



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

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## 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.

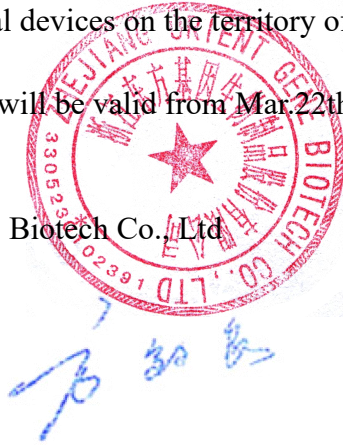
We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

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



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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



# 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](http://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





Zhejiang Orient Gene Biotech Co., LTD

## CERTIFICATE OF ANALYSIS

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

Purchase NO.: 2024-IEU010#

Lot NO.: 2401182

Quantity: 4000pcs

Expiration Date: 2025.12

CONTROLS		SPECIFICATION	TEST RESULT	CONCLUSION
Negative Specimens		Negative	Negative	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
Positive Specimens	1ng/ml	Positive	Positive	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	2ng/ml	Positive	Positive	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	3ng/ml	Positive	Positive	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	5ng/ml	Positive	Positive	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail

Conclusion: Pass: All results meet QC standard.  
Fail



Test by:

查妍

QC Supervisor:

雷似愚

Date: 2024.01.24

Date: 2024.01.24



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-OG060  
Version 1.0

# EC Declaration of Conformity

In accordance with Directive 98/79/EC

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

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

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

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

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

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

We hereby explicitly appoint

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

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

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

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

Date Signed: November 28, 2017

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



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](http://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



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**

<b>Model(s):</b>	<b>HCV Hepatitis C Virus Rapid Test</b>	
<b>Facility(ies):</b>	Zhejiang Orient Gene Biotech Co., Ltd. 3787#, East Yangguang Avenue, Dipu Street Anji, 313300 Huzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA	
<b>Parameters:</b>	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





# 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.

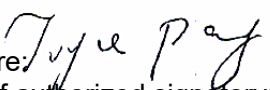
We hereby explicitly appoint

**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

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

## INTENDED USE

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

## INTRODUCTION

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

## PRINCIPLE

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

## PRODUCT CONTENTS

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

## MATERIALS SUPPLIED

Test cassette	Dropper	Buffer	Package insert
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## MATERIAL REQUIRED BUT NOT PROVIDED

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

## STORAGE AND STABILITY

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

## WARNINGS AND PRECAUTIONS

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

3. Do not use it if the tube/pouch is damaged or broken.
4. Test is for single use only. Do not re-use under any circumstances.
5. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7. Humidity and temperature can adversely affect results.
8. Do not perform the test in a room with strong air flow, i.e. electric fan or strong air-conditioning.

## SPECIMEN COLLECTION AND PREPARATION

1. Hepatitis B Surface Antigen Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
2. To collect Fingerstick Whole Blood specimens:
  - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
  - Puncture the skin with a new sterile lancet for each person. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
  - Add the Fingerstick Whole Blood specimen to the test cassette by using a capillary tube:
    - Touch the end of the capillary tube to the blood until filled to approximately 50µL. Avoid air bubbles.
    - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood into the specimen well (S) of the test cassette.
  - Add the Fingerstick Whole Blood specimen to the test cassette by using hanging drops:
    - Position the patient's finger so that the drop of blood is just above the specimen well (S) of the test cassette.
    - Allow 2 hanging drops of fingerstick whole blood to fall into the center of specimen well (S) on the test cassette, or move the patient's finger so that the hanging drop touches the center of the specimen well (S). Avoid touching the finger directly to the specimen well (S).
3. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
4. Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
5. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
6. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

## TEST PROCEDURE

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

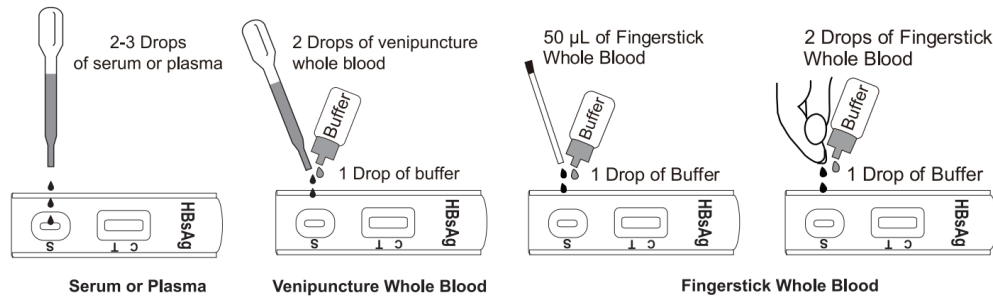
1. Remove the test cassette from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test cassette on a clean and level surface.

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

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

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

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



### INTERPRETATION OF RESULTS



**Positive Negative Invalid**

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

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

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

### QUALITY CONTROL

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

### LIMITATIONS

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

### PERFORMANCE CHARACTERISTICS

#### Sensitivity:

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

#### Specificity:

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

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

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

Relative sensitivity: 99.4%

Relative specificity 99.5%

Accuracy: 99.5%

### REFERENCE

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

Catalogue No:GCHBsg-402a

Effective Date: 2023-08-22

B20137-05

# Fecal Occult Blood Rapid Test Cassette (Feces)



## INTENDED USE

Fecal Occult Blood Rapid Test Cassette (Feces) is a rapid chromatographic immunoassay for the qualitative detection of human occult blood in feces by professional laboratories or physician's offices. It is useful to detect bleeding caused by a number of gastrointestinal disorders, e.g., diverticulitis, colitis, polyps, and colorectal cancer.

Fecal Occult Blood Rapid Test Cassette (Feces) is recommended for use in 1) routine physical examinations, 2) hospital monitoring for bleeding in patients, and 3) screening for colorectal cancer or gastrointestinal bleeding from any source.

## INTRODUCTION

Most of diseases can cause hidden blood in the stool. In the early stages, gastrointestinal problems such as colon cancer, ulcers, polyps, colitis, diverticulitis, and fissures may not show any visible symptoms, only occult blood. Traditional guaiac-based method lacks sensitivity and specificity, and has diet-restriction prior to the testing.

Fecal Occult Blood Rapid Test Cassette (Feces) is a rapid test to qualitatively detect low levels of fecal occult blood in feces. The test uses double antibody-sandwich assay to selectively detect as low as 50 ng/mL of hemoglobin or 6 µg hemoglobin/g feces. In addition, unlike the guaiac assays, the accuracy of the test is not affected by the diet of the patients.

## PRINCIPLE

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

## MATERIALS PROVIDED

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

## MATERIALS REQUIRED BUT NOT PROVIDED

1. Specimen collection containers
2. Clock or timer

## STORAGE AND STABILITY

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

## PRECAUTIONS

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

## PATIENT PREPARATION

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

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

## SPECIMEN COLLECTION AND PREPARATION

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

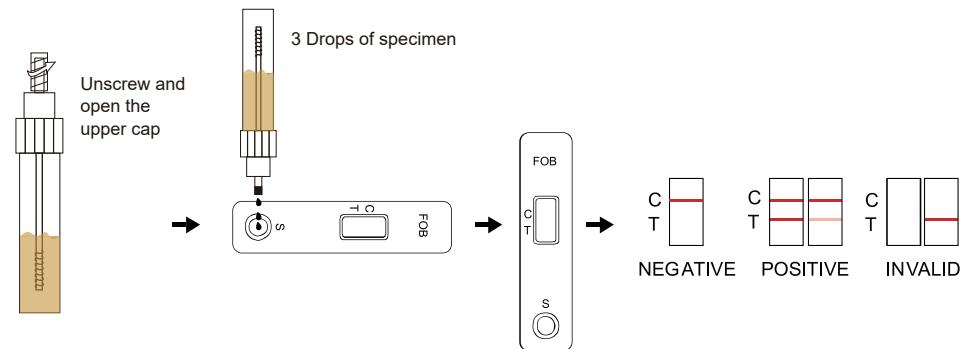
1. Collect a random sample of feces in a clean, dry receptacle.
2. Unscrew the top of the collection tube and remove the applicator stick.
3. Randomly pierce the fecal specimen in at least five (5) different sites.
4. Remove excess sample off the shaft and outer grooves. Be sure sample remains on inside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

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

## TEST PROCEDURE

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

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



## INTERPRETATION OF RESULTS

(Please refer to the illustration above)

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

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

**Invalid:** Control line fails to appear. The test should be repeated using a new cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

**NOTE:**

1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Note that this is a qualitative test only, and

# Fecal Occult Blood Rapid Test Cassette (Feces)

cannot determine the concentration of analytes in the specimen.

2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

## QUALITY CONTROL

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

## PERFORMANCE CHARACTERISTICS

### 1. Sensitivity: 99.6%

Fecal Occult Blood Rapid Test Cassette (Feces) can detect the levels of human occult blood as low as 50 ng/mL hemoglobin or 6 µg hemoglobin/g feces.

### 2. Prozone Effect:

It is observed that this FOB test can detect 2 mg/mL hemoglobin.

### 3. Specificity: 99.9%










Fecal Occult Blood Rapid Test Cassette (Feces) is specific to human hemoglobin. Specimen containing the following substances at the standard concentration was tested on both positive and negative controls and showed no effects on test results at standard concentration.


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


## REFERENCES

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

## INDEX OF SYMBOLS

	Consult instructions for use		Tests per kit		Authorized Representative
	For <i>in vitro</i> diagnostic use only		Use by		Do not reuse
	Store between 2~30°C		Lot Number		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

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

 GEFOB-602b

# H. pylori Ag Rapid Test Cassette (Feces)



## 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.<sup>1,2</sup> 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.<sup>3</sup> H. Pylori colonizing in the gastrointestinal system elicits specific antibody responses<sup>4,5,6</sup> 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.<sup>7</sup>

## 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.

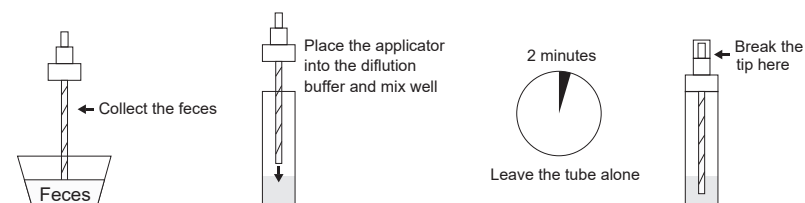
To process fecal specimens:

• 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:

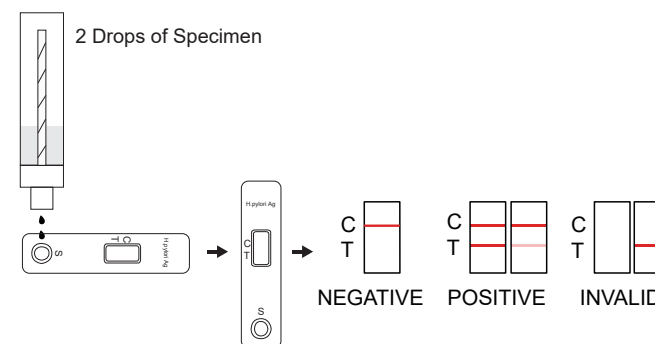
Hold the dropper vertically, aspirate fecal specimens, and then transfer 2 drops (approximately 80 µL) into the specimen collection tube containing the dilution buffer. Screw on and tighten the cap onto the specimen collection tube, then shake the specimen collection tube vigorously to mix the specimen 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 antigen 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: 98.8%

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.

5. Parsonnet,J.et.al. Helicobacter pylori infection and the risk of gastric carcinoma. New England J.Med. 325:1127-31,1991.

6. Ansong,R. et.al. Evaluation of techniques for isolation, subcultivation and preservation of Helicobacter pylori. J.Clin.Micro. 29:51-53,1991.


7. Pronovost,A.P.et.al. Evaluation of a new immunodiagnostic assay for Helicobacter pylori antibody detection: Correlation with histopathological and microbiological results. J.Clin.Microbiol.32:46-50,1994.

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	For <i>in vitro</i> diagnostic use only		Use by		Do not reuse
	Store between 2~30°C		Lot Number		Catalog#



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Anji 313300, Huzhou, Zhejiang, China.  
TEL: +86-572-5226111 FAX: +86-572-5226222  
Website: www.orientgene.com

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

 GCHP-602a

Revision Date: 2022-03-08  
B20435-03

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



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

- 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)
- 1 Package insert

- 1 Buffer (4 mL) (Casein-salt: 1%, NaCl: 0.9%, Na<sub>2</sub>HPO<sub>4</sub>: 0.286%, NaN<sub>3</sub>: 0.5%)



Warning

Warning: 0.5% NaN<sub>3</sub>  
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

- Specimen collection containers
- Sterile lancets (for fingerstick whole blood only)
- Centrifuge (for plasma only)
- Timer
- 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

- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- 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.
- Do not use it if the tube/pouch is damaged or broken.
- Test is for single use only. Do not re-use under any circumstances.
- 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 assayed.
- Humidity and temperature can adversely affect results.
- Do not perform the test in a room with strong air flow, ie. an electric fan or strong air conditioning.

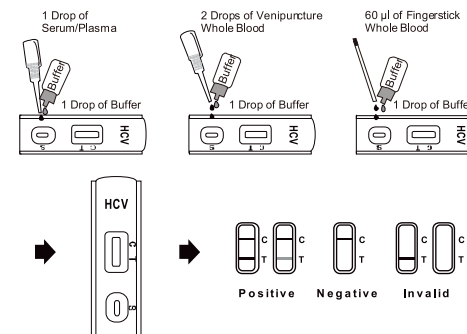
## SPECIMEN COLLECTION

- 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.
- For venipuncture whole blood and plasma: K-EDTA, 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.
- 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.
- 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.
- 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 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.

- 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.
- 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.
- 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<sub>2</sub>EDTA, 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 Serocoverison 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 of out 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, Acetaminophen, Oxalic Acid, Albumin, Caffeine, 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	Caffeine	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
Acetaminophen	1.0 mg/mL	Aspirin	0.2 mg/mL
Oxalic Acid	0.2 mg/mL	Methanol	1.0%

**REFERENCE**

1. Choo, Q.L., G.Kuo, A.J. Weiner, L.R. Overby, D.W. Bradley, and M. Houghton. Isolation of a cDNA clone derived from a blood-borne non-A, non-B viral hepatitis genome. *Science* 189; 244: 359
2. Kuo, G., Q.L. Choo, H.J. Alter, and M. Houghton. An assay for circulating antibodies to a major etiologic 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 C infection: a review. *J. Clin. Immunoassay* 1993; 16: 204

**INDEX OF SYMBOLS**

	Consult instructions for use		Tests per kit		Authorized Representative
	For <i>in vitro</i> diagnostic use only		Use by		Do not reuse
	Store between 2-30°C		Lot Number		Catalog #
	Manufacturer		Warning		

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