Atlas Medical

Contract No:Co2403079

Date:09/03/2024

Letter of Authorization

Manufacturer: Atlas Medical GmbH
Ludwig-Erhard-Ring 3,
15827Blankenfelde-Mahlow, Germany
Tel: +49 33 70 83 55 030
Email: amug@atlas-medical.com

Regulatory Office: William James House, Cowley Road, Cambridge, CB4 0WX, UK
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Middle East Site: Sahab Free Zone Area
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Tel.: +962 6 4026468
Fax: +962 6 4022588
Email: info@atlas-medical.com

Agent: San Medico
Republic of Moldova, city Chisina
+37368228890

Atlas Medical, hereby appoint the above mentioned agent to import, register and distribute Atlas Medical Products in Maldova

Appointment Conditions:

1. This appointment is valid for 3 year from the above mentioned date.
2. Either Party can cancel this appointment by giving the other party a 60 day notice.

On behalf of the Manufacturer
General Manager
Haya Amawi

Atlas Medical
Quality Diagnostic Products

CERTIFICAT
CERTIFICATE OF REGISTRATION
N° 36655 rev.2

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

GMED certifies that the quality management system developed by

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

pour les activités
for the activities

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

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

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

Voir addendum

See addendum

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

ISO 13485: 2016

Début de validité */ Effective date* **October 9th, 2023 (included)**
Valable jusqu'au */ Expiry date :* **October 8th, 2026 (included)**
Etabli le */ Issued on :* **October 9th, 2023**

DocuSigned by:
Beatrice Lys
EF33BDA9BAA04A3...

On behalf of the President
Béatrice LYS
Technical Director

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

GMED N° 36655–2
Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

Renouvelle le certificat 36655-1

GMED • Société par Actions Simplifiée au capital de 300 000 € • Organisme Notifié/Notified Body n° 0459
Siège social : 1, rue Gaston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • gmed.fr

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

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

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

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

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

****

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

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

****

2 sites / *2 sites*

DocuSigned by:
Beatrice Lys
FF33BDA9BAA04A3...

On behalf of the President
Béatrice LYS
Technical Director

Atlas Medical

Declaration Ref No: DC21-0194

Date: 06.09.2021

CE Declaration of Conformity

Name and address of Manufacturer	**Atlas Medical GmbH** Ludwig-Erhard-Ring 3, 15827 Blankenfelde-Mahlow Germany . Tel: +49(0)33708355030 Email: info@atlas-medical.com

Atlas Medical GmbH declared our his own responsibility that the following IVD medical devices:

Product Code	Product Name	GMDN code
8.00.19.0.0050	Atlas TPHA Kit , 50 Tests	51819
8.00.19.0.0100	Atlas TPHA Kit , 100 Tests	51819
8.00.19.0.0200	Atlas TPHA Kit , 200 Tests	51819

Meets the essential requirments of In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex I
And
EN ISO 13485 :2016 , EN 18113-1, -2,:2011, EN ISO 15223:2016
EN ISO 14971:2019, EN ISO 23640:2015, ISO 2859/1:1999,
EN ISO 13612:2002, EN ISO 13641:2002 , EN ISO 62366-1+A1:2020.

IVD Categorization	Directive 98/79, Other IVDs (Non-annex II, non-self-test).
Conformity Assesment Route	Directive 98/79/EC , Annex III.
Name , Address and Identification number of notified body	N/A

Date of issuance:	06.September.2021
Place	Atlas Medical GmbH
Signed by: **Position :**	Amani AL-Habahbeh Regulatory Affairs Manager

Atlas Medical GmbH
Ludwig - Erhard Ring 3
15827 Blankenfelde - Mahlow
Tel. (0049) 33708 - 355030

Atlas Medical

TPHA TEST KIT

A passive particle agglutination assay for the qualitative and semi-quantitative detection of IgG and IgM antibodies to *Treponema pallidum*

IVD For *in vitro* diagnostic and professional use only

2°C 8°C Store at 2° to 8° C CE

INTENDED USE

TPHA test kit is designed for the detection of antibodies to *Treponema pallidum* (IgG and IgM antibodies) in human serum or plasma based on the principle of passive particle agglutination.

INTRODUCTION

Syphilis is a venereal disease caused by the spirochaete microorganism *Treponema pallidum*. As this organism cannot be cultured on artificial media the diagnosis of syphilis depends on the correlation of clinical data with the specific antibody demonstrated by serological tests. Serological screening tests for syphilis using cardiolipin and lecithin as antigens are simple to perform but biological false positive (BFP) reactions occur frequently because the tests use non-treponemal antigens.

The TPI and FTA-ABS tests utilize pathogenic *Treponema pallidum* as the antigen but these tests present some difficulties for routine serodiagnosis. The TPI test requires living pathogenic *T.Pallidum* and the FTA-ABS test requires a fluorescence microscope. Both tests require a high level of expertise.

TPHA test kit has been shown to be a convenient and specific test for the diagnosis of treponemal infection, having specificity similar to that of the TPI test and sensitivity comparable to that of the FTAABS test. It requires minimum laboratory equipment and is very simple to perform.

PRINCIPLE OF THE TEST

Atlas TPHA uses preserved avian erythrocytes coated with extracted antigens of T.pallidum (Nichols strain). Specific antibodies present in a sample of plasma or serum bind to these antigens when the sample is incubated with the particles. This causes the particles to agglutinate, then settle to form a characteristic pattern in the test well.

Non-specific reactions are eliminated by the use of absorbents. The assay can be run and interpreted manually or with an auto-analyzer using an agglutination interpretation program.

MATERIALS PROVIDED

- Test cells; avian erythrocytes coated with antigens of *T. Pallidum.*
- Control cells; avian erythrocytes.
- Sample Diluent; Saline solution containing absorbents.
- Positive control; Rabbit antiserum, titer 1/1280, **Pre-diluted.**
- Negative control; Normal Rabbit Serum, **Pre-diluted.**
- Package Insert.

MATERIALS NEEDED BUT NOT PROVIDED

- Micropipettes capable of delivering: 10, 25, 75 and 190µl.
- U-Well microtitration plates.

PACKAGING CONTENTS

REF **8.00.19.0.0200 (2x20 ml Diluent, 2x8.5 ml Control Cell, 2x8.5 ml Test Cells, 1x1 ml Positive Control, 1x1 ml Negative Control)**

REF **8.00.19.0.0100 (20ml Diluent, 8.5ml Control Cell, 8.5ml Test Cells, 1ml Positive Control, 1ml Negative Control)**

PRECAUTIONS

- For i*n vitro* diagnostic and professional use.
- Protective clothing should be worn when handling the reagents.
- Wash hands and the test table top with water and soap once the testing is done.
- If spillage of reagent occur clean with disinfectant (disinfectant used could be irritable so handle with care).
- The test is for well-trained professional health user not for lay user.
- Do not use these reagents if the label is not available or damaged.
- Do not use the kit if damaged or the glass vials are broken or leaking and discard the contents immediately.
- Test materials and samples should be discarded properly in a biohazard container.
- Reagents and controls contain 0.1% sodium azide as a preservative which is toxic and can be absorbed through the skin when drained, the drains should be thoroughly washed with water.
- The reagent is considered toxic, avoid drinking, ingestion and contact with skin or mucus membrane.

REAGENTS HANDELING

- All the reagents must be allowed to equilibrate to room temperature before use.
- Do not freeze any of the reagents.

REAGENTS STORAGE

- Store bottles upright at **2–8°C**.
- **Do not freeze**
- Do not use after the expiry date.

SAMPLE PREPARATION AND HANDLING

- Use fresh serum or plasma samples free of cells and microbial contamination.
- Samples may be stored at 2-8°C for up to 7 days prior to testing.
- Samples can be frozen at -20°C or lower, these should be thawed and mixed prior to testing.

INTERFERING SUBSTANCES AND LIMITATION OF THE TEST

- Atlas TPHA test kit can be used for serum and plasma samples.
- No interfering substances have been identified.
- Atlas TPHA test kit can cross react with other treponemal infections such as *T.pertenue* and *T.carateum* so positive results should be confirmed by another method.
- In early primary syphilis, occasionally, specific antibodies may not be detected.

PROCEDURES

Bring all reagents and samples to room temperature before use.

Kit controls must be run with each assay.

Ensure Test and Control Cells are thoroughly re-suspended.

QUALITATIVE METHOD

Each sample requires 3 wells of a microtitration plate.

1. Add 190 µl of diluent to Well 1.
2. Add 10 µl sample to Well 1. (Sample dilution 1:20).
3. Using a micropipette, mix contents of Well 1 and transfer 25 µl to Wells 2 & 3.
4. Ensure that the Test and Control Cells are thoroughly suspended. Add 75 µl of control cells to Well 2. Add 75µl of Test Cells to Well 3.
5. Tap the plate gently to mix the contents thoroughly.
6. Incubate 45-60 minutes at 15-30° C. **Caution! Keep the plate away from heat, direct sunlight and any source of vibration.**
7. Read results. Results are stable if the plate is covered and the above precautions are observed.

NOTE

Kit controls must be run in parallel and are diluted and ready for use.

SEMI-QUANTITATIVE TEST

9 wells are needed for each sample.

Sample Dilution (to 1 in 20)

1. Add 190µL of sample diluent to a well.
2. Add 10µL of sample to the same well. Mix thoroughly.

Note: Kit controls are pre-diluted (i.e. diluted 1 in 20)

Titration

1. Leave the first well empty, add 25µL of diluent all other wells in the sequence.

2. Transfer 25µL from step 1 to the first well.
3. Transfer 25µL from step 1 to the second well and mix, then serially dilute along the well sequence, discard the excess 25µL from the final well.

Test

Re-suspend the Test and Control Cells thoroughly

4. Add 75µL of Test Cells to each well.

(Final sample dilution is 1 in 80 – 1 in 10,240)

5. Mix wells thoroughly.
6. Incubate at 15-30°C on a vibration-free surface for 45 - 60 minutes. Caution! Keep the plate away from heat, direct sunlight and any source of vibration.
7. Read results. Results are stable if the plate is covered and the above precautions are observed.

The titer of the sample is the reciprocal of the final positive sample dilution.

INTERPRETATION AND ASSAY VALIDATION

Assay Control

The Kit Controls must be give the correct result; Negative is Negative and Positive is Positive. When the Kit Positive is titrated the expected end point is 640 – 2560.

Positive **Equivocal Negative**

A sample where the Test Cell well is non-reactive should be considered as **negative for *T.pallidum***. Reactivity less than equivocal is considered negative.

A sample where the Test Cell well is reactive indicates antibodies to *T.pallidum* resulting from a syphilis infection. The sample should be repeated in duplicate. Where 2 or more wells are positive the sample should be considered as **positive *for T.pallidum***.

A repeatable equivocal sample should be considered positive.

Where a sample is reactive in both Test and Control Cells, if the agglutination is greater in the Test Cells, then the sample is considered positive and should be repeated as above.

Where a sample has greater or equal agglutination in the Control Cells then the sample should be absorbed using the following procedure.

Absorption of Non-specific Reactions

1. Add 10µL of sample to 190µL of re-suspended Control Cells, mix thoroughly and leave for 30 minutes.
2. Centrifuge to deposit the cells at a minimum of 1500g for 3 minutes.
3. Add 25µL of supernatant from step 2 to each of 2 wells.
4. Ensure Test and Control Cells are re-suspended.

   Add 75µL of Test Cells to the first well.
   Add 75µL of Control Cells to the second well.
5. Mix wells thoroughly and Incubate at 15-30°C on a vibration-free surface for 45 - 60 minutes
6. Read and interpret patterns as above.

PERFORMANCE CHARACTERISTICS

Specificity

A study on 300 donor serum showed 100% specificity. (95% confidence limits 98.8 – 100%).
A study on 300 donor EDTA plasma showed 100% specificity. (95% confidence limits 98.8– 100%).

Sensitivity

A study on 100 syphilis positive samples showed 100% sensitivity. (95% confidence limits 96.6 – 100%).

Analytical sensitivity

Atlas TPHA has an expected sensitivity of between 0.1 and 0.025 IU/ml against the 1st IS for human syphilitic plasma IgG and IgM NIBSC code: 05/132

REFRENCES

1. Rathlev T. - Haemagglutination tests utilizing antigens from pathogenic and apathogenic Treponema pallidum WHO/VDT/RES 1965 ; 77 : 65.
2. Tomizawa T, Kasamatsu S. - Haemagglutination tests for diagnosis of syphilis. A preliminary report. Japan. J. Med. Sci. Biol. 19, 305-308, 1966.
3. Rathlev T. - Haemagglutination test utilizing pathogenic Treponema pallidum for the serodiagnosis of syphilis. Br J Vener Dis 1967 ; 43 : 181-5
4. Tomizawa T. Kasamatsu S. Yamaya S. - Usefulness of the haemagglutination test using Treponema pallidum antigen (TPHA) for the serodiagnosis of syphilis. Jap J Med Sci Biol 1969 ; 22 : 341-50.
5. Sequeira P,J,L. Eldridge A,E. - Treponemal Haemagglutination test. Br J Vener Dis 1973 ; 49 : 242-8.
6. Larsen S.A., Hambie E.A., et coll., Specificity, sensitivity and reproducibility among the fluorescent treponemal antibody absorption test, the microhemagglutination assay for Treponema pallidum antibodies, and the hemagglutination treponemal test for syphilis. J. Clin. Microbiol., 1981; 14 : 441 – 445.
7. Wasley G.D. & Wong H.H.Y. Syphilis Serology Priciples and Practice. Oxford Medical Publications 104 - 105

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Website: www.atlas-medical.com

PPI2388A01
Rev B (22.02.2024)

REF	Catalogue Number		Temperature limit
IVD	In Vitro diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry

***: Indication of the introduced modifications.**

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

Document No.: GP-GMSQ-2023121301

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 **1st Jan, 2024** and will be valid to **31th, December, 2024** .

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

基蛋生物科技股份有限公司
GETEIN BIOTECH, INC.

Getein Biotech, Inc.
Seal & Signature

Authority Person Name: **Steven Zhou**
Authority Person Position: **Regional Manager**
Date: **2023.12.13**

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

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

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

Holds Certificate No: **MD 728432**

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

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

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

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

...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

Declaration of Conformity

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

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

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

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

Signatory representative declares herein the above mentioned device meets the basic requirements of the European Parliament and the Council's in vitro diagnostic medical devices directive: 98/79/EC Annex III. This declaration of conformity is based on European Parliament and the Council's 98/79/EC directive Annex III. The compiled technical file and quality system document according to 98/79/EC directive Annex III are testified and the quality system certificate has issued by TÜV Rheinland (Shanghai) Co., Ltd.

General Manager: Enben Su

Nanjing, 20th, Jul, 2019

(place and date of issue)

(name and signature or equivalent marking of authorized person)

CE IVD

Cardiac Troponin I Fast Test Kit

User Manual Cat.# CG2001

INTENDED USE

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

SUMMARY

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

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

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

PRINCIPLE

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

CONTENTS

A kit contains:

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

A test card consists of:

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

Whole blood buffer composition:

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

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

STORAGE AND STABILITY

Store the test card at 4~30°C with a valid period of 24 months. Use the test card within 1 hour once the foil pouch is opened. Store the whole blood buffer at 0~30°C with a valid period of 24 months.

Store the whole blood buffer at 2~8°C for better results.

PRECAUTIONS

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

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for ***serum, plasma or whole blood samples. Heparin,EDTA or sodium citrate*** should be used as the anticoagulant for plasma and whole blood. Samples should be free of hemolysis.
2. Suggest using serum or plasma for better results.
3. Serum or plasma can be used directly. For whole blood sample, whole blood buffer must be added before testing.
4. If testing will be delayed, serum and plasma samples may be stored up to 7 days at 2~8°C or stored at -20°C for 6 months before testing (whole blood sample may be stored up to 3 days at 2~8°C).

5. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
6. Do not use heat-inactivated samples.
7. SAMPLE VOLUME: ***80 µl***.

TEST PROCEDURE

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

TEST RESULTS

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

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

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

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

EXPECTED VALUE

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

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

LIMITATIONS

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

REFERENCES

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

DESCRIPTION OF SYMBOLS USED

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

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

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

Version: WCG01A-DX-S-02

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

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 non-exclusive authorized representative for Orient Gene Brand product in correspondence with the conditions of directive 98/79/EEC.

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

This Statement letter will be valid from Mar.22th,2024 to Mar.21th, 2025.

Zhejiang Orient Gene Biotech Co., Ltd

General Manager：

Date:2024/3/22

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

.

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

TÜV®

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

CE-DOC-OG039
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)

H. pylori Ag Rapid Test Strip (Feces)	GCHP-601a
H. pylori Ag Rapid Test Cassette (Feces)	GCHP-602a

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

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

CE-DOC-OG048
Version 3.0

CE

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)

D-Dimer Rapid Test Cassette (Whole Blood/Plasma)	GDDDI-402b

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: QARAD BV

EC Representative's Address: Cipalstraat 3, 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

Date Signed: November 11, 2021

Joyce Pang

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

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

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

Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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

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

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Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07

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

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

TÜV®

D-Dimer Rapid Test Cassette (Whole Blood/Plasma)

CE

INTENDED USE

The D-Dimer Rapid Test Cassette (Whole Blood/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of D-dimer in human whole blood or plasma. It is intended to be used as a screening test and as an aid in the diagnosis of disseminated intravascular coagulation (DIC), deep vein thrombosis (DVT). Any reactive specimen with the D-Dimer Rapid Test Cassette (Whole Blood/Plasma) must be confirmed with alternative testing method(s) and clinical findings.

INTRODUCTION

During blood coagulation process, fibrinogen is converted to fibrin by the activation of thrombin. The resulting fibrin monomers polymerise to form a soluble gel of non-cross-linked fibrin. This fibrin gel is then converted to cross-linked fibrin by thrombin activated Factor XIII to form an insoluble fibrin clot. Production of plasmin, the major clot-lysing enzyme, is triggered when a fibrin clot is formed. Although fibrinogen and fibrin are both cleaved by the fibrinolytic enzyme plasmin to yield degradation products, only degradation products from cross-linked fibrin contain D-dimer and are called cross-linked fibrin degradation products. Therefore, fibrin derivatives in human blood or plasma containing D-dimer are a specific marker of fibrinolysis.

The D-Dimer Rapid Test Cassette (Whole Blood/Plasma) is a rapid test that qualitative detects the presence of D-dimer in whole blood or plasma specimens at the sensitivity of 500 ng/mL. The test utilizes a combination of monoclonal antibodies to selectively detect elevated levels of D-dimer in whole blood or plasma. At the level of claimed sensitivity, the D-Dimer Rapid Test Cassette (Whole Blood/Plasma) shows no cross-reactivity interference from the related Troponin I, Troponin T, CK-MB, Myoglobin or others at high physiological levels.

PRINCIPLE

The D-Dimer Rapid Test Cassette (Whole Blood/Plasma) is immunochromatographic assay including D-Dimer specific monoclonal antibody conjugated to colloidal gold particles, second D-Dimer specific monoclonal antibody on test line and Goat anti-mouse IgG antibody on the control line. When the specimen containing D-Dimer is added to sample pad, it moves to conjugate pad and forms a complex (D-Dimer and antibody-gold conjugate). The complex migrates through a nitrocellulose membrane by capillary action and captured at test line which is second D-Dimer specific monoclonal antibody has been bound. The complex is concentrated at test line and a pink or purple line is showed if the D-Dimer concentration is higher than the clinically established cut-off. Uncaptured gold conjugate continues to flow towards control line which Goat anti-mouse IgG is bound and forms a pink or purple color line, indicating test is working as designed and the result is valid. If the control line does not appear, the test result is not valid.

PRODUCT CONTENTS

The D-Dimer Rapid Test Cassette (Whole Blood/Plasma) containing Anti-D-dimer particles and Anti-D-dimer coated on the membrane.

MATERIALS SUPPLIED

25 Sealed pouches each containing a test cassette, a pipette dropper and a desiccant
1 Buffer, 4.0 mL
1 Package insert

MATERIAL REQUIRED BUT NOT PROVIDED

Timer Lancing device for whole blood test

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.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
3. This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled by observing usual safety precautions (e.g., do not ingest or inhale).
4. Read the entire procedure carefully prior to testing.
5. Do not eat, drink or smoke in any area where specimens and kits are handled.
6. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7. Do not interchange or mix reagents from different lots. Do not mix solution bottle caps.
8. Humidity and temperature can adversely affect results.

SPECIMEN COLLECTION AND PREPARATION

1. The D-Dimer Rapid Test Cassette (Whole Blood/Plasma) is intended for use with human whole blood or plasma specimens only.
2. Only clear, non-hemolyzed specimens are recommended for use with this test. Whole blood or Plasma should be separated as soon as possible to avoid hemolysis.
3. Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. 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.
4. Containers containing anticoagulants such as EDTA, citrate, or heparin should be used for whole blood storage.
5. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
6. If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.
7. Icteric, lipemic, hemolysed, heat treated and contaminated specimens may cause erroneous results.

TEST PROCEDURE

Bring tests, specimens, reagents and/or controls to room temperature (15-30°C) prior to testing.

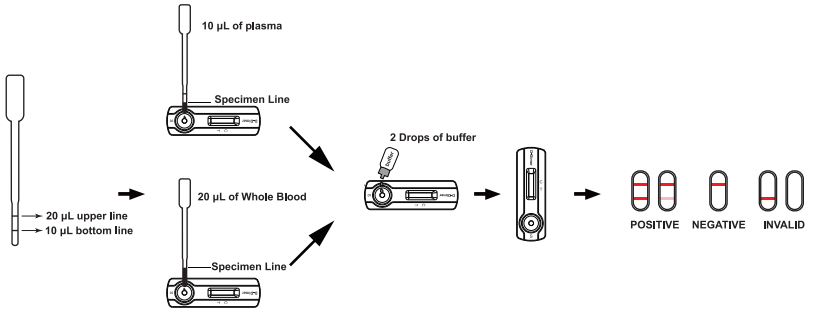
1. Remove the test cassette from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test cassette on a clean and level surface.

For Whole Blood Specimen: With the 10/20µL mini plastic dropper provided, draw the whole blood specimen to the upper scale line as showed in the following image and then transfer drawn whole blood into the sample well (S) of the test device., then add 2 drops of buffer (approximately 80µL) and start the timer. See illustration below.

For Plasma Specimen: With the 10/20µL mini plastic dropper provided, draw the plasma specimen to the bottom scale line as showed in the following image and then transfer drawn plasma into the sample well (S) of the test device. Then add 2 drops of buffer (approximately 80µL) and start the timer. See illustration below.

Note: Practice a few times prior to testing if you are not familiar with the mini dropper. For better precision, transfer specimen by pipette capable to deliver 10 and 20µL of volume.

3. As the test begins to work, color will migrate across the membrane.
4. Wait for the colored band(s) to appear. The result should be read in 10 minutes. Do not interpret the result after 15 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 D-Dimer Rapid Test Cassette (Whole Blood/Plasma) is for in vitro diagnostic use only. This test should be used for the detection of D-dimer in whole blood or plasma specimens only. Neither the quantitative value nor the rate of increase in D-dimer can be determined by this qualitative test.
2. The D-Dimer Rapid Test Cassette (Whole Blood/Plasma) will only indicate the qualitative level of D-dimer in the specimen and should not be used as the sole criteria for the diagnosis of Disseminated Intravascular Coagulopathy (DIC), Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE).
3. During the process of serum is formed, also fibrinogen is converted to fibrin by the activation of thrombin and it also can be detected by D-dimer antibody. So serum specimen can't be used for D-Dimer Rapid Test Device (Whole Blood/Plasma).
4. The D-Dimer Rapid Test Cassette (Whole Blood/Plasma) cannot detect less than 500 ng/mL D-dimer in specimens. A negative result at any time does not preclude the possibility of Disseminated Intravascular Coagulopathy (DIC), Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE).
5. False negative readings can occur if the sample is taken either too early after thrombus formation, if testing is delayed for several days or if the sample was take too later after the occurrence of thromboembolic infarction, because the D-dimer concentration may decrease to normal values after one week already. Additionally, a treatment with anti-coagulants prior sample collection can render the test negative because it prevents thrombus extension.
6. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician. E.g. use "Wells score" for DVT resp. PE, Ultrasound, quantitative laboratory D-Dimer results etc.
7. Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor (RF) may affect expected results. Even if the test results are positive, further clinical evaluation should be considered with other clinical information available to the physician

PERFORMANCE CHARACTERISTICS

1. Sensitivity and Specificity

The D-Dimer Rapid Test Cassette (Whole Blood/Plasma) has been evaluated with a leading commercial D-dimer EIA test using clinical specimens. The results show that the sensitivity of the D-Dimer Rapid Test Cassette (Whole Blood/Plasma) is 98.6% and the specificity is 98.6% relative to the leading EIA test.

Method		EIA		Total Results
D-Dimer Rapid Test Cassette	Results	Positive	Negative	
	Positive	71	3	74
	Negative	1	211	212
Total Results		72	214	286

Relative Sensitivity: 98.6%
Relative Specificity: 98.6%
Accuracy: 98.6%

2. Precision

Within-run precision has been determined by using 15 replicates of below five specimens: D-dimer specimen levels at 0 ng/mL, 500 ng/mL, 1,000 ng/mL, 1,500 ng/mL and 3,000 ng/mL. The specimens were correctly identified at the prescribed reading time.

3. Inter-Assay

Between-run precision has been determined by 3 independent assays on the same five specimens: 0 ng/mL, 500 ng/mL, 1,000ng/mL, 1,500 ng/mL and 3,000 ng/mL of D-dimer. Three different lots of the D-Dimer Rapid Test Cassette (Whole Blood/Plasma) have been tested using these specimens. The specimens were correctly identified at the prescribed reading time.

4. Cross-reactivity

The D-Dimer Rapid Test Cassette (Whole Blood/Plasma) has been tested with HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, anti-syphilis, anti-HIV, anti-H.pylori, IM heterophile antibodies, anti-CMV, anti-Rubella and anti-Toxoplasma positive specimens. The results showed no cross-reactivity.

5. Interfering Substances

The following potentially interfering substances were added to D-dimer negative and positive specimens, repectively.

Substances	Concentration
Acetaminophen	20 mg/dL
Caffeine	20 mg/dL
Acetylsalicylic Acid	20 mg/dL
Gentisic Acid	20 mg/dL
Ascorbic Acid	20 mg/dL
Albumin	10,500 mg/dL
Creatin	200 mg/dL
Hemoglobin	1,000 mg/dL
Bilirubin	1,000 mg/dL
Oxalic Acid	600 mg/dL
Cholesterol	800 mg/dL
Triglycerides	1,600 mg/dL

None of the substances at the concentration tested interfered in the assay.

REFERENCE

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6. Hunt, F.A. et al. Serum Cross-Linked Fibrin (XDP) and Fibrinogen/Fibrin Degradation Products (FDP) in Disorders Associated with Activation of the Coagulation or Fibrinolytic Systems. Br. J. Haematol. 60: 715-722; 1985.
7. Subramanian, R.M. et. al. Does an Immunochromatographic D-dimer exclude acute lower limb deep venous thrombosis? Emer. Med. Austral. 18: 457-463; 2006.
8. Runyon, M.S. et. al. Comparison of the Simplify D-dimer assay performed at the bedside with a laboratory based quantitative D-dimer assay for the diagnosis of pulmonary embolism in a low prevalence emergency department population. Emerg. Med. J. 25:70-75; 2008.

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: +86-572-5226 111 Fax: +86-572-5226222
Website: www.orientgene.com

EC REP QARAD BV
Cipalstraat 3, 2440 Geel BELGIUM

REF GDDDI-402b

Revision Date: 2022-10-08
B22211-02

H. pylori Ag Rapid Test Cassette (Feces)

CE

INTENDED USE

H. pylori Ag Rapid Test Cassette (Feces) is a sandwich lateral flow chromatographic immunoassay for the qualitative detection of H.Pylori antigen in feces.It is for professional *in vitro* diagnostic use only.

INTRODUCTION

H.Pylori is associated with a variety of gastrointestinal diseases included non-ulcer dyspepsia, duodenal and gastric ulcer and active, chronic gastritis.[1,2] The prevalence of H.pylori infection could exceed 90% in patients with signs and symptoms of gastrointestinal diseases. Recent studies indicate an association of H. Pylori infection with stomach cancer.[3]H. Pylori colonizing in the gastrointestinal system elicits specific antibody responses[4,5,6] which aids in the diagnosis of H. Pylori infection and in monitoring the prognosis of the treatment of H. Pylori related diseases. Antibiotics in combination with bismuth compounds have been shown to be effective in treating active H. Pylori infection. Successful eradication of H. pylori is associated with clinical improvement in patients with gastrointestinal diseases providing a further evidence.[7]

PRINCIPLE

H. pylori Ag Rapid Test Cassette (Feces) is a lateral flow chromatographic immunoassay based on the principle of the double antibody–sandwich technique. The test cassette consists of: 1) a burgundy colored conjugate pad containing H. Pylori antibodies conjugated with color particles (H. Pylori conjugates. 2) a nitrocellulose membrane strip containing a test band (T band) and a control band (C band). The T band is pre-coated with non-conjugated H. Pylori antibodies.

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 antigen of H. Pylori if present in the specimen will bind to the H. Pylori antibodies conjugates. The immunocomplex is then captured on the membrane by the pre-coated H. Pylori antibodies, forming a burgundy colored T band, indicating a H. Pylori antigen positive test 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. Otherwise, the test result is invalid and the specimen must be retested with another device.

PRODUCT CONTENTS

H. pylori Ag Rapid Test Cassette (Feces) containing anti- H.pylori antibodies particles and anti-H.pylori antibodies coated on the membrane.

MATERIALS SUPPLIED

20 Sealed pouches each containing a test cassette and a desiccant
20 Specimen collection tubes with extraction buffer, 2.0 mL
1 Package insert

MATERIAL REQUIRED BUT NOT PROVIDED

1. Clock or timer
2. Specimen collection containers.

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 off the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

WARNINGS AND PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. Do not use it if the tube/pouch is damaged or broken.
3. Test is for single use only. Do not re- use under any circumstances.
4. Handle all specimens as if they contain infectious agents. Observe established standard procedure for proper disposal of specimens
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assay.
6. Humidity and temperature can adversely affect results

SPECIMEN COLLECTION

Collect sufficient quantity of feces (1-2 mL or 1-2 g) in a clean, dry specimen collection container to obtain maximum antigens (if present). Best results will be obtained if the assay is performed within 6 hours after collection. Specimen collected may be stored for 3 days at 2-8˚C if not tested within 6 hours. For long term storage, specimens should be kept below -20˚C.

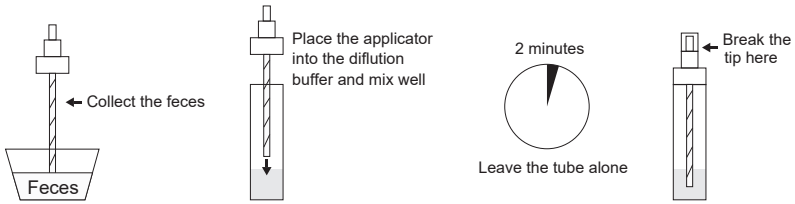
To process fecal specimens:

◦ For Solid Specimens:

Unscrew the cap of the specimen collection tube， then randomly stab the specimen collection applicator into the fecal specimen in at least 3 different sites to collect approximately 50 mg of feces (equivalent to 1/4 of a pea). Do not scoop the fecal specimen.

◦ For Liquid Specimens:

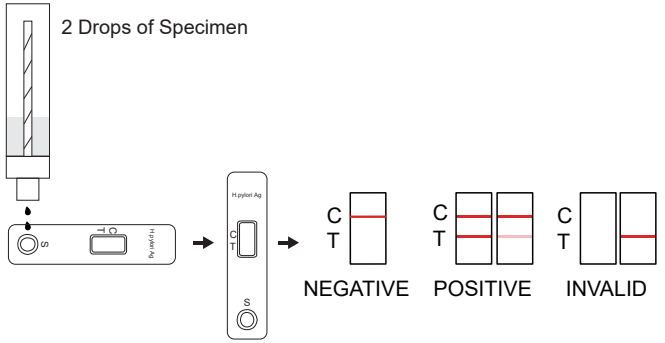
Hold the dropper vertically, aspirate fecal specimens, and then transfer 2 drops (approximately 80 µL) into the specimen collection tube containing the dilution buffer. Screw on and tighten the cap onto the specimen collection tube, then shake the specimen collection tube vigorously to mix the specimen and the dilution buffer. Leave the tube alone for 2 minutes.



TEST PROCEDURE

1. Remove the test device from its foil pouch by tearing along the notch and use it as soon as possible.
2. Specimen collection. See also specimen collection.
3. Holding the sample collection device upright, carefully break off the tip of collection device.
4. Squeeze 2 drops (~80 µL) of the sample solution in the sample well of the cassette, as in the illustration.
5. Read the test results in 10 minutes. It is important that the background is clear before the result is read. Do not read results after 10 minutes. To avoid confusion, discard the test device after interpreting the result.

INTERPRETATION OF RESULTS



H. pylori Ag Rapid Test Cassette (Feces)

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.

QUALITY CONTROL

A 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 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 Assay Procedure and the Assay Result Interpretation must be followed closely when testing the presence of H. Pylori antigen in feces from individual subjects. Failure to follow the procedure may give inaccurate results.
2. H. pylori Ag Rapid Test Cassette (Feces) is limited to the qualitative detection of H. Pylori antigen in feces. The intensity of the test band does not have linear correlation with the antigen titer in the specimen.
3. A negative result for an individual subject indicates absence of detectable H. Pylori antigen. However, a negative test result does not preclude the possibility of exposure to or infection with H. Pylori.
4. A negative result can occur if the quantity of the H. Pylori angtigen present in the specimen is below the detection limits of the assay, or the antigen that are detected are not present during the stage of disease in which a sample is collected.
5. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

PERFORMANCE CHARACTERISTICS

A study was performed with 165 patient feces samples including both symptomatic gastrointestinal disorders and samples from non-symptomatic patients and 100 normal feces samples.Comparison for all subjects with H. pylori Ag Rapid Test Cassette (Feces) and reference ELISA kit is showed in the following table:

Method		EIA		Total Results
H.P Test Cassette	Results	Positive	Negative	
	Positive	163	0	163
	Negative	2	100	102
Total Results		165	100	265

Relative sensitivity: 99.0%
Relative specificity: 100%
Accuracy:98.9%

REFERENCE

1. Marshall,B.J.et.al. Pyloric Campylobacter infection and gastroduodenal disease. Med. J. Australia.149:439-44, 1985.
2. Marshall,B.J.et.al. Prospective double-blind trial of duodenal ulcer relapse after eradication of Campylobacter pylori. Lancet. Dec.1437-42,1988.
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4. Soll,A.H. Pathogenesis of peptic ulcer and implications for therapy. New England J. Med.322:909-916,1990.
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6. Ansong,R. et.al. Evaluation of techniques for isolation, subcultivation and preservation of Helicobacter pylori. J.Clin.Micro. 29:51-53,1991.
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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
2°C 30°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 GCHP-602a

Revision Date: 2022-03-08
B20435-03

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

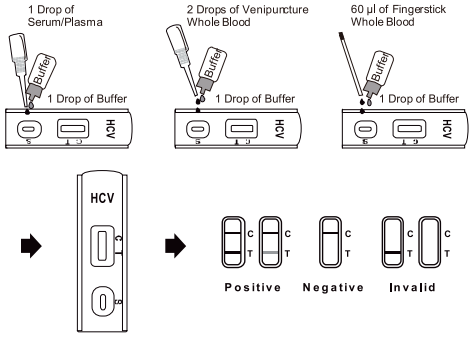
1. For professional *in vitro* diagnostic use only. Do not use after expiration date.
2. Warning: the reagents in this kit contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of 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
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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		

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