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

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 Feb.21th,2023 to Feb.20th, 2024.

Zhejiang Orient Gene Biotech Co., Ltd

General Manager:

Date:2023/2/21

Digitally signed by Dolgopol Iulian
Date: 2024.02.20 10:51:58 EET
Reason: MoldSign Signature
Location: Moldova

地址：浙江省湖州市安吉县递铺镇阳光大道东段 3787 号
Add: **3787#, East Yangguang Avenue, Dipu Street Anji 313300, Huzhou, Zhejiang, China**
电话 Tel:+86-572-5226111　　传真 Fax: +86-572-5226222　邮编 P.C.:313300

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. 01

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. 01

Report No.: SH2198802

Valid from: 2022-04-11
Valid until: 2024-03-16

Date, 2022-04-11

Christoph Dicks
Head of Certification/Notified Body

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

TÜV®

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

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

TÜV SÜD Product Service

Certificate

No. Q5 092305 0001 Rev. 01

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

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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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

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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

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TÜV®

3818 Fuqua street
Houston, TX 77047, USA
Tel: +1 713 733 8088
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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

Zhejiang Orient Gene Biotech Co., LTD

CERTIFICATE OF ANALYSIS

Product Name：HBV Combo Rapid Test (Whole blood Serum Plasma) (Cassette)

Catalog NO.: GCHBV-455a

Purchase NO.：2023-SI234#

Lot NO.：S2305106

Quantity: 140 pcs

Expiration Date：2025 04

	CONTROLS		SPECIFICATION	TEST RESULT	CONCLUSION
HBsAg Part:	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
HBsAb Part:	Negative Specimens		Negative	Negative	☑Pass □Fail
	Positive Specimens		Positive	Positive	☑Pass □Fail
HBcAb Part:	Negative Specimens		Negative	Negative	☑Pass □Fail
	Positive Specimens		Positive	Positive	☑Pass □Fail
HBeAg Part:	Negative Specimens		Negative	Negative	☑Pass □Fail
	Positive Specimens		Positive	Positive	☑Pass □Fail
HBeAb Part:	Negative Specimens		Negative	Negative	☑Pass □Fail
	Positive Specimens		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:

QC Supervisor:

Date：2023.5.10

HCV Ab Rapid Test Cassette
(Whole Blood/Serum/Plasma)

INTENDED USE

The HCV Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) is a sandwich lateral flow chromatographic immunoassay for the qualitative detection of antibodies (IgG, IgM, and IgA) anti- 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 Ab Rapid 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 Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) 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 elveated levels of HCV antibodies in whole blood, serum or plasma.

PRINCIPLE

The HCV Ab 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 strip 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 pre-coated 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/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 device.

PRODUCT CONTENTS

HCV Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) containing HCV antigen coated particles and HCV antigen coated on the membrane.

MATERIALS SUPPLIED

1. Test Strip 2. Pipette Dropper 3.Desiccant 4.Buffer 5.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 device 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 .

SPECIMEN COLLECTION

1.The HCV 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 device by using a capillary tube:
  · Touch the end of the capillary tube to the blood until filled to approximately 50 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.
- Add the Fingerstick Whole Blood specimen to the test device 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 device.
  · Allow 2 hanging drops of fingerstick whole blood to fall into the center of specimen well (S) on the test device 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).

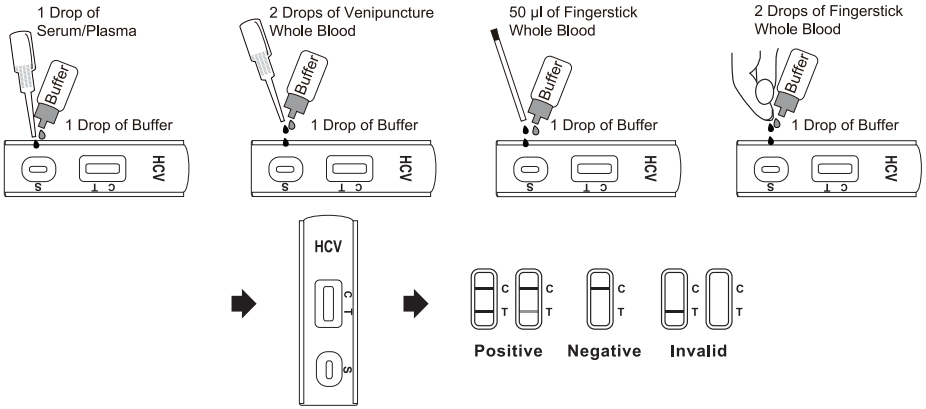
3.Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
4.Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 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 device, specimen, buffer and/or controls to equilibrate to room temperature (15-30°C) prior to testing.
1.Remove the test device 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 device 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 device, 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 50µL) to the specimen well (S) of the test device, 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 device, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.

HCV Ab Rapid Test Cassette
(Whole Blood/Serum/Plasma)

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

(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 device. 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 Ab Rapid Test Cassette (Whole Blood/ Serum/Plasma) 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 Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) 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 r esult 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.

PERFORMANCE CHARACTERISTICS

Sensitivity: HCV Ab Rapid Test Cassette (Whole Blood/ Serum/Plasma) has passed a seroconversion panel and compared with leading commercial HCV EIA test using clinical specimens.
Specificity: The recombinant antigens used for HCV Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) are encoded by genes for both structural (nucleocapsid) and non-structural proteins. HCV Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) is highly specific for antibodies to Hepatitis C Virus compared with a leading commercial HCV EIA test.
The HCV Ab Rapid Test Cassette vs EIA test

Method		EIA		Total Results
HCV Ab RapidTest	Results	Positive	Negative	
	Positive	105	19	124
	Negative	2	1760	1762
Total Results		107	1779	1886

Relative sensitivity: 98.1%
Relative specificity: 98.9%
Accuracy: 98.9%

REFERRENCE

1. Choo, Q.L., G.Kuo,A.J. Weiner, L.R. Overby,D.W. Bradley, andM. 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.

HBV Hepatitis B Virus Combo Rapid Test Cassette (Whole Blood/Serum/Plasma)

For professional *in vitro* diagnostic use only.

INTENDED USE

HBV Hepatitis B Virus Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of Hepatitis B Surface Antigen (HBsAg), Hepatitis B Surface Antibody (HBsAb), Hepatitis B Envelope Antigen (HBeAg), Hepatitis B Envelope Antibody (HBeAb), and Hepatitis B Core Antibody (HBcAb) in human whole blood, serum and plasma.

SUMMARY

Chronic hepatitis B is a serious, debilitating illness that can cause cirrhosis of the liver, liver cancer and death.
Chronic hepatitis B is the main cause of liver cancer and the tenth leading cause of death worldwide, with 400,000,000 people infected with the virus. Every year, one million people worldwide are expected to die from this infection.
Most people fight off the infection themselves, but approximately 5-10 percent of those infected with the virus become carriers, and an additional 5-10 percent of those infected each year will progress to chronic liver disease, cirrhosis and possibly liver cancer.
HBV Hepatitis B Virus Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid test to qualitatively detect the presence of HBsAg, HBsAb, HBeAg, HBeAb and HBcAb in human whole blood, serum and plasma without the use of an instrument.[1]

PRINCIPLE

HBsAg and HBeAg

The HBsAg and HBeAg tests are qualitative, two-site sandwich immunoassays for the detection of HBsAg or HBeAg in human whole blood,serum or plasma. The membrane is pre-coated with anti-HBsAg or anti-HBeAg antibodies on the test line region of the strip. During testing, the whole blood, serum or plasma specimen reacts with the particle coated with anti-HBsAg or anti-HBeAg antibodies. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-HBsAg or anti-HBeAg antibodies on the membrane and generate a colored line. The presence of this colored line in the test line region indicates a positive result, while its absence indicates a negative result.

HBsAb

Hepatitis B surface Antibody (HBsAb) is also known as anti-Hepatitis B surface Antigen (anti-HBs). This test is a qualitative, lateral flow immunoassay for the detection of HBsAb in human whole blood, serum or plasma. The membrane is pre-coated with HBsAg on the test line region of the strip. During testing, the whole blood, serum or plasma specimen reacts with the particle coated with HBsAg. The mixture migrates upward on the membrane chromatographically by capillary action to react with HBsAg on the membrane and generate a colored line. The presence of this colored line in the test line region indicates a positive result, while its absence indicates a negative result.

HBeAb and HBcAb

Hepatitis B envelope Antibody (HBeAb) is also known as anti-Hepatitis B envelope Antigen (anti-HBe). Hepatitis B core Antibody (HBcAb) is also known as anti-Hepatitis B core Antigen (anti-HBc). These tests are immunoassays 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 HBeAg or HBcAg on the test line region of the strip. During testing, anti-HBe antibody or anti-HBc antibody, if present in the specimen, will compete with particle coated anti-HBe antibody or anti-HBc antibody for limited amount of HBeAg or HBcAg on the membrane, and no line will form in the test line region, indicating a positive result. A visible colored line will form in the test line region if there is no anti-HBe antibody or anti-HBc antibody in the specimen because all the antibody coated particles will be captured by the antigen 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.

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- 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.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either 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.

SPECIMEN COLLECTION AND PREPARATION

- HBV Hepatitis B Virus Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using human whole blood, serum and plasma.
- Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, nonhemolyzed specimens can be used.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. 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.
- 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.
- If specimens are to be shipped, they should be packed in compliance with local regulations for the transportation of etiologic agents.

MATERIALS

Materials Provided

• Test cassette Buffer Dropper Package insert

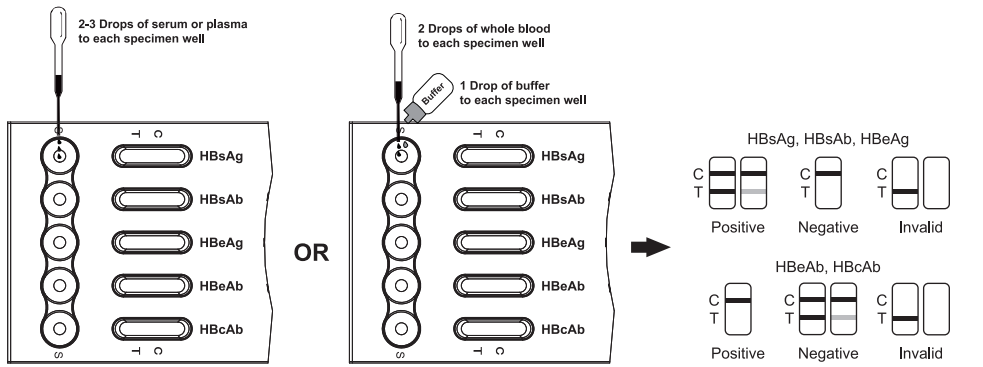
Materials Required but Not Provided

• Specimen collection container Centrifuge (for plasma only) Timer

DIRECTIONA FOR USE

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

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed 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 to each specimen well (S) of the test cassette respectively, then start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration below.
   For Venipuncture Whole Blood specimens: Hold the dropper vertically and transfer 2 drops of whole blood to the specimen well (S) of the test cassette, then add 1 drop of buffer and start the timer. See illustration below.
3. Wait for the red line(s) to appear. The results should be read at 15 minutes. Do not interpret the results after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

WARNING: Do not interpret all 5 tests with the same criteria. Carefully follow the directions below.

HBsAg, HBsAb, HBeAg

POSITIVE: Two red lines appear. One line should be in the control line region (C) and another line should be in the test line region (T).
NEGATIVE: One red line appears in the control line region (C). No apparent red or pink 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 device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

HBeAb, HBcAb

POSITIVE: One red line appears in the control line region(C), No apparent red or pink line appears in the test region (T).

NEGATIVE: Two red lines appear. One line should be in the control line region (C) and another line should be 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 device. 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 line 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 good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATION

1. The HBV Hepatitis B Virus Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. This test should be used for the detection of HBsAg, HBsAb, HBeAg, HBeAb and HBcAb in human whole blood, serum or plasma. Neither the quantitative value nor the rate of increase in the concentration of HBsAg, HBsAb, HBeAg, HBeAb and HBcAb can be determined by this qualitative test.
2. The HBV Hepatitis B Virus Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) will only indicate the presence of HBsAg, HBsAb, HBeAg, HBeAb and 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.
4. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested. A negative result at any time does not preclude the possibility of Hepatitis B Virus infection.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The HBV Hepatitis B Virus Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) was compared with leading commercial ELISA of HBsAg, HBsAb, HBeAg, HBeAb, HBcAb tests, the results show that the HBV Hepatitis B Virus Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) has a high sensitivity and Specificity.

HBsAg

Method		ELISA		Total results
HBsAg test cassette	Results	Positive	Negative	
	Positive	145	5	150
	Negative	0	150	150
Total results		145	155	300
Analysis of the results				
Relative Sensitivity		>99.0%		
Relative Specificity		96.8%		
Accuracy		98.3%		

HBsAb

Method		ELISA		Total results
HBsAb test cassette	Results	Positive	Negative	
	Positive	220	2	222
	Negative	0	150	150
Total results		220	152	372
Analysis of the results				
Relative Sensitivity		>99.0%		
Relative Specificity		98.7%		
Accuracy		99.5%		

HBeAg

Method		ELISA		Total results
HBeAg test cassette	Results	Positive	Negative	
	Positive	111	6	117
	Negative	2	332	334
Total results		113	338	451
Analysis of the results				
Relative Sensitivity		98.2%		
Relative Specificity		98.2%		
Accuracy		98.2%		

HBeAb

Method		ELISA		Total results
HBeAb test cassette	Results	Positive	Negative	
	Positive	103	9	112
	Negative	6	321	327
Total results		109	330	439
Analysis of the results				
Relative Sensitivity		94.5%		
Relative Specificity		97.3%		
Accuracy		96.6%		

HBcAb

Method		ELISA		Total results
HBcAb test cassette	Results	Positive	Negative	
	Positive	443	4	447
	Negative	17	120	137
Total results		460	124	584
Analysis of the results				
Relative Sensitivity		96.3%		
Relative Specificity		96.8%		
Accuracy		96.4%		

Precision

Intra-Assay

Within-run precision has been determined by using 15 replicates of three specimens containing negative, low positive and high positive of HBsAg, HBsAb, HBeAg, HBeAb and HBcAb. 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 HBsAg, HBsAb, HBeAg, HBeAb and HBcAb in 15 independent assays. Three different lots of the HBV One Step Hepatitis B Virus Combo Test Device (Whole blood/Serum/Plasma) have been tested over a 3 months period using negative, low positive and high positive specimens. The specimens were correctly identified 99% of the time.

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