a	TEST RAPID	Orient Gene	HAV Ag Rapid Test Cassette (Feces)

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GCHAV(IgG/IgM) -302a	TEST RAPID	Orient Gene	HAV IgG/IgM Rapid Test Cassette (Serum/plasma)
GCHSV(IgG)-402a	TEST RAPID	Orient Gene	HSV IgG Rapid Test Cassette (Whole blood/serum/plasma)
GCHSV(IgM)-302a	TEST RAPID	Orient Gene	HSV IgM Rapid test Cassette (serum/plasma)
GCHP-601a	TEST RAPID	Orient Gene	H.pylori Ag Rapid Test Strip (feces)
GCHP-602a	TEST RAPID	Orient Gene	H.pylori Ag Rapid Test Cassette(feces)
GCTB-302a	TEST RAPID	Orient Gene	Tuberculosis IgG/IgM Rapid Test Cassette (serum/plasma)
GCTB-402a	TEST RAPID	Orient Gene	Tuberculosis IgG/IgM Rapid Test Cassette (whole blood/serum/plasma)
GCFLU(A/B)-501a	TEST RAPID	Orient Gene	Influenza A&B Ag Rapid Test Strip (Swab)
GCFLU(A/B)-502a	TEST RAPID	Orient Gene	Influenza A&B Ag Rapid Test Cassette (Swab)
GCFLU(A/B)-502Ca	TEST RAPID	Orient Gene	Influenza A&B Ag Rapid Test Cassette (Swab)
GCFLU(A)-501a	TEST RAPID	Orient Gene	Influenza A Ag Rapid Test Strip (Swab)
GCFLU(A)-502a	TEST RAPID	Orient Gene	Influenza A Ag Rapid Test Cassette (Swab)
GCHP-301a	TEST RAPID	Orient Gene	H.Pylori Ab Rapid Test Strip (serum/plasma)
GCHP-302a	TEST RAPID	Orient Gene	H.pylori Ab Rapid Test Cassette (serum/plasma)
GCHP-401a	TEST RAPID	Orient Gene	H.pylori Ab Rapid Test Strip (Whole blood/serum/plasma)
GCHP-402a	TEST RAPID	Orient Gene	H.pylori Ab Rapid Test Cassette (Whole blood/serum/plasma)
GCCA-502a	TEST RAPID	Orient Gene	Candida albicans Antigen rapid test cassette (swab)
GCGON-502b	TEST RAPID	Orient Gene	Gonorrhea Rapid Test Cassette (Swab)
GCGIA-602a	TEST RAPID	Orient Gene	Giardia lamblia Antigen Rapid tests cassette (feces)

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GCSTR-501a	TEST RAPID	Orient Gene	Strep A Rapid Test Strip (Throat swab)
GCSTR-502a	TEST RAPID	Orient Gene	Strep A Rapid Test Cassette (Throat swab)
GCFC-525a	TEST RAPID	Orient Gene	Rapid COVID-19 + Influenza Antigen Test
GCRSV-502a	TEST RAPID	Orient Gene	RSV Antigen Rapid Test Cassette (swab)
GCADE-502a	TEST RAPID	Orient Gene	Adenovirus antigen rapid test cassette (swab)
GCADE-602a	TEST RAPID	Orient Gene	Adenovirus Rapid test cassette (feces)
GCCD(GDH)-602a	TEST RAPID	Orient Gene	Clostridium difficile Antigen GDH Rapid Test cassette (feces)
GCCD (Toxin A/B)-602a	TEST RAPID	Orient Gene	Clostridium difficile Toxin A&B rapid test cassette (feces)
GCCD-602a	TEST RAPID	Orient Gene	Clostridium difficile GDH & Toxin A/B Rapid Test Cassette (Feces)
GCHSV (IgM)-402a	TEST RAPID	Orient Gene	HSV IgM Rapid test Cassette (whole blood/serum/plasma)
GCHSV(IgG)-302a	TEST RAPID	Orient Gene	HSV IgG Rapid Test Cassette (serum/plasma)
GCSYP-301a	TEST RAPID	Orient Gene	Syphilis Ab Rapid Test Strip (serum/plasma)
GCSYP-302a	TEST RAPID	Orient Gene	Syphilis Ab Rapid Test Cassette (serum/plasma)
GCSYP-401a	TEST RAPID	Orient Gene	Syphilis Ab Rapid test strip (whole blood/serum/plasma)
GCSYP-402a	TEST RAPID	Orient Gene	Syphilis Ab Rapid test cassette (whole blood/serum/plasma)
GBBAR-101a	TEST RAPID	Orient Gene	One Step Barbiturates Test Strip (Urine)
GBBAR-102a	TEST RAPID	Orient Gene	One Step Barbiturates Test Cassette (Urine)
GBAMP-101a	TEST RAPID	Orient Gene	One Step Amphetamine Test Strip (Urine)
GBAMP-102a	TEST RAPID	Orient Gene	One Step Amphetamine Test Cassette (Urine)
GBAMP-105a	TEST RAPID	Orient Gene	One Step Amphetamine Dip Card (Urine)

GBPPX-101a	TEST RAPID	Orient Gene	One Step Propoxyphene Test Strip (Urine)
GBPPX-102a	TEST RAPID	Orient Gene	One Step Propoxyphene Test Cassette (Urine)
GBDSA-XXXXFX	TEST RAPID	Orient Gene	Oral Fluid Drug test Cube
GBDSA-XXXXEX	TEST RAPID	Orient Gene	Oral Fluid Drug test
GBDSA-XXXXFSI	TEST RAPID	Orient Gene	Oral Fluid Drug test Cube
GBDSA-XXXXCX	TEST RAPID	Orient Gene	Oral Fluid Drug test cylinder
GBOPI-102a	TEST RAPID	Orient Gene	One Step Opiate Test Cassette (Urine)
GBOPI-101a	TEST RAPID	Orient Gene	One Step Opiate Test Strip (Urine)
GBETG-101b	TEST RAPID	Orient Gene	One Step Ethyl Glucoronide Test Strip (urine)
GBETG-102b	TEST RAPID	Orient Gene	One Step Ethyl Glucoronide Test Cassette (urine)
GBMOP-101a	TEST RAPID	Orient Gene	One step Morphine Test strip (urine)
GBMOP-102a	TEST RAPID	Orient Gene	One step Morphine Test Cassette (urine)
GBMOP-105a	TEST RAPID	Orient Gene	One step Morphine Test dip card (urine)
GBTHC-101a	TEST RAPID	Orient Gene	One Step Marijuana Test Strip (Urine)
GBTHC-102a	TEST RAPID	Orient Gene	One Step Marijuana Test Cassette (Urine)
GBTHC-105a	TEST RAPID	Orient Gene	One Step Marijuana Test Dip Card (Urine)
GBMTD-101a	TEST RAPID	Orient Gene	One step Methadone Test strip (urine)
GBMTD-102a	TEST RAPID	Orient Gene	One step Methadone Test cassette (urine)
GBXXX-101	TEST RAPID	Orient Gene	One Step Drugs of Abuse Test Strip (Urine)
GBXXX-102	TEST RAPID	Orient Gene	One Step Drugs of Abuse Test Cassette (Urine)
GBXXX-105	TEST RAPID	Orient Gene	One Step Drugs of Abuse Test Dip Card (Urine)

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GBDSA-XXXXJSI	TEST RAPID	Orient Gene	Oral fluid drug test cylinder
GBDSA-XXXXJX	TEST RAPID	Orient Gene	Oral fluid drug test cylinder
GBDSA-XXXXKX	TEST RAPID	Orient Gene	Oral fluid drug test cylinder
GBDSA-XXXXMX	TEST RAPID	Orient Gene	Oral fluid drug test device
GBDSA-XXXXA/B/G/H/I	TEST RAPID	Orient Gene	Multi-drug rapid screen test cassette (oral fluid)
GBMTC-101a	TEST RAPID	Orient Gene	One Step Methcathinone Test Strip (Urine)
GBMTC-102a	TEST RAPID	Orient Gene	One Step Methcathinone Test Cassette (Urine)
GBKRA-101a	TEST RAPID	Orient Gene	One step kratom test strip (urine)
GBKRA-102a	TEST RAPID	Orient Gene	One step kratom test cassette (urine)
GBLSD-101a	TEST RAPID	Orient Gene	One Step Lysergic Acid Diethylamide Test Strip (Urine)
GBLSD-102a	TEST RAPID	Orient Gene	One Step Lysergic Acid Diethylamide Test Cassette (Urine)
FBXXX-1102	TEST RAPID	Orient Gene	Hair Multi-drug rapid test kit
GBETG-105a	TEST RAPID	Orient Gene	One step ethyl glucuronide test dip card (urine)
GBPGB-102b	TEST RAPID	Orient Gene	One step pregabalin test cassette (urine)
GBTRA-101a	TEST RAPID	Orient Gene	One step tramadol test strip (urine)
GBTRA-102a	TEST RAPID	Orient Gene	One step tramadol test cassette (urine)
GBOXY-101a	TEST RAPID	Orient Gene	One step oxycodone Test strip (urine)
GBOXY-102a	TEST RAPID	Orient Gene	One step oxycodone Test cassette (urine)
GBMDP-101a	TEST RAPID	Orient Gene	One step 3,4-Methylenedioxypyrovalerone Test strip (urine)

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GBMDP-101a	TEST RAPID	Orient Gene	One step 3,4-Methylenedioxypyrovalerone Test cassette (urine)
GBMQL-102a	TEST RAPID	Orient Gene	One step Methaqualone Test cassette (urine)
GBMQL-101a	TEST RAPID	Orient Gene	One step Methaqualone Test strip (urine)
GBMPD-101a	TEST RAPID	Orient Gene	One step Methylphenidate Test strip (urine)
GBMPD-102a	TEST RAPID	Orient Gene	One step Methylphenidate Test cassette (urine)
GBUR-101a	TEST RAPID	Orient Gene	One step UR-144 test strip (urine)
GBUR-102a	TEST RAPID	Orient Gene	One step UR-144 test cassette (urine)
GBBUP-101a	TEST RAPID	Orient Gene	One step buprenorphine test strip (urine)
GBBUP-102a	TEST RAPID	Orient Gene	One step buprenorphine test cassette (urine)
GBPCP-101a	TEST RAPID	Orient Gene	One step Phencyclidine Test strip (urine)
GBPCP-102a	TEST RAPID	Orient Gene	One step Phencyclidine Test cassette (urine)
GBTCA-101a	TEST RAPID	Orient Gene	One step Tricyclic Antidepressants test strip (urine)
GBTCA-102a	TEST RAPID	Orient Gene	One step Tricyclic Antidepressants test cassette (urine)
GBEDD-101a	TEST RAPID	Orient Gene	One step EDDP test strip (urine)
GBEDD-102a	TEST RAPID	Orient Gene	One step EDDP test cassette (urine)
GBFEN-101b	TEST RAPID	Orient Gene	One step Fentanyl Test strip (urine)
GBFEN-102b	TEST RAPID	Orient Gene	One step Fentanyl Test cassette (urine)
GBALC-101a	TEST RAPID	Orient Gene	Urine Alcohol Test Strip
GBMAM-S102	TEST RAPID	Orient Gene	One step 6-MAM Test cassette (urine)

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电话 Tel:+86-572-5226111　　传真 Fax: +86-572-5226222　邮编 P.C.:313300

GBMAM-S101	TEST RAPID	Orient Gene	One step 6-MAM Test cassette (urine)
GBHCD-101a	TEST RAPID	Orient Gene	One step Hydrocodone test strip (urine)
GBHCD-102a	TEST RAPID	Orient Gene	One step Hydrocodone test cassette (urine)
GBNFT-101c	TEST RAPID	Orient Gene	One step Norfentanyl test strip (urine)
GBNFT-102c	TEST RAPID	Orient Gene	One step Norfentanyl test cassette (urine)
GBXXX-1102	TEST RAPID	Orient Gene	Hair Multi-Drug Rapid Test Kit (ICA)
GBDSA-XXXXLX	TEST RAPID	Orient Gene	Oral Fluid Drug Test Mini Cube
GBDUA-1X4	TEST RAPID	Orient Gene	One Step Multi-Drug Screen Test Dip Card (urine)
GBDOA-1X5	TEST RAPID	Orient Gene	One Step Multi-Drug Screen Test Cassette (urine)
GBDUA-1X6	TEST RAPID	Orient Gene	One Step Multi-Drug Screen Test Cup (urine)
GBCOT-102a	TEST RAPID	Orient Gene	One step cotinine test cassette (urine)
GBK2-101a	TEST RAPID	Orient Gene	One step K2 Test strip (urine)
GBK2-102a	TEST RAPID	Orient Gene	One step K2 Test cassette (urine)
GBKET-101a	TEST RAPID	Orient Gene	One step Ketamine Test strip (urine)
GBKET-102a	TEST RAPID	Orient Gene	One step Ketamine Test cassette (urine)
GBBZO-101a	TEST RAPID	Orient Gene	One step Benzodiazepines Test Strip (urine)
GBBZO-102a	TEST RAPID	Orient Gene	One step Benzodiazepines Test Cassette (urine)
GBCOC-101a	TEST RAPID	Orient Gene	One step Cocaine Test strip (urine)
GBCOC-102a	TEST RAPID	Orient Gene	One step Cocaine Test cassette (urine)
GBCOC-105a	TEST RAPID	Orient Gene	One step Cocaine Test dip card (urine)
GBMDM-101a	TEST RAPID	Orient Gene	One step ecstasy Test strip (urine)

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GBMDM-102a	TEST RAPID	Orient Gene	One step ecstasy Test cassette (urine)
GBMET-101a	TEST RAPID	Orient Gene	One step Methamphetamine test strip (urine)
GBMET-102a	TEST RAPID	Orient Gene	One step Methamphetamine test cassette (urine)
GBMET-105a	TEST RAPID	Orient Gene	One step Methamphetamine test dip card (urine)
GCTOXI(IgG/IgM)-302a	TEST RAPID	Orient Gene	Toxoplasma gondii test cassette (serum/plasma)
GCTOXI(IgG)-302a	TEST RAPID	Orient Gene	Toxoplasma gondii IgG test cassette (serum/plasma)
GCTOXI(IgM)-302a	TEST RAPID	Orient Gene	Toxoplasma gondii IgM test cassette (serum/plasma)
GCCHL-502a	TEST RAPID	Orient Gene	Chlamydia Trachomatis Antigen test cassette (swab/urine)
GEPSA-402a	TEST RAPID	Orient Gene	Prostate specific antigen test cassette (whole blood/serum/plasma)
GEPSA-401a	TEST RAPID	Orient Gene	Prostate specific antigen test strip (whole blood/serum/plasma)
GEPSA-302a	TEST RAPID	Orient Gene	Prostate specific antigen test cassette (serum/plasma)
GEPSA-301a	TEST RAPID	Orient Gene	Prostate specific antigen test strip (serum/plasma)
GALH-101a-1T	TEST RAPID	Orient Gene	LH Ovulation Test Strip
GALH-101a-5T	TEST RAPID	Orient Gene	LH Ovulation Test Strip
GALH-101a-7T	TEST RAPID	Orient Gene	LH Ovulation Test Strip
GALH-101b-1T	TEST RAPID	Orient Gene	LH Ovulation Test Strip
GALH-101b-5T	TEST RAPID	Orient Gene	LH Ovulation Test Strip
GALH-101b-7T	TEST RAPID	Orient Gene	LH Ovulation Test Strip
GALH-102a-1T	TEST RAPID	Orient Gene	LH Ovulation Test Cassette
GALH-102a-5T	TEST RAPID	Orient Gene	LH Ovulation Test Cassette
GALH-102a-7T	TEST RAPID	Orient Gene	LH Ovulation Test Cassette
GALH-102b-5T	TEST RAPID	Orient Gene	LH Ovulation Test Cassette
GALH-102b-1T	TEST RAPID	Orient Gene	LH Ovulation Test Cassette

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GALH-102b-7T	TEST RAPID	Orient Gene	LH Ovulation Test Cassette

VPH-502a	TEST RAPID	Orient Gene	Vaginal pH test cassette (Vaginal secretions)

URS-1T to 14T with various combination	STRIPURI DE URINA	Orient Gene	LEU/NIT/URO/MA/PRO/PH/BLO/SG/ASC/CRE/KET/BIL/GLU/CA
GCHCV-302a	TEST RAPID	Orient Gene	HCV Hepatitis C Virus Rapid Test (serum/plasma) cassette
GCHCV-402a	TEST RAPID	Orient Gene	HCV Hepatitis C Virus Rapid Test (whole blood/serum/plasma) cassette
GCHIV-302a	TEST RAPID	Orient gene	HIV 1/2 Human Immunodeficiency Virus (Serum/Plasma) cassette
GCHIV-402a	TEST RAPID	Orient gene	HIV 1/2 Human Immunodeficiency Virus (Whole blood/serum/plasma)cassette
GCHBsg-302a	TEST RAPID	Orient gene	HBsAg Hepatitis B Surface Antigen Rapid Test (Serum/Plasma)
GCHBsg-402a	TEST RAPID	Orient gene	HBsAg Hepatitis B Surface Antigen Rapid Test(Whole Blood/Serum/Plasma)

The end.

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 092305 0001 Rev. 02

Holder of Certificate: **Zhejiang Orient Gene Biotech Co., Ltd.**
3787#, East Yangguang Avenue, Dipu Street Anji
313300 Huzhou, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of In Vitro Diagnostic Reagent and Instrument for the Detection of Drugs of Abuse, Fertility, Infectious Diseases, Oncology, Biochemistry, Cardiac Diseases, Allergic Disease based on Rapid Test, PCR and Liquid Biochip Method.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 092305 0001 Rev. 02

Report No.: SH2398804

Valid from: 2024-03-17
Valid until: 2027-03-16

Date, 2024-03-01

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 092305 0001 Rev. 02

Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies):

Zhejiang Orient Gene Biotech Co., Ltd.
3787#, East Yangguang Avenue, Dipu Street Anji, 313300
Huzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

.

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www.zlg.de
ZLG-BS-245.10.07

Product Service

EC Certificate

EC Design-Examination Certificate
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV (4) (List A)

No. V7 092378 0009 Rev. 00

Manufacturer:

Healgen Scientific Limited Liability Company
3818 Fuqua Street
Houston TX 77047
USA

Product: **Screening test for Hepatitis C marker**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with IVDD Annex IV (4). The design of the devices conforms to the requirements of this Directive. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V7 092378 0009 Rev. 00

Report No.: 713234651

Valid from: 2022-04-22
Valid until: 2025-05-26

Date, 2022-04-22

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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TÜV SÜD Product Service

EC Certificate

EC Design-Examination Certificate
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV (4) (List A)

No. V7 092378 0009 Rev. 00

Model(s): **HCV Hepatitis C Virus Rapid Test**

Facility(ies):

Zhejiang Orient Gene Biotech Co., Ltd.
3787#, East Yangguang Avenue, Dipu Street Anji,
313300 Huzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

Parameters:

Model Name:	Model No.:
--	
HCV Hepatitis C Virus Rapid Test (Serum / Plasma) (Cassette)	GCHCV-302a
HCV Hepatitis C Virus Rapid Test (Whole Blood /Serum / Plasma) (Cassette)	GCHCV-402a

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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TÜV®

3818 Fuqua street
Houston, TX 77047, USA
Tel: +1 713 733 8088
Fax: +1 713 733 8848
Web: www.Healgen.com
E-mail: sales@healgen.com

CE-DOC-H003
Ver.1.7

EC Declaration of Conformity

In accordance with Directive 98/79/EC

Legal Manufacturer: Healgen Scientific Limited Liability Company

Legal Manufacturer Address: *3818 Fuqua Street, Houston, TX 77047, USA.*

Declares, that the products
Product Name and Model(s)

Orient Gene HCV Hepatitis C Virus Rapid Test (Serum/Plasma) (Cassette)	GCHCV-302a
Orient Gene HCV Hepatitis C Virus Rapid Test (Whole blood/Serum/Plasma)(Cassette)	GCHCV-402a

EDMA Code: 15 70 02 02

Classification: *Annex II List A*
Conformity assessment route: *Annex IV (Full Quality Assurance)*

Compliance of the designated product with the Directive 98/79/EC has been assessed and certified by the Notified Body
Notified Body: TÜV SÜD Product Service GmbH
Notified Body Address: Munich Branch Ridlerstraße 65 80339 München Germany
EC Certificate No.: V1 092378 0004 Rev. 02 Valid until: 2025-05-26
EC Design-Examination Certificate No.: V7 092378 0009 Rev. 00 Valid until: 2025-05-26

It bears the mark

CE 0123

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.
We hereby explicitly appoint
EC Representative Name: QARAD b.v.b.a.
EC Representative Address: Cipalstraat 3, B-2440 Geel, Belgium

to act as our European Authorized Representative as defined in the aforementioned Directive.

I, the undersigned, hereby declare that the medical devices specified above conform with the directive 98/79/EC on in vitro diagnostic medical devices and pertinent essential requirements

Signature:
Name of authorized signatory: Joyce Pang
Position held in the company: Vice-President
Date: 2022.4.22

HCV Hepatitis C Virus Rapid Test (whole blood/serum/plasma)(Cassette)（CE）
Final Products inspection Report (Certificate of Analysis)

Item	HCV Hepatitis C Virus Rapid Test(whole blood/serum/plasma) (Cassette) Catalog No:GCHCV-402a	Specification	Cassette
Lot No.	2407232	Quantity	100000 tests
Source From	Workshop	Inspection Basis	HCV Hepatitis C Virus Rapid Test(whole blood/serum/plasma)(Cassette)Finished Product Quality Standards and Inspection SOP(CE)
Validity Date	2026.06	Date of Sampling	2024.07.26

Inspection Item		Acceptance Standard	Results
Functional Requirement : S-1 (AQL:2.5)	P1(20-22)	T line should be ≥G7 at 15 min.	Conformity☑ / Non-Conformity□
	P2(12-14)	T line should be ≥G6 at 15 min.	Conformity☑ / Non-Conformity□
	P3(6-8)	T line should be ≥G5 at 15 min.	Conformity☑ / Non-Conformity□
	P4(1-3)	T line signal should be G4≤T≤G6 at 15 min.	Conformity☑ / Non-Conformity□
Functional Requirement : /	100 negative serum	T line should be ≤G2 at 15 min. C line should be visible ≥G3 within 3 min,and should be ≥G7 at 15 min. Note: when negative Serum/Plasma moving over T line, T line should be ＜ G5 and fade within 3 min. If doing this, it is qualified. If not, it is unqualified	Conformity☑ / Non-Conformity□
Functional Requirement: S-2 AQL:1.0	clinical whole blood specimens	Membrane background is clean at 15min, not impacting reading results.	Conformity☑ / Non-Conformity□
Pouch Leakage tightness S-2（ AQL=0.65）		Leakage tightness is good	Conformity☑ / Non-Conformity□
Remarks:N/A			
Conclusion: Conformity☑ / Non-Conformity□			
Tester/Date: 2024.07.26		Reviewer/Date: 2024.07.26	

HCV Hepatitis C Virus Rapid Test (Whole blood/Serum/Plasma)(Cassette)

CE 0123

REF GCHCV-402a

INTENDED USE

The HCV Hepatitis C Virus Rapid Test (Whole blood/Serum/Plasma)(Cassette) is a sandwich lateral flow chromatographic immunoassay for the qualitative detection of antibodies (IgG, IgM, and IgA) to Hepatitis C virus (HCV) in human whole blood, serum or plasma. It is intended to be used as a screening test and as an aid in the diagnosis of infection with HCV. Any reactive specimen with the HCV Hepatitis C Virus Rapid Test Cassette must be confirmed with alternative testing method(s) and clinical findings.

INTRODUCTION

Hepatitis C Virus (HCV) is a small, enveloped, positive-sense, single-stranded RNA virus. Antibody to HCV is found in over 80% of patients with well-documented non-A, non-B hepatitis. Conventional methods fail to isolate the virus in cell culture or visualize it by electron microscope. Cloning the viral genome has made it possible to develop serologic assays that use recombinant antigens (1, 2). Compared to the first generation HCV EIAs using single recombinant antigen, multiple antigens using recombinant protein and/or synthetic peptides have been added in new serologic tests to avoid nonspecific cross-reactivity and to increase the sensitivity of the HCV antibody tests (3, 4). HCV Hepatitis C Virus Rapid Test (Whole blood/Serum/Plasma)(Cassette) is a rapid test to qualitatively detect the presence of antibody to HCV in a whole blood, serum or plasma specimen. The test utilizes a combination of recombinant antigen to selectively detect elevated levels of HCV antibodies in whole blood, serum or plasma.

PRINCIPLE

The HCV Hepatitis C Virus Rapid Test Cassette is a lateral flow chromatographic immunoassay based on the principle of the double antigen–sandwich technique. The test Cassette consists of: 1) a burgundy colored conjugate pad containing HCV antigens conjugated with colloidal gold (HCV Ag conjugates) and rabbit IgG-gold conjugates, 2) a nitrocellulose membrane Cassette containing a test band (T band) and a control band (C band). The T band is pre-coated with non-conjugated HCV antigens, and the C band is pre-coated with goat anti-rabbit IgG. When an adequate volume of test specimen is dispensed into the sample well of the Cassette, the specimen migrates by capillary action across the Cassette. The antibodies: either the IgG, the IgM, or the IgA, to HCV if present in the specimen will bind to the HCV Ag conjugates. The immunocomplex is then captured on the membrane by the precoated HCV antigens, forming a burgundy colored T band, indicating a HCV Ab positive test result. Absence of the T band suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti-rabbit IgG and rabbit IgG-gold conjugate regardless the presence of any antibodies to HCV. Otherwise, the test result is invalid and the specimen must be retested with another Cassette.

PRODUCT CONTENTS

HCV Hepatitis C Virus Rapid Test (Whole blood/Serum/Plasma)(Cassette) containing HCV antigen (HCV antigen includes core, NS3, NS4 and NS5 segment) coated particles and HCV antigen (HCV recombinant antigen includes core, NS3, NS4 and NS5 segment) coated on the membrane.

MATERIALS SUPPLIED

1. 25 sealed pouches each containing a test cassette, a pipette dropper and a desiccant
(Test Cassette T band is pre-coated with non-conjugated HCV antigens, and the C band is pre-coated with goat anti-rabbit IgG on the nitrocellulose and coupled to colloidal gold on label pad)
2. 1 Package insert

3. 1 Buffer (4 mL) (Casein-salt: 1%, NaCl: 0.9%, Na_2HPO_4: 0.286%, NaN_3: 0.5%)	Warning	Warning: 0.5% NaN_3 Harmful if swallowed; Harmful to aquatic life with long lasting effects Prevention Wash face, hands and any exposed skin thoroughly after handling Wear protective gloves/protective clothing/eye protection/face protection Do not breathe dust/fume/gas/mist/vapors/spray Do not eat, drink or smoke when using this product Avoid release to the environment. Response IF SWALLOWED: rinse mouth. Do NOT induce vomiting. Get medical attention/advice if you feel unwell

MATERIAL REQUIRED BUT NOT PROVIDED

1. Specimen collection containers
2. Sterile lancets (for fingerstick whole blood only)
3. Centrifuge (for plasma only)
4. Timer
5. Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test Cassette is stable through the expiration date printed on the sealed pouch. The test Cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

WARNINGS AND PRECAUTIONS

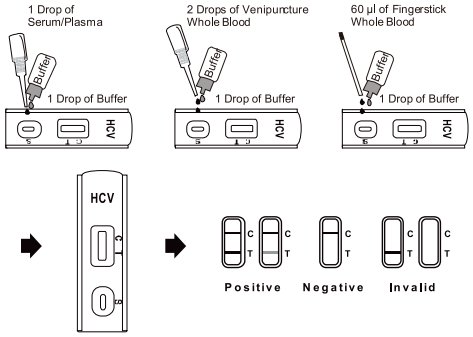
1. For professional *in vitro* diagnostic use only. Do not use after expiration date.
2. Warning: the reagents in this kit contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up.
3. Do not use it if the tube/pouch is damaged or broken.
4. Test is for single use only. Do not re-use under any circumstances.
5. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7. Humidity and temperature can adversely affect results.
8. Do not perform the test in a room with strong air flow, ie. an electric fan or strong airconditioning.

SPECIMEN COLLECTION

1. The HCV Hepatitis C Virus Rapid Test (Whole Blood/Serum/Plasma) (Cassette) can be performed using whole blood (from venipuncture and fingerstick), serum or plasma.
2. For venipuncture whole blood and plasma: K_2EDTA, Sodium Heparin, Sodium citrate Sterile, and Lithium heparin should be used as the anticoagulant. Other anticoagulants have not been tested and may give incorrect results.
3. To collect Fingerstick Whole Blood specimens:
 • Wash the patient's hand with soap and warm water or clean with an alcohol wipe . Allow to dry.
 • Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
 • Puncture the skin with a new sterile lancet for each person. Wipe away the first sign of blood.
 • Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
 • Add the Fingerstick Whole Blood specimen to the test device by using a capillary tube:
 • Touch the end of the capillary tube to the blood until filled to approximately 60 µL. Avoid air bubbles.
 • Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood into the specimen well (S) of the test device.
 • Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, nonhemolyzed specimens.
4. Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days and may be stored at -20°C for 6 months. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
5. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
6. If specimens are to be shipped, they should be packed in compliance with usual regulations for transportation of etiological agents.

TEST PROCEDURE

Allow test cassette, specimen, buffer and/or controls to equilibrate to room temperature (15-30°C) prior to testing.
1. Remove the test Cassette from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test Cassette on a clean and level surface.
For Serum or Plasma Specimens: Hold the dropper vertically and transfer 1 drop of serum or plasma (approximately 30 µL) to the specimen well (S) of the test Cassette, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.
For Venipuncture Whole Blood Specimens: Hold the dropper vertically and transfer 2 drops of venipuncture whole blood (approximately 60 µL) to the specimen well (S) of the test Cassette, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.
For Fingerstick Whole Blood specimens: To use a capillary tube: Fill the capillary tube and transfer approximately 60 µL of fingerstick whole blood specimen to the specimen well (S) of the test device, then add 1 drops of buffer (approximately 40 µL) and start the timer. See illustration below.
3. Wait for the red line(s) to appear. The result should be read at 15 minutes. Do not interpret the result after 30 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)
Positive: Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).
Negative: One colored line appears in the control line region (C). No line appears in the test line region (T).
Invalid: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test Cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this test. However, it is recommended that positive and negative controls are sourced from a local competent authority and tested as a good laboratory practice, to confirm the test procedure and verify the test performance.

LIMITATIONS

1. The HCV Hepatitis C Virus Rapid Test (Whole blood/Serum/Plasma)(Cassette) is for *in vitro* diagnostic use only. This test should be used for the detection of antibodies to HCV in whole blood, serum or plasma specimen.
2. The HCV Hepatitis C Virus Rapid Test (Whole blood/Serum/Plasma)(Cassette) will only indicate the presence of antibodies to HCV in the specimen and should not be used as the sole criteria for the diagnosis of Hepatitis C viral infection.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is recommended. A negative result at any time does not preclude the possibility of Hepatitis C Virus infection.
5. A negative result can occur if the quantity of the antibodies to HCV present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
6. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
7. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
8. Results should not be used to determine the genotype of HCV infections.
9. Due to possible cross reactivity, the appearance of lines in T line does not necessarily indicate co-infection from IgG, IgM or IgA, nor can it identify the serotype.
10. The recommended anticoagulants are K_2EDTA, Sodium Heparin, Sodium citrate Sterile and Lithium heparin for venous whole blood. Other anticoagulants have not been evaluated with this test.

PERFORMANCE CHARACTERISTICS

Relative Sensitivity

A total of 506 HCV positive specimens were tested using the HCV Hepatitis C Virus Rapid Test (Whole blood/Serum/Plasma)(Cassette) and a commercially available test (Table 1). The relative sensitivity of the test is >99.9% (95% confidence interval: 99.27% – 100%).
Table 1: Sensitivity of HCV Hepatitis C Virus Rapid Test (Whole blood/Serum/Plasma)(Cassette)

Population	Specimen Type	Number of Specimens Tested	Positive by HCV Hepatitis C Virus Rapid Test	Positive by Commercially Available Test
Anti-HCV (any genotype)	plasma	329	329/329 (100%)	329/329 (100%)
Anti-HCV (any genotype)	Serum	26	26/26 (100%)	26/26 (100%)
Anti-HCV (genotype 1, 2, 3, 4 (non-subtype A), 4, 5, 6)	Serum/Plasma	151	151/151 (100%)	151/151 (100%)
Total		506	506/506 (100%)	506/506 (100%)

30 Serocoversion panels have been done and details of the 30 seroconversion are in the table below.

No.	Panel	Specimens No.	Results
1	PHV907	7	Positive from 0 days since first bleed
2	PHV908	13	Positive from 3 days since first bleed
3	PHV206(M)	25	/
4	PHV911(M)	5	Positive from 3 days since first bleed
5	PHV919	7	Positive from 28 days since first bleed
6	PHV920	10, No. 2 can't be got because ofout of stock from the vendor	Positive from 16 days since first bleed
7	HCV9047	10	Positive from 28 days since first bleed
8	HCV9046	5	Positive from 69 days since first bleed
9	HCV6229	8	Positive from 17 days since first bleed
10	HCV10041	3	Positive from 6 days since first bleed
11	HCV9041	8	Positive from 62 days since first bleed
12	HCV9045	8	Positive from 37 days since first bleed
13	HCV6222	3	Positive from 40 days since first bleed
14	HCV6224	8	Positive from 19 days since first bleed
15	HCV6227	7	Positive from 75 days since first bleed
16	HCV6228	12	Positive from 31 days since first bleed
17	HCV10071	7	Positive from 84 days since first bleed
18	HCV6220	6	Positive from 18 days since first bleed
19	HCV10185	5	Positive from 130 days since first bleed
20	HCV10235	5	Positive from 96 days since first bleed
21	HCV6215	4	Positive from 20 days since first bleed
22	HCV9042	6	Positive from 8 days since first bleed
23	HCV9058	5	Positive from 10 days since first bleed
24	HCV9094	5	Positive from 9 days since first bleed
25	HCV9095	5	Positive from 10 days since first bleed
26	HCV9055	11	Positive from 65 days since first bleed
27	HCV9054	10	Positive from 72 days since first bleed
28	HCV9044	6	Positive from 21 days since first bleed
29	HCV10165	9	Positive from 19 days since first bleed
30	HCV6226	12	Positive from 39 days since first bleed

Relative Specificity

A total of HCV 1259 negative specimens were tested using the HCV Hepatitis C Virus Rapid Test (Whole blood/Serum/Plasma)(Cassette) and a commercially available test (Table 2). The relative specificity of the test is ＞99.9% (95% confidence interval: 99.71% – 100%).
Table 2: Specificity of the HCV Hepatitis C Virus Rapid Test (Whole blood/Serum/Plasma)(Cassette)

Population	Specimens Tested	Number of Specimens Tested	Negative by HCV Hepatitis C Virus Rapid Test	Negative by Commercially Available Test
Clinical Negative	Serum/plasma	202	202/202 (100%)	202/202 (100%)
Potentially cross-reacting	Serum/Plasma	30	30/30 (100%)	30/30 (100%)
Unselected Donors	Serum	1000	1000/1000 (100%)	1000/1000 (100%)
Inhibition Panel	Serum	27	27/27 (100%)	27/27 (100%)
Total		1259	1259/1259 (100%)	1259/1259 (100%)

Whole Blood vs. Serum vs. Plasma

Total 25 clinical negative samples (whole blood, serum, plasma) have been collected from patients in local hospital. The whole blood collected and separated into three tubes. One was stored as whole blood. One was collected into tube for plasma, one was collected into tube for serum (Table 3). There is a very good correlation of results between whole blood, serum, and plasma with HCV negative samples.
Table 3: A Comparison of HCV Hepatitis C Virus Rapid Test (Whole blood/Serum/Plasma)(Cassette) Specificity in negative Whole Blood and Paired Serum and Plasma Specimens

Specimen Type	Number of Specimens Tested	Negative by HCV Ab
Serum	25	25/25 (100%)
Plasma	25	25/25 (100%)
Whole blood	25	25/25 (100%)

A total of 25 positive specimens (whole blood, serum, plasma) were tested using the HCV Hepatitis C Virus Rapid Test (Whole blood/Serum/Plasma)(Cassette) (Table 4). There is a very good correlation of results between whole blood and paired plasma with HCV positive samples.

Table 4: A Comparison of HCV Hepatitis C Virus Rapid Test (Whole blood/Serum/Plasma)(Cassette) Specificity in positive Whole Blood and Paired Serum and Plasma Specimens.

Specimen Type	Number of Specimens Tested	Positive by HCV Ab
Serum	25	25/25 (100%)
Plasma	25	25/25 (100%)
Whole blood	25	25/25 (100%)

Precision

Intra Assay

Within-run precision has been determined by using 20 replicates of four specimens: a negative, a low positive, medium positive and a high positive. The negative, low positive, medium positive and high positive values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 5 independent assays on the same four specimens: a negative, a low positive, medium positive and a high positive. Three different lots of the HCV Hepatitis C Virus Rapid Test (Whole blood/Serum/Plasma)(Cassette) have been tested using negative, low positive, medium positive and high positive specimens. The specimens were correctly identified >99% of the time.

Cross Reactivity

No cross-reactivity was observed when samples positive for other diseases such as HIV, Syphilis, Infectious Mononucleosis, HBV, Rheumatoid Factor, HAMA, Hyper IgG, Hyper IgM, anti-HAV, anti-HSV2, anti-HEV, anti- EBV and anti-CMV were tested.

Interfering Substances

No interference was observed in samples with high concentrations of Uric acid,Ascorbic Acid, Hemoglobin, Gentistic Acid, Acetaminnophen, Oxalic Acid, Albumin, Caffein, Bilirubin, EDTA, Aspirin and Methanol.

Analytes	Conc	Analytes	Conc
Control	0	Control	0
Uric acid	0.15 mg/mL	Albumin	20 mg/mL
Ascorbic Acid	0.2 mg/mL	Caffein	0.2 mg/mL
Hemoglobin	5.0 mg/mL	Bilirubin	0.3 mg/mL
Gentistic Acid	0.2 mg/mL	EDTA	0.2 mg/mL
Acetaminnophen	1.0 mg/mL	Aspirin	0.2 mg/mL
Oxalic Acid	0.2 mg/mL	Methanol	1.0%

REFERENCE

1. Choo, Q.L., G.Kuo, A.J. Weiner, L.R. Overby, D.W. Bradley, and M. Houghton. Isolation of a cDNA clone derived from a blood-borne non-A, non-B viral hepatitis genome. Science 189; 244: 359
2. Kuo, G., Q.L. Choo, H.J. Alter, and M. Houghton. An assay for circulating antibodies to a major etiolog Virus of human non-A, non-B hepatitis. Science 1989; 244: 362
3. Van der Poel, C.L., H.T.M. Cuypers, H.W. Reesink, and P.N. Lelie. Confirmation of hepatitis C Virus infection by new four-antigen recombinant immunoblot assay. Lancet 1991; 337: 317
4. Wilber, J.C. Development and use of laboratory tests for hepatitis Cinfection: a review. J. Clin. Immunoassy 1993; 16: 204

INDEX OF SYMBOLS

	Consult instructions for use		Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Manufacturer		Warning		

Healgen Scientific Limited Liability Company
Address: 3818 Fuqua Street, Houston, TX 77047, USA.
Tel: +1 713-733-8088 Fax: +1 713-733-8848
Website: www.healgen.com

EC REP QARAD b.v.b.a.
Cipalstraat 3, B-2440 Geel, Belgium

B21304-05
Revision Date: 2022-11-10

浙江东方基因生物制品股份有限公司
Zhejiang Orient Gene Biotech Co., LTD

CE-DOC-OG060
Version 1.0

EC Declaration of Conformity

In accordance with Directive 98/79/EC

Legal Manufacturer: *Zhejiang Orient Gene Biotech Co., Ltd*

Legal Manufacturer Address: *3787#, East Yangguang Avenue, Dipu Street, Anji 313300, Huzhou, Zhejiang, China*

Declares, that the products
Product Name and Model(s)

Fecal Occult Blood Rapid Test Strip (Feces)	GEFOB-601b
Fecal Occult Blood Rapid Test Cassette (Feces)	GEFOB-602b

Classification: *Other*
Conformity assessment route: *Annex III (EC DECLARATION OF CONFORMITY)*

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint

EC Representative's Name: Shanghai International Holding Corp. GmbH (Europe)

EC Representative's Address: Eiffestrasse 80, 20537 Hamburg, Germany

to act as our European Authorized Representative as defined in the aforementioned Directive.

I, the undersigned, hereby declare that the medical devices specified above conform with the directive 98/79/EC on in vitro diagnostic medical devices and pertinent essential requirements

Date Signed: November 28, 2017

Name of authorized signatory: Joyce Pang
Position held in the company: Vice-President

Zhejiang Orient Gene Biotech Co., LTD

CERTIFICATE OF ANALYSIS

Product Name：FOB Rapid Test (Feces) (Cassette)

Catalog NO.: GEFOB-602b

Purchase NO.: 2025-IEU010#

Lot NO.：2501183

Quantity: 15000pcs

Expiration Date：2026.12

CONTROLS		SPECIFICATION	TEST RESULT	CONCLUSION
Negative Specimens		Negative	Negative	☑Pass □Fail
Positive Specimens	50ng/ml	Positive	Positive	☑Pass □Fail
	200ng/ml	Positive	Positive	☑Pass □Fail
	10ug/ml	Positive	Positive	☑Pass □Fail
	2mg/ml	Positive	Positive	☑Pass □Fail

Conclusion: ☑Pass: All results meet QC standard.

□Fail

Test by：

Date: 2025.01.22

QC Supervisor:

Date: 2025.01.22

Fecal Occult Blood Rapid Test Cassette (Feces) CE

INTENDED USE

Fecal Occult Blood Rapid Test Cassette (Feces) is a rapid chromatographic immunoassay for the qualitative detection of human occult blood in feces by professional laboratories or physician's offices. It is useful to detect bleeding caused by a number of gastrointestinal disorders, e.g., diverticulitis, colitis, polyps, and colorectal cancer.
Fecal Occult Blood Rapid Test Cassette (Feces) is recommended for use in1) routine physical examinations, 2) hospital monitoring for bleeding in patients, and 3) screening for colorectal cancer or gastrointestinal bleeding from any source.

INTRODUCTION

Most of diseases can cause hidden blood in the stool. In the early stages, gastrointestinal problems such as colon cancer, ulcers, polyps, colitis, diverticulitis, and fissures may not show any visible symptoms, only occult blood. Traditional guaiac-based method lacks sensitivity and specificity, and has diet-restriction prior to the testing.
Fecal Occult Blood Rapid Test Cassette (Feces) is a rapid test to qualitatively detect low levels of fecal occult blood in feces. The test uses double antibod- sandwich assay to selectively detect as low as 50 ng/mL of hemoglobin or 6 µg hemoglobin/g feces. In addition, unlike the guaiac assays, the accuracy of the test is not affected by the diet of the patients.

PRINCIPLE

Fecal Occult Blood Rapid Test Cassette (Feces) is a lateral flow chromatographic immunoassay based on the principle of the double antibody-sandwich technique. The membrane is pre-coated with anti-hemoglobin antibodies on the test line region of the device. During testing, the specimen reacts with the colloidal gold coated withl anti-hemoglobin antibodies. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-hemoglobin antibodies on the membrane and generate a colored line. The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS PROVIDED

20 Test cassettes
20 Specimen collection tubes with buffer
1 Package insert

MATERIALS REQUIRED BUT NOT PROVIDED

1. Specimen collection containers 2. Clock or timer

STORAGE AND STABILITY

All reagents are ready to use as supplied. Store unused test device unopened at 2°C-30°C. If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test is not stable out of the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
3. Do not use it if the tube/pouch is damaged or broken.
4. Test is for single use only. Do not re-use under any circumstances.
5. Do not use specimen with visible blood for the testing.
6. Handel all specimens as if they contain infectious agents. Observe established standard procedure for proper disposal of specimens.
7. Specimen extraction buffer contains Sodium Azide (0.1%). Avoid contact with skin or eyes. Do not ingest.
8. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assay.
9. Humidity and temperature can adversely affect results.
10. Do not perform the test in a room with strong air flow, ie. electric fan or strong airconditioning.

PATIENT PREPARATION

1. A specimen should not be collected from a patient with following conditions that may interfere with the test results:

- Menstrual bleeding
- Bleeding hemorrhoids
- Constipating bleeding
- Urinary bleeding.

2. Dietary restrictions are not necessary.
3. Alcohol and certain medications such as aspirin, indomethacin, phenylbutazone, reserpine, cortocosteroids, and nonsteroidal anti-inflammatory drugs may cause gastrointestinal irritation and subsequent bleeding, thus gives positive reactions. On the advice of the physician, such substances should be discontinued at least 48 hours prior to testing.

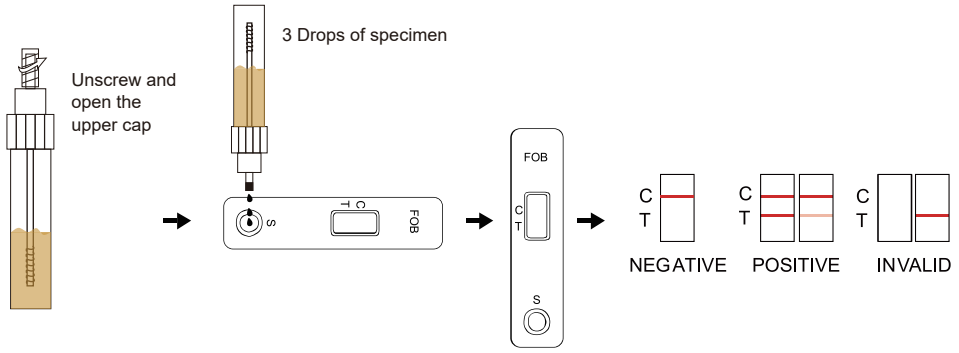
SPECIMEN COLLECTION AND PREPARATION

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.
1. Collect a random sample of feces in a clean, dry receptacle.
2. Unscrew the top of the collection tube and remove the applicator stick.
3. Randomly pierce the fecal specimen in at least five (5) different sites.
4. Remove excess sample off the shaft and outer grooves. Be sure sample remains on inside grooves.
5. Replace the stick in the tube and tighten securely.
6. Shake the specimen collection bottle so that there is proper homogenisation of feces in buffer solution.

Note: Specimens prepared in the specimen collection tube may be stored at room temperature (15-30°C) for 3 days maximum, at 2-8°C for 7 days maximum or at -20°C for 3 months maximum if not tested within 1 hour after preparation.

TEST PROCEDURE

Allow the test cassette, specimen, and/or controls to reach room temperature (15-30°C) prior to testing.
1. Remove the test cassette from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test cassette on a clean, flat surface.
3. Shake the specimen collection tube several times.
4. Hold the specimen collection tube upright and then unscrew and open the upper cap.
5. Squeeze 3 drops (~90 µL) of the sample solution in the sample well of the cassette and start the timer.
6. Wait for the colored line(s) to appear. Read results in 5 minutes. Do not interpret the result after 5 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)
Positive: Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).
Negative: One colored line appears in the control line region(C). No line appears in the test line region (T).
Invalid: Control line fails to appear. The test should be repeated using a new cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.
NOTE:
1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Note that this is a qualitative test only, and

Fecal Occult Blood Rapid Test Cassette (Feces)

cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

An internal procedural control is included in the test. A colored line appearing in the control line region (C) is an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correctl procedural technique. Control standards are not supplied with this kit; however it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. This test kit is to be used for the qualitative detection of human hemoglobin in fecal samples. A positive result suggests the presence of human hemoglobin in fecal samples. In addition to intestinal bleeding the presence of blood in stools may have other causes such as hemorrhoids, blood in urine etc.
2. Not all colorectal bleedings are due to precancerous or cancerous polyps. The information obtained by this test should be used in conjunction with other clinical findings and testing methods, such as colonoscopy gathered by the physician.
3. Negative results do not exclude bleeding since some polyps and colorectal region cancers can bleed intermittently or not at all. Additionally, blood may not be uniformly distributed in fecal samples. Colorectal polyps at an early stage may not bleed.
4. Urine and excessive dilution of sample with water from toilet bowl may cause erroneous test results. The use of a receptacle is recommended.
5. Feces specimens should not collect during the menstrual period and not three day before or afterwards, at bleeding due to constipation, bleeding haemorrhoids,or at taking rectally administered medication. It could cause false positive results.
6. This test may be less sensitive for detecting upper g.i. Bleeding because blood degrades as it passes through the g.i. Track.
7. The Fecal Occult Blood Rapid Test Cassette (Feces) is to aid indiagnosis and is not intended to replace other diagnostic procedures such as G.I. fibroscope, endoscopy, colonoscopy, or X-ray analysis. Test results should not be deemed conclusive with respect to the presence or absence of gastrointestinal bleeding or pathology. A positive result should be followed up with additional diagnostic procedures to determine the exact cause and source for the occult blood in the feces.

PERFORMANCE CHARACTERISTICS

1. Sensitivity: 99.6%
Fecal Occult Blood Rapid Test Cassette (Feces) can detect the levels of human occult blood as low as 50 ng/mL hemoglobin or 6 µg hemoglobin/g feces.
2. Prozone Effect:
It is observed that this FOB test can detect 2 mg/mL hemoglobin.
3. Specificity: 99.9%
Fecal Occult Blood Rapid Test Cassette (Feces) is specific to human hemoglobin. Specimen containing the following substances at the standard concentration was tested on both positive and negative controls and showed no effects on test results at standards concentration.

Substances	Concentrations (Diluted with the extraction buffer)
Beef hemoglobin	2 mg/mL
Chicken hemoglobin	0.5 mg/mL
Pig hemoglobin	0.5 mg/mL
Goat hemoglobin	0.5 mg/mL
Horse hemoglobin	20 mg/mL
Rabbit hemoglobin	0.06 mg/mL

REFERENCES

1. Simon J.B. Occult Blood Screening for Colorectal Carcinoma: A Critical Review, Gastroenterology, Vol. 1985;88:820.
2. Blebea J. and Ncpherson RA. False-Positive Guaiac Testing With Iodine, Arch Pathol Lab Med, 1985;109:437-40.

INDEX OF SYMBOLS

	Consult instructions for use		Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
30°C 2°C	Store between 2~30°C	LOT	Lot Number	REF	Catalog#

Zhejiang Orient Gene Biotech Co.,Ltd
Address: 3787#, East Yangguang Avenue, Dipu Street,
Anji 313300, Huzhou, Zhejiang, China
Tel: +86-572-5226111 Fax: +86-572-5226222
Website: www.orientgene.com

EC REP Shanghai International Holding Corp. GmbH (Europe)
Add: Eiffestrasse 80, 20537 Hamburg, Germany

REF GEFOB-602b

Revision Date: 2023-04-18
B21056-04

Zhejiang Orient Gene Biotech Co., LTD

CERTIFICATE OF ANALYSIS

Product Name：HBsAg Rapid Test (Whole blood/Serum/Plasma) (Cassette)

Catalog NO.: GCHBsg-402a

Purchase NO.: 2025-IEU010#

Lot NO.: 2501182

Quantity: 3000pcs

Expiration Date: 2026.12

CONTROLS		SPECIFICATION	TEST RESULT	CONCLUSION
Negative Specimens		Negative	Negative	☑Pass □Fail
Positive Specimens	1ng/ml	Positive	Positive	☑Pass □Fail
	2ng/ml	Positive	Positive	☑Pass □Fail
	3ng/ml	Positive	Positive	☑Pass □Fail
	5ng/ml	Positive	Positive	☑Pass □Fail

Conclusion: ☑Pass:All results meet QC standard.
□Fail

ZHEJIANG ORIENT GENE BIOTECH CO.,LTD 浙江东方基因生物制品股份有限公司 检验专用章

Test by: 查妍 Date: 2025.01.22

QC Supervisor: 黄仪愚 Date: 2025.01.22

Hepatitis B Surface Antigen Rapid Test Cassette (Whole blood/Serum/Plasma)

INTENDED USE

The Hepatitis B Surface Antigen Rapid Test Cassette (Whole Blood/Serum/Plasma) is a lateral flow chromatographic immunoassay for the qualitative detection of Hepatitis B surface antigen (HBsAg) in human whole blood, serum or plasma. It is intended to be used as a. screening test and as an aid in the diagnosis of infection with Hepatitis B virus (HBV). Any reactive specimen with the HBsAg Rapid Test Cassette must be confirmed with alternative testing method(s) and clinical findings.

INTRODUCTION

Viral hepatitis is a systemic disease primarily involving the liver. Most cases of acute viral hepatitis are caused by Hepatitis A virus, Hepatitis B virus (HBV) or Hepatitis C virus. The complex antigen found on the surface of HBV is called HBsAg. The presence of HBsAg in serum or plasma is an indication of an active Hepatitis B infection, either acute or chronic. In a typical Hepatitis B infection, HBsAg will be detected 2 to 4 weeks before the ALT level becomes abnormal and 3 to 5 weeks before symptoms or jaundice develop. HBsAg has four principal subtypes: adw, ayw, adr and ayr. Because of antigenic heterogeneity of the determinant, there are 10 major serotypes of Hepatitis B virus. The HBsAg Test Cassette (Whole Blood/Serum/Plasma) is a rapid test to qualitatively detect the presence of HBsAg in whole blood, serum or plasma specimens. The test utilizes a combination of double monoclonal antibodies to selectively detect elevated levels of HBsAg in whole blood, serum or plasma.

PRINCIPLE

The Hepatitis B Surface Antigen Rapid Test Cassette (Whole Blood/Serum/Plasma) is a lateral flow chromatographic immunoassay based on the principle of the double antibody-sandwich technique. The membrane is pre-coated with anti-HBsAg antibodies on the test line region of the test. During testing, Hepatitis B Surface Antigen in the whole blood, serum or plasma specimen reacts with the particle coated with anti-HBsAg antibody. The mixture migrates upward on the membrane, chromatographically by capillary action to react with anti-HBsAg antibodies on the membrane and generate a colored line. The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that the proper volume of specimen has been added and membrane wicking has occurred.

PRODUCT CONTENTS

The Hepatitis B Surface Antigen Rapid Test Cassette (Whole Blood/Serum/Plasma) containing anti-HBsAg antibodies particles and anti-HBsAg antibodies coated on the membrane.

MATERIALS SUPPLIED

Test cassette Dropper Buffer Package insert

MATERIAL REQUIRED BUT NOT PROVIDED

1. Specimen collection containers
2. Lancets (for fingerstick whole blood only)
3. Centrifuge (for plasma only)
4. Timer
5. Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

WARNINGS AND PRECAUTIONS

1. For professional In Vitro diagnostic use only. Do not use after expiration date.
2. Warning: the reagents in this kit contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up.
3. Do not use it if the tube/pouch is damaged or broken.
4. Test is for single use only. Do not re-use under any circumstances.
5. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7. Humidity and temperature can adversely affect results.
8. Do not perform the test in a room with strong air flow, i.e. electric fan or strong air-conditioning.

SPECIMEN COLLECTION AND PREPARATION

1. Hepatitis B Surface Antigen Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
2. To collect Fingerstick Whole Blood specimens:

- Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
- Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
- Puncture the skin with a new sterile lancet for each person. Wipe away the first sign of blood.
- Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Add the Fingerstick Whole Blood specimen to the test cassette by using a capillary tube:
  - Touch the end of the capillary tube to the blood until filled to approximately 50µL. Avoid air bubbles.
  - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood into the specimen well (S) of the test cassette.
- Add the Fingerstick Whole Blood specimen to the test cassette by using hanging drops:
  - Position the patient's finger so that the drop of blood is just above the specimen well (S) of the test cassette.
  - Allow 2 hanging drops of fingerstick whole blood to fall into the center of specimen well (S) on the test cassette, or move the patient's finger so that the hanging drop touches the center of the specimen well (S). Avoid touching the finger directly to the specimen well (S).

3. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
4. Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
5. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
6. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

TEST PROCEDURE

Allow test cassette, specimen, buffer and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

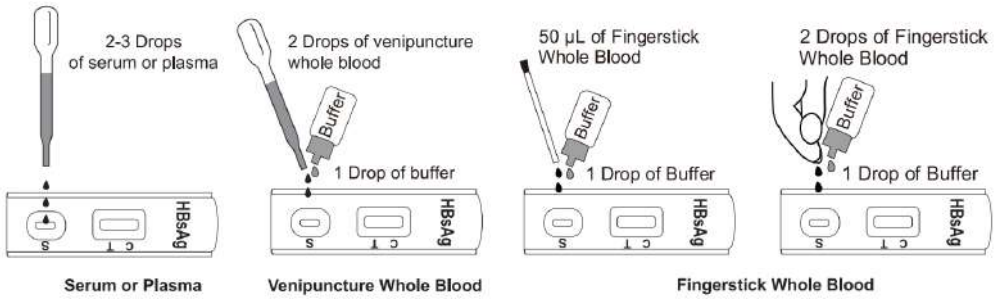
1. Remove the test cassette from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test cassette on a clean and level surface.

For Serum or Plasma Specimens: Hold the dropper vertically and transfer 2-3 drops of serum or plasma (approximately 60-90µL) to the specimen well (S) of the test cassette. See illustration below.

For Venipuncture Whole Blood Specimens: Hold the dropper vertically and transfer 2 drops of venipuncture whole blood (approximately 50µL) to the specimen well (S) of the test cassette, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.

For Fingerstick Whole Blood Specimens: Allow 2 hanging drops of fingerstick whole blood (approximately 50 µL) to fall into the center of the specimen well (S) on the test cassette, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.

3. Wait for the red line(s) to appear. The result should be read in 15 minutes. Do not interpret the result after 15 minutes



INTERPRETATION OF RESULTS

POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T).
NEGATIVE: One red line appears in the control region (C). No apparent red or pink line appears in the test region (T).
INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test Cassette. If the problem persists discontinue using the test kit immediately and contact your local distributor

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. Though the Hepatitis B Surface Antigen Rapid Test Cassette (Whole Blood/Serum/Plasma) is a reliable screening assay, it should not be used as a sole criterion for diagnosis of HBV infection.
2. The HBsAg Rapid Test Cassette is limited to the qualitative detection of HBsAg in human whole blood, serum or plasma. The intensity of the test band does not have linear correlation with HBsAg titer in the specimen.
3. A negative test result does not preclude the possibility of exposure to or infection with HBV. Infection through recent exposure (seroconversion) to HBV may not be detectable.
4. A negative result can occur if the quantity of HBsAg present in the specimen is below the detection limits of the assay (lower than1 ng/mL), or the HBsAg that are detected are not present during the stage of disease in which a sample is collected.
5. Interference due to heterophile antibodies, Rheumatoid Factors and other nonanalyte substances in patient's serum, capable of binding antibodies multivalently and providing erroneous analyte detection in immunoassays, has been reported in various studies. Both laboratory professionals and clinicians must be vigilant to this possibility of antibody interference. Results that appear to be internally inconsistent or incompatible with the clinical presentation should invoke suspicion of the presence of an endogenous artifact and lead to appropriate in vitro investigative action.
6. This kit is intended ONLY for testing of individual samples. Do not use it for testing of cadaver samples, saliva, urine or other body fluids, or pooled (mixed) blood.
7. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS

Sensitivity:

The Hepatitis B Surface Antigen Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested with a sensitivity panel ranging from 0 to 300 ng/mL. All 10 HBsAg subtypes produced positive results on the Hepatitis B Surface Antigen Rapid Test Cassette (Whole Blood/Serum/Plasma). The test can detect 5ng/mL of HBsAg in 10 minutes, and 1 ng/mL of HBsAg in 15 minutes.

Specificity:

Antibodies used for the Hepatitis B Surface Antigen Rapid Test Cassette (Whole Blood/Serum/Plasma) were developed against whole Hepatitis B antigen isolated from Hepatitis B virus. Specificity of the Hepatitis B Surface Antigen Rapid Test Cassette (Whole Blood/Serum/Plasma) was also tested with laboratory strains of Hepatitis A and Hepatitis C. They all yielded negative results.

Hepatitis B Surface Antigen Rapid Test Cassette (Whole Blood/Serum/Plasma) **vs. EIA test**

Method		EIA		Total Results
Hepatitis B Surface Antigen Rapid Test Cassette (Whole Blood/Serum/Plasma)	Results	Positive	Negative	
	Positive	345	5	350
	Negative	2	980	982
Total Results		347	985	1332

Relative sensitivity: 99.4%
Relative specificity 99.5%
Accuracy: 99.5%

REFERENCE

1. Blumberg, B. S. The Discovery of Australian Antigen and its relation to viral hepatitis. Vitro. 1971; 7: 223

Catalogue No:GCHBsg-402a

Effective Date: 2023-08-22

B20137-05

STATEMENT

We, **Rapid Labs Limited** having a registered office at Unit 2 & 2A, Hall Farm Business Centre, Church Road, Little Bentley, Colchester, Essex CO7 8SD, United Kingdom assign SRL Sanmedico, having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova, as authorized representative in Republic of Moldova.

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.

Date: March 5th, 2025

Signature: Tracy Wu Rapid Labs Rapid Labs Limited

Unit 2 & 2A, Hall Farm Business Centre,
Church Road, Little Bentley, Colchester,
Essex CO7 8SD, United Kingdom

Certificate of Registration

This certificate has been awarded to

Rapid Labs Limited

Unit 2 & 2A Hall Farm, Business Centre, Church Road, Little Bentley, Colchester, Essex, CO7 8SD, United Kingdom

in recognition of the organization's Quality Management System which complies with

ISO 13485:2016

The scope of activities covered by this certificate is defined below

Please refer to the Appendix

Certificate Number **55321/A/0001/UK/En**

A certificate number of 0001, confirms the Client has a single site Certified & the site is their Head Office or Main site in relation to the Certified scope with URS. A certificate number of 0002, or greater (e.g.: xxxx/B/0002/UK/En) refers to a client that has more than one site certified with URS, as such, the following statement shall apply - 'The validity of this certificate depends on the validity of the main certificate'.

Date of Issue of Certification Cycle	Issue Number	Certificate Expiry Date	Certification Cycle
16 October 2024	**10**	**15 October 2027**	**5**
Revision Date	Revision Number	Original Certificate Issue Date	Scheme Number
11 July 2024	**0**	**09 November 2012**	**n/a**

For detailed explanation for the data fields above, refer to http://www.urs-holdings.com/logos-and-regulations

Issued by Mukesh Singhal - On behalf of the Schemes Manager

Appendix to Certificate

Design, Development, Manufacture and Supply of In-Vitro Diagnostic Products for the Blood Grouping products, Detection of Hormones, Drug of Abuse, Infectious Disease, Tumour Markers and Cardiac Markers, and the related POCT Analyzer. Supply of Glass Vials and Bottles

Certificate Number **55321/A/0001/UK/En**

A certificate number of 0001, confirms the Client has a single site Certified & the site is their Head Office or Main site in relation to the Certified scope with URS. A certificate number of 0002, or greater (e.g.: xxxx/B/0002/UK/En) refers to a client that has more than one site certified with URS, as such, the following statement shall apply - 'The validity of this certificate depends on the validity of the main certificate'.

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11 July 2024	**0**	**09 November 2012**	**n/a**

For detailed explanation for the data fields above, refer to http://www.urs-holdings.com/logos-and-regulations

Issued by

Mukesh Singhal - On behalf of the Schemes Manager

Certificate of Analysis

Product Name: HBcAb Rapid Test -Serum/Plasma

Catalog No.: D-HBCBD20

Batch No.: HBCB25020002

Quantity:500PCS

Expiry Date:2027-01

Date of Sampling:2025-02-15

Date of Analysis: 2025-02-15

Other information:/

QC Item		QC Criterion	QC Result	Conclusion
Physical	Appearance	Good	Good	Pass
Functional Performance	Low Positive	Low Positive	100% Positive	Pass
	High Positive	High Positive	100% Positive	Pass
	Negative Sample	Negative	100% Negative	Pass

Others	/

Final QC Conclusion:	This batch of product met the QC Criteria.

QC supervisor:

Date:2025.02.15

Rapid Labs
Rapid Labs Limited
Unit 2 • Hall Farm • Church Road • Little Bentley
Colchester • Essex • CO7 8SD • UK
Registered No. 06519288

RAPID BIOTEC™

IVD

HBcAb Rapid Test Device

(Serum/Plasma)

CATALOGUE NUMBER
D-HBCBD20

A rapid test for the qualitative detection of Hepatitis B Core Antibody (HBcAb) in human serum or plasma.
For professional in vitro diagnostic use only.

INTENDED USE

The HBcAb Rapid Test Device (Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of *Hepatitis B Core Antibody (HBcAb) in serum or plasma.*

SUMMARY

Viral hepatitis is a systemic disease primarily involving the liver. Most cases of acute viral hepatitis are caused by Hepatitis A virus (HAV), Hepatitis B virus (HBV) or Hepatitis C virus (HCV). Hepatitis B core antibody is a viral protein secreted by HBV infected cells.[1] Its presence indicates high levels of virus in the blood, and it is an indicator of the infectiousness of the carrier. If this test is negative, but a person is known to be HBcAb positive, then it indicates low levels of virus in the blood or an "integrated phase" of HBV in which the virus is integrated into the host's DNA.[2]
The HBcAb Rapid Test Device (Serum/Plasma) is a rapid test to qualitatively detect the presence of HBcAb in serum or plasma specimen. The test utilizes a combination of monoclonal antibodies and antigen to selectively detect elevated levels of HBcAb in serum or plasma. This one step test is very sensitive and only takes about 15-20 minutes. Test results are read visually without any instrument.

PRINCIPLE

The HBcAb test is immunoassay based on the principle of competitive binding. During testing, the mixture migrates upward on the membrane chromatographically by capillary action. The membrane is pre-coated with anti-HBcAg on the test line region of the strip. During testing, if HBcAb presents in the specimen, it will compete with particle coated HBcAg antibody for limited amount of recombine HBcAg on the membrane. No line will form in the test region. And a visible colored line will form in the test region if there is no HBcAb in the specimen because all the antigen coated particles will be captured by the anti-HBcAg coated in the test line region. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test device contains HBcAg particles and anti-HBcAg coated on the membrane.

PRECAUTIONS

Please read all the information in this package insert before performing the test.

1. For professional *in vitro* diagnostic use only. Do not use after the expiration date.
2. Do not eat, drink or smoke in the area where the specimen or kits are handled.
3. Handle all the specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested .
5. Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

Store as packaged at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

1. The HBcAb Rapid Test Device (Serum/Plasma) can be performed using serum or plasma.
2. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
3. Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C.
4. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
5. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

MATERIALS

Materials provided

• Test devices • Droppers • Package insert

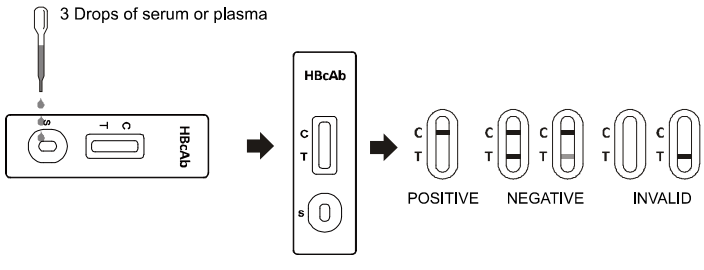
Materials required but not provided

• Specimen collection containers • Centrifuge • Timer

DIRECTIONS FOR USE

Allow test device, serum or plasma specimen and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test device from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
2. Hold the dropper vertically and transfer **3 drops of serum or plasma (approximately 75µL)** to the specimen well of test device and start the timer. Avoid trapping air bubbles in the specimen well. See illustration below.
3. Wait for the colored line is appeared. The result should be read **at 15 minutes.** Do not interpret the result after **20 minutes**.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

NEGATIVE:* Two colored lines appear. One colored line should be in the control region (C) and another colored line should be in the test region (T).

***NOTE**: The shade of red in the test line region (T) may vary, but it should be considered negative whenever there is even a faint pink line.

POSITIVE: One colored line appears in the control region (C). No line appears in the test region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique.
Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The HBcAb Rapid Test Device (Serum/Plasma) is for *in vitro* diagnostic use only. This test should be used for the detection of HBcAb in serum or plasma specimen.
2. The HBcAb Rapid Test Device (Serum/Plasma) will only indicate the presence of HBcAb in the specimen and should not be used as the sole criteria for the diagnosis of Hepatitis B viral infection.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The HBcAb Rapid Test Device (Serum/Plasma) was compared with a leading commercial ELISA HBcAb test, the result show that the HBcAb Rapid Test Device (Serum/Plasma) has a high sensitivity and specificity.

Method		ELISA		Total Results
HBcAb Rapid Test Device (Serum/Plasma)	Results	Positive	Negative	
	Positive	358	4	362
	Negative	8	167	175
Total Results		366	171	537

Relative Sensitivity: 97.8% (95%CI*: 95.7%-99.1%)
Relative Specificity: 97.7% (95%CI*: 94.1%-99.4%)
Accuracy: 97.8% (95%CI*: 96.1%-98.8%) *Confidence Intervals

Precision

Intra-Assay

Within-run precision has been determined by using 15 replicates of three specimens containing negative, low positive and high positive. The negative and positive values were correctly identified 99% of the time.

Inter-Assay

Between-run precision has been determined by using the same three specimens of negative, low positive and high positive of HBcAb in 15 independent assays. Three different lots of the HBcAb Rapid Test Device (Serum/Plasma) has been tested over a 10 days period using negative, low positive and high positive specimens. The specimens were correctly identified 99% of the time.

Cross-reactivity

The HBcAb Rapid Test Device (Serum/Plasma) has been tested by HAMA, Rheumatoid factor (RF), HAV, Syphilis, HIV, *H. pylori*, MONO, CMV, Rubella and TOXO positive specimens. The results showed no cross-reactivity

Interfering Substances

The HBcAb Rapid Test Device (Serum/Plasma) has been tested for possible interference from visibly hemolyzed and lipemic specimens. No interference was observed.
In addition, no interference was observed in specimens containing up to 2,000 mg/dL Hemoglobin, 1000 mg/dL Bilirubin, and 2000 mg/dL human serum Albumin.

BIBLIOGRAPHY

1.Kobayashi E, Deguchi M, Kagita M, et al. Performance evaluation of four dominant anti-hepatitis B core antigen (HBcAb) kits in Japan for preventing de novo hepatitis B virus (HBV) infection. Clin Lab. 2015; 61 (1-2):77-85.
2.Li T, Wang SK, Zhou J, et al. Positive HBcAb is associated with higher risk of early recurrence and poorer survival after curative resection of HBV-related HCC. Liver Int. 2016;36(2):284-92.

Index of Symbols

	Consult instructions for use		Contains sufficient for <*n*> test		Do not reuse
IVD	*In vitro* diagnostic medical device		Use-by date	REF	Catalogue number
2°C 30°C	Store between 2-30°C	LOT	Batch code		Date of manufacture
	Do not use if package is damaged and consult instructions for use		Manufacturer		

Rapid Labs Ltd
Unit 2 & 2A Hall Farm Business
Centre Church Road Little Bentley Colchester
Essex CO7 8SD
United Kingdom

Revision 2 29/04/2024