# HBsAg Rapid Test Cassette (Whole Blood/Serum/Plasma)

## Package Insert

**REF IHBSG-402** **English**



*A rapid test for the qualitative detection of Hepatitis B Surface Antigen (HBsAg) in human whole blood, serum or plasma.*
*For laboratory professional in vitro diagnostic use only.*

**【INTENDED USE】**

The HBsAg Rapid Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of Hepatitis B Surface Antigen in human whole blood, serum or plasma to aid in the diagnosis of HBsAg infection.

The product is intended to be used by trained laboratory personnel. For laboratory use only.

The test provides preliminary test results. Negative results will not preclude Hepatitis B virus infection and they can't be used as the sole basis for treatment or other management decision. Not for Self-testing use. Not for near-patient use. Not for blood donor screening.

**【SUMMARY】**

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. Previous designations included the Australia or Au antigen. In a typical Hepatitis B infection, Chronic HBV infection is defined as either the presence of HBsAg in the serum for at least 6 months or the presence of HBsAg in a person who tests negative for immunoglobulin M antibodies to hepatitis B core antigen. Unlike persons who recover from acute HBV infection, persons with chronic HBV infection do not develop anti-HBs, and HBsAg typically persists for decades.[1] The presence of HBsAg in serum indicates that the patient has contracted HBV infection.[2] 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 Rapid Test Cassette is a rapid test to qualitatively detect the presence of HBsAg in whole blood, serum or plasma specimen. The test utilizes a combination of monoclonal and monoclonal antibodies to selectively detect elevated levels of HBsAg in whole blood, serum or plasma.

**【PRINCIPLE】**

The HBsAg Rapid Test Cassette is a qualitative, solid phase, two-site sandwich immunoassay for the detection of HBsAg in whole blood, serum or plasma. The membrane is pre-coated with anti-HBsAg antibodies on the test line region of the test. During testing, the whole blood, serum or plasma specimen reacts with the particle coated with anti-HBsAg antibodies to form a complex. The complex 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 proper volume of specimen has been added and membrane wicking has occurred.

**【REAGENTS】**

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

**【WARNINGS AND PRECAUTIONS】**

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

•For laboratory professional use only. For *in vitro* diagnostic use only.
•Do not use after the expiration date. Do not reuse the test.
•The test should remain in the sealed pouch until use. Do not use test if the pouch is damaged.
•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 all procedures 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.
•The used test should be discarded according to local regulations.
•Humidity and temperature may adversely affect results.
•Wash hands thoroughly before and after handling.
•Any serious incident that has occurred in relation to the test shall be reported to the manufacturer and the competent authority.
•Components provided in the kit are approved for use in the HBsAg Rapid Test Cassette. Do not use any other commercial kit component.

**【STORAGE AND STABILITY】**

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

**Note:** It is suggested to use test within one hour after removing it from the foil pouch.

**【SPECIMEN COLLECTION AND PREPARATION】**

- The HBsAg Rapid Test Cassette can be performed using whole blood (from venipuncture), serum or plasma.

- **Venipuncture whole blood:**
  Collect whole blood specimen into a collection tube (with specified anticoagulant, namely EDTA K2, heparin sodium, sodium citrate or potassium oxalate) according to standard venous blood sampling process. Other anticoagulants may lead to incorrect results. Whole blood specimen can be stored at 2-8 °C for up to 2 days if it is not used immediately after being sampled. Do not freeze whole blood specimen. Before testing, gently shake the blood tube to obtain a homogeneous specimen.

- **Serum:**
  Collect whole blood specimen into a collection tube without anticoagulant according to standard venous blood sampling process. Leave to settle for 30 minutes for blood coagulation, and then spin at 1,000 to 1,200 g for 10 to 15 minutes at room temperature to obtain the serum supernatant. Don't leave samples in centrifuge after spinning.

- **Plasma:**
  Collect whole blood specimen into a collection tube (with specified anticoagulant, namely EDTA K2, heparin sodium, citrate sodium or potassium oxalate) according to standard venous blood sampling process. Gently invert the collection tube for several times and leave to settle for 30 minutes for blood coagulation, and then spin at 1,000 to 1,200 g for 10 to 15 minutes at room temperature to obtain the plasma supernatant. Don't leave samples in centrifuge after spinning.

- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Testing should be performed immediately after the specimens have been collected. 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.
- 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 covering the transportation of etiologic agents.

**【MATERIALS】**

**Materials provided**

| | Kit size | 40T/kits | 25T/kits |
|---|---|---|---|
| **Components** | **Test Cassettes** | 40 | 25 |
| | **Package insert** | 1 | 1 |
| | **Droppers** | 40 | 25 |
| | **Buffer**<br>3 mL (PBS, 0.02% Proclin 300, ≤0.02% $NaN_3$) | 2 | 1 |

**Materials required but not provided**

• Specimen collection containers • Centrifuge • Timer

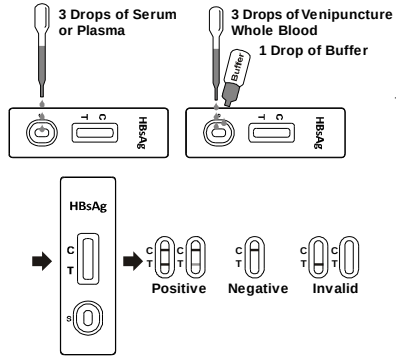
**【DIRECTIONS FOR USE】**

**Allow the test, specimen and buffer to reach 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.
2. Place the cassette on a clean and level surface.
   For **Serum or Plasma** specimen:
   - Hold the dropper vertically and transfer **3 drops of serum or plasma** to the specimen well (S) of test cassette and start the timer. See illustration below.

   For **Venipuncture Whole Blood** specimen:
   - Hold the dropper vertically and transfer **3 drops of whole blood** to the specimen well (S) of test cassette, then **add 1 drop of buffer**, and start the timer. See illustration below.
3. Wait for the colored line(s) to appear. **Read results at 15~30 minutes.** Do not interpret the result after 30 minutes.

**Note:** It is suggested not to use the buffer beyond 6 months after opening the vial.




**【INTERPRETATION OF RESULTS】**

(Please refer to the illustration above)

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

***NOTE**: The intensity of the color in the test line region (T) will vary depending on the concentration of HBsAg present in the specimen. Therefore, any shade of color in the test region (T) should be considered positive.

**NEGATIVE: One colored line appears in the control region (C).** No colored 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. If the problem persists, discontinue using the test kit immediately and contact local distributor.

**【QUALITY CONTROL】**

A procedural control is included in the test. A colored line appearing in the control line region(C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

**【LIMITATIONS】**

1. The HBsAg Rapid Test Cassette is for professional *in vitro* diagnostic use only. The test should be used for the detection of HBsAg in human whole blood, serum or plasma specimen. Neither the quantitative value nor the rate of HBsAg concentration can be determined by this qualitative test.
2. The HBsAg Rapid Test Cassette will only indicate the presence of HBsAg in the specimen and should not be used as the sole criteria for the diagnosis of Hepatitis B viral infection.
3. Other forms of infection like seronegative infection in window period and occult hepatitis B infection could be missed by HBsAg assays.
4. When the test results and clinical symptoms are inconsistent, it should be confirmed by ELISA, CMIA or NAT.
5. The HBsAg Rapid Test Cassette cannot detect less than 1 ng/mL of HBsAg in specimens. 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 infection.
6. The hematocrit of the whole blood should be between 25% and 65%.

**【PERFORMANCE CHARACTERISTICS】**

**Sensitivity and Specificity**

The HBsAg Rapid Test Cassette (Whole Blood/Serum/Plasma) was tested serum, plasma and whole blood clinical specimens and compared with CE marked CMIA test. The results show that the relative sensitivity of the HBsAg Rapid Test Cassette (Whole Blood/Serum/Plasma) is 99.87% and the relative specificity is 99.86%.

For Whole Blood/Serum/Plasma Specimen

| Sample Status | Sample HBsAg Status | Comparator Method | Serum/Plasma Specimen | | | Whole Blood Specimen | | |
|---|---|---|---|---|---|---|---|---|
| | | | Specimen Number | HBsAg Rapid Test | | Specimen Number | HBsAg Rapid Test | |
| | | | | Positive | Negative | | Positive | Negative |
| HBsAg positive sample | Positive | CMIA | 722 | 721 | 1 | 50 | 50 | 0 |
| Blood Donation | Negative | CMIA | 900 | 2 | 898 | 200 | 0 | 200 |
| Clinical (hospital) sample | Negative | CMIA | 1282 | 2 | 1280 | 30 | 0 | 30 |
| Pregnant Woman | Negative | CMIA | 215 | 0 | 215 | / | / | / |
| Interference Substance | Negative | CMIA | 140 | 0 | 140 | / | / | / |

Relative Sensitivity =99.87%(95%CI*:99.28%->99.99%)
Relative Specificity =99.86% (95%CI*:99. 63%-99.96%)
Overall Accuracy=99.86% (95% CI*: 99.67%-99.95%) *Confidence Intervals

Separately for Serum Specimen

| Sample Status | Sample HBsAg Status | Comparator Method | Serum Specimen | | |
|---|---|---|---|---|---|
| | | | Specimen Number | HBsAg Rapid Test | |
| | | | | Positive | Negative |
| HBsAg positive sample | Positive | CMIA | 492 | 492 | 0 |
| Blood Donation | Negative | CMIA | 800 | 2 | 798 |
| Clinical (hospital) sample | Negative | CMIA | 1062 | 2 | 1060 |
| Pregnant Woman | Negative | CMIA | 215 | 0 | 215 |
| Interference Substance | Negative | CMIA | 140 | 0 | 140 |

Relative Sensitivity =>99.99%(95%CI*:99.25%->99.99%)
Relative Specificity =99.82% (95%CI*:99.54%-99.95%)
Overall Accuracy=99.85% (95% CI*: 99.62%-99.96%) *Confidence Intervals

Separately for Plasma Specimen

| Sample Status | Sample HBsAg Status | Comparator Method | Plasma Specimen | | |
|---|---|---|---|---|---|
| | | | Specimen Number | HBsAg Rapid Test | |
| | | | | Positive | Negative |
| HBsAg positive sample | Positive | CMIA | 230 | 229 | 1 |
| Blood Donation | Negative | CMIA | 100 | 0 | 100 |
| Clinical (hospital) sample | Negative | CMIA | 220 | 0 | 220 |
| Pregnant Woman | Negative | CMIA | / | / | / |
| Interference Substance | Negative | CMIA | / | / | / |

Relative Sensitivity =99.57%(95%CI*:97.60%-99.99%)
Relative Specificity =>99.99% (95%CI*:98.85%->99.99%)
Overall Accuracy=99.82% (95% CI*: 98.99%->99.99%) *Confidence Intervals

Separately for Whole Blood Specimen

| Sample Status | Sample HBsAg Status | Comparator Method | Whole Blood Specimen | | |
|---|---|---|---|---|---|
| | | | Specimen Number | HBsAg Rapid Test | |
| | | | | Positive | Negative |
| HBsAg positive sample | Positive | CMIA | 50 | 50 | 0 |
| Blood Donation | Negative | CMIA | 200 | 0 | 200 |
| Clinical (hospital) sample | Negative | CMIA | 30 | 0 | 30 |
| Pregnant Woman | Negative | CMIA | / | / | / |
| Interference Substance | Negative | CMIA | / | / | / |

Relative Sensitivity =>99.99%(95%CI*:92.89%->99.99%)

Relative Specificity =>99.99% (95%CI*:98.41%->99.99%)
Overall Accuracy=>99.99% (95% CI*: 98.69%->99.99%) *Confidence Intervals

**Serum vs. Plasma**

**Sensitivity in seropositive paired serum and plasma specimens:**

A total of 100 seropositive paired serum and plasma were tested with HBsAg Rapid Test Cassette, respectively. There was a good correlation of testing results between serum and plasma with HBsAg seropositive samples.

| Specimen Type | Number of specimens tested | Agreement for positive results by HBsAg Rapid Test |
|---|---|---|
| Serum | 100 | >99.9%(100/100) |
| Plasma | 100 | >99.9%(100/100) |

**Specificity in seropositive paired serum and plasma specimens:**

A total of 220 seronegative paired serum and plasma were tested with HBsAg Rapid Test Cassette, respectively. There was a good correlation of testing results between serum and plasma with HBsAg seronegative samples.

| Specimen Type | Number of specimens tested | Agreement for negative results by HBsAg Rapid Test |
|---|---|---|
| Serum | 220 | >99.9%(220/220) |
| Plasma | 220 | >99.9%(220/220) |

**Sero-conversion panels**

30 sero-conversion panels were studied with HBsAg Rapid Test Cassette (Whole Blood/ Serum/Plasma) and compared to results from CE marked Turklab HBsAg and Biotest HBsAg tests as reference assay. HBsAg Rapid Test Cassette (Whole Blood/Serum/Plasma) has the similar detection capacity as reference assay.

**Hook Effect**

There is no dose hook effect with the test, when the HBsAg level is no more than 500 ng/mL.

**Intra-Assay**

Within-run precision has been determined by using four specimens: 0 ng/mL, 1 ng/mL, 7 ng/mL and 20 ng/mL positive specimens. The study was performed 15 replicates per day for 5 consecutive days by one operator using 1 lot of HBsAg Rapid Test, 1 lot of buffer. No difference was detected in intra lot.

**Inter-Assay**

Between-run precision has been determined by using four specimens: 0 ng/mL, 1 ng/mL, 7 ng/mL and 20 ng/mL positive specimens. The study was performed 15 replicates per day for 5 consecutive days in 3 different sites using 3 separate lots of HBsAg Rapid Test (one lot per site), and three operators per site. No difference was detected between days, sites, lots and operators.

**Cross-reactivity**

The HBsAg Rapid Test Cassette has been tested for anti-HCV, anti-HEV, anti-Syphilis, anti-EBV, CEA, AFP, PSA, CA15-3, CA19-9, CA125, anti-HAV IgM, anti-HIV, anti-RF, anti-*H.pylori*, anti-CMV IgG, anti-Rubella IgG, anti-TOXO IgG, anti-HSV 1 IgG, anti-HSV 2 IgG, Dengue NS1 and Zika NS1 positive specimens. The results showed no cross-reactivity.

**Interfering Substances**

The following potentially interfering substances were added to HBsAg negative and positive specimens. None of the substances at the concentration tested interfered in the assay.

| | |
|---|---|
| Acetaminophen: 20 mg/dL | Caffeine: 20 mg/dL |
| Acetylsalicylic Acid: 20 mg/dL | Gentisic Acid: 20 mg/dL |
| Ascorbic Acid: 1 g/dL | Albumin: 2 g/dL |
| Creatin: 200 mg/dL | Hemoglobin: 2000 mg/dL |
| Bilirubin: 0.5 g/dL | Oxalic Acid: 60 mg/dL |
| Cocaine: 20 mg/dL | Methadone: 20 mg/dL |

**【BIBLIOGRAPHY】**


1. Colin W. Shepard, Edgar P. Simard, Lyn Finelli, Anthony E. Fiore, Beth P. Bell, Hepatitis B Virus Infection: Epidemiology and Vaccination, Epidemiologic Reviews, Volume 28, Issue 1, August 2006, Pages 112–125.
2. Ravi Kaul,Chapter 9.17 - Hepatitis, Editor(s): David Wild, The Immunoassay Handbook(Fourth Edition),Elsevier,2013,Pages 901-911.


**Index of Symbols**

| | | | | | |
|---|---|---|---|---|---|
| | Consult instructions for use or consult electronic instructions for use | Σ | Contains sufficient for <n> tests | 30°C 2°C | Temperature limit |
| IVD | *In vitro* diagnostic medical device | LOT | Batch code | REF | Catalogue number |
| EC REP | Authorized representative in the European Community | | Use-by date | | Do not re-use |
| | Do not use if package is damaged and consult instructions for use | | Manufacturer | | Caution |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Number: 146262000
Effective date: 2022-05-30

# HCV Rapid Test Cassette (Whole Blood/Serum/Plasma) Package Insert

| REF IHC-402 | English |
|---|---|

*A rapid test for the qualitative detection of antibodies to Hepatitis C Virus in human whole blood, serum or plasma.*
*For professional in vitro diagnostic use only.*

**【INTENDED USE】**

The HCV Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of antibody to Hepatitis C Virus in human whole blood, serum or plasma.
The test is intended for professional *in vitro* diagnostic use only. Not for screening.

**【SUMMARY】**

Hepatitis C is a liver disease caused by the hepatitis C virus (HCV) that causes acute and chronic infection.[1,2] Hepatitis C Virus (HCV) is a small, enveloped, positive-sense, single-stranded RNA Virus. HCV is now known to be the major cause of parenterally transmitted non-A, non-B hepatitis. Antibody to HCV is found in over 80% of patients with well-documented non-A, non-B hepatitis. An estimated 71 million people had chronic hepatitis C infection worldwide in 2015.[3]
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. 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.
The HCV 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 colloid gold conjugate and recombinant HCV proteins to selectively detect antibody to HCV in whole blood, serum or plasma. The recombinant HCV proteins used in the test kit are encoded by the genes for both structural (nucleocapsid) and non-structural proteins.

**【PRINCIPLE】**

The HCV Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative, membrane based immunoassay for the detection of antibody to HCV in whole blood, serum or plasma. The membrane is pre-coated with recombinant HCV antigen on the test line region of the test. During testing, the whole blood, serum or plasma specimen reacts with recombinant HCV antigen conjugated colloid gold. The mixture migrates upward on the membrane chromatographically by capillary action to react with recombinant HCV antigen on the membrane and generate a colored line. Presence of this colored line indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

**【REAGENTS】**

The test cassette contains recombinant HCV antigen conjugated colloid gold and HCV antigen coated on the membrane.

**【PRECAUTIONS】**

- For professional *in vitro* diagnostic use only. Do not use after the 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 the procedure 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 may adversely affect results.

**【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 must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

**【SPECIMEN COLLECTION AND PREPARATION】**

- The HCV Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood, serum or plasma.
- **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 sterile lancet. 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 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 to the specimen well of the test cassette.
- **Venous whole blood:**
  - Collect whole blood specimen into a collection tube (with specified anticoagulant, namely EDTA K2, heparin sodium, sodium citrate or potassium oxalate) according to standard venous blood sampling process. Other anticoagulants may lead to incorrect results. Store whole blood specimen at 2-8 °C for up to 3 days if it is not used immediately after being sampled. Do not freeze whole blood specimen. Before testing, gently shake the blood tube to obtain a homogeneous specimen.
- **Serum:**
  - Collect whole blood specimen into a collection tube without anticoagulant according to standard venous blood sampling process. Leave to settle for 30 minutes for blood coagulation, then centrifuge at 3,000 rpm for at least 5 minutes to obtain the serum supernatant.
- **Plasma:**
  - Collect whole blood specimen into a collection tube (with specified anticoagulant, namely EDTA K2, heparin sodium, citrate sodium or potassium oxalate) according to standard venous blood sampling process. Gently invert the collection tube for several times and leave to settle for 30 minutes for blood coagulation, then centrifuge at 3,000 rpm for at least 5 minutes to obtain the plasma supernatant.
- Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed 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. 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 3 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 local regulations.

**【MATERIALS 】**

**Materials provided**

| | Kit size | 10T/kits |
|---|---|---|
| **Components** | **Test Cassettes** | 10 |
| | **Package Insert** | 1 |
| | **Droppers** | 10 |
| | **Buffer**<br>3 mL (PBS, 0.02% Proclin 300, ≤0.02% $NaN_3$) | 1 |

**Materials required but not provided**

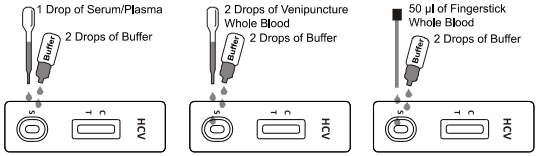
• Specimen collection containers • Centrifuge • Timer
• Lancets (for fingerstick whole blood only)
• Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

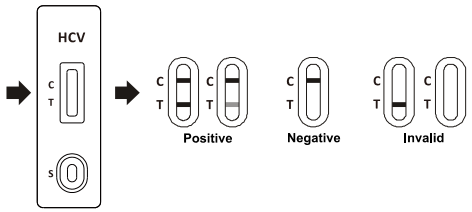
**【DIRECTIONS FOR USE】**

**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 cassette on a clean and level surface.
• For **Serum or Plasma** specimen: Hold the dropper vertically and **transfer 1 drop of serum or plasma** (approximately 25 μL) to the **specimen well (S)**, then **add 2 drops of buffer** (approximately 80 μL), and start the timer, see illustration below.
• For **Venipuncture Whole Blood** specimen: Hold the dropper vertically and **transfer 2 drops of whole blood** (approximately 50 μL) to the **specimen well (S)**, then **add 2 drops of buffer** (approximately 80 μL), and start the timer. See illustration below.
• For **Fingerstick Whole Blood** specimen: To use a capillary tube: Fill the capillary tube **and transfer approximately 50 μL of fingerstick whole blood specimen** to the **specimen well (S)** of test cassette, then **add 2 drops of buffer** (approximately 80 μL) and start the timer. See illustration below.
3. Wait for the colored line(s) to appear. The test result should be read at **10 minutes**. Do not interpret the result after **20 minutes**.

**Note:** It is suggested not to use the buffer beyond 6 months after opening the vial.




**【INTERPRETATION OF RESULTS】**

(Please refer to the illustration above)

**POSITIVE: * Two colored lines appear.** One colored line should be in the control region (C) and another colored line should be in the test region (T). Positive result in the Test region indicates detection of HCV antibodies in the specimen.
***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of HCV antibodies present in the specimen. Therefore, any shade of color in the test region should be considered positive.
**NEGATIVE: One colored line appears in the control region (C).** No colored line appears in the test region (T). Negative result in the Test region indicates negative results of HCV antibody in the specimen.
**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. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

**【QUALITY CONTROL】**

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

**【LIMITATIONS】**

1. The HCV Rapid Test Cassette (Whole Blood/Serum/Plasma) is not screening device for blood donors.
2. The HCV 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.
3. The HCV 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.
4. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
5. 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.
6. The hematocrit of the whole blood should be between 25% and 65%.

**【PERFORMANCE CHARACTERISTICS】**

**Sensitivity and Specificity**

The HCV Rapid Test Cassette (Whole Blood/Serum/Plasma) tested serum, plasma and whole blood specimens and was compared with CE marked EIA or CMIA test .The results show that the relative sensitivity of the HCV Rapid Test Cassette (Whole Blood/Serum/Plasma) is 100% and the relative specificity is 100%.

| Method | | | HCV Rapid Test Cassette (Whole Blood/Serum/Plasma) | | Agreement |
|---|---|---|---|---|---|
| | Result | | Positive | Negative | |
| Predicated Test (EIA or CMIA) | Positive | HCV | 397 | 0 | >99.9% (397/397) |
| | | Genotypes 1,2,3,4,5,6 | 93 | 0 | >99.9% (93/93) |
| | | Total | 490 | 0 | >99.9% (490/490) |
| | Negative | Blood Donation | 0 | 1,000 | >99.9% (1,000/1,000) |
| | | Clinical Negative | 0 | 209 | >99.9% (209/209) |
| | | Pregnant Woman | 0 | 200 | >99.9% (200/200) |
| | | Interference Substance | 0 | 135 | >99.9% (135/135) |
| | | Total | 0 | 1,544 | >99.9% (1,544/1,544) |
| **Total Result** | | | 490 | 1,544 | >99.9% (2,034/2,034) |

Sensitivity: 100% (95%CI*: 99.4%-100%)
Specificity: 100% (95%CI*: 99.8%-100%)
Accuracy: 100% (95%CI*: 99.9%-100%) *Confidence Intervals

**Sero-conversion Panels**

30 sero-conversion panels were studied with HCV Rapid Test Cassette (Whole Blood/ Serum/Plasma) and compared to results from CE marked test as reference assay. HCV Rapid Test Cassette (Whole Blood/Serum/Plasma) has the similar detection capacity as reference assay.

**Precision**

**Intra-Assay**

Within-run precision has been determined by using 15 replicates of four specimens: a negative, a HCV low positive, a HCV middle positive and a HCV high positive. The negative, HCV low positive, HCV middle positive and HCV high positive values were correctly identified 100% of the time.

**Inter-Assay**

Between-run precision has been determined by 15 independent assays on the same four specimens: a negative, a HCV low positive, a middle positive and a HCV high positive. Three different lots of the HCV Rapid Test Cassette (Whole Blood/Serum/Plasma) have been tested using these specimens. The specimens were correctly identified 100% of the time.

**Cross-reactivity**

The HCV Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested by HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, anti-Syphilis, anti-EBV, CEA, AFP, PSA, CA15-3, CA19-9, CA125, anti-HAV IgM, anti-HIV, anti-RF, anti-*H.pylori*, anti-CMV IgG, anti-Rubella IgG, anti-TOXO IgG, anti-HSV 1 IgG，anti-HSV 2 IgG positive and hCG positive specimens. The results showed no cross-reactivity.

**Interfering Substances**

The following potentially interfering substances were added to HCV negative and positive specimens.

| | |
|---|---|
| Acetaminophen: 20 mg/dL | Caffeine: 20 mg/dL |
| Acetylsalicylic Acid: 20 mg/dL | Gentisic Acid: 20 mg/dL |
| Ascorbic Acid: 2 g/dL | Albumin: 2 g/dL |
| Creatin: 200 mg/dL | Hemoglobin: 1,000 mg/dL |
| Bilirubin: 1 g/dL | Oxalic Acid: 60 mg/dL |

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

**【BIBLIOGRAPHY】**


1. World Health Organization. New recommendations in the updated WHO guidelines for the screening, care and treatment of persons with chronic hepatitis C infection. Geneva: WHO; 2016. http://www.who.int/hepatitis/publications/hepatitis-c-guidelines-2016/en/.
2. Lavanchy D. The global burden of hepatitis C. Liver Int. 2009;29(s1):74–81.
3. World Health Organization. Global Hepatitis Report, 2017. Geneva; 2017. http://www.who.int/hepatitis/publications/global-hepatitis-report2017/en/. Accessed 6 Oct 2017.


**Index of Symbols**

| | | | | | |
|---|---|---|---|---|---|
|  | Consult instructions for use or consult electronic instructions for use |  | Contains sufficient for <n> tests |  | Temperature limit |
| IVD | *In vitro* diagnostic medical device | LOT | Batch code | REF | Catalogue number |
| EC REP | Authorized representative in the European Community |  | Use-by date |  | Do not re-use |
|  | Do not use if package is damaged and consult instructions for use |  | Manufacturer |  | Caution |


**Hangzhou AllTest Biotech Co.,Ltd.**
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CE 2934

EC REP
MedNet EC-REP GmbH
Borkstrasse 10,
48163 Muenster,
Germany



Number: 14601027000
Revision date: 2022-08-23

# CERTIFICATE

DIRECTIVE 98/79/EC
EC DESIGN-EXAMINATION

CeCert Sp. z o.o. hereby confirms that manufactured by

**Hangzhou AllTest Biotech Co., Ltd.**
#550, Yinhai Street, Hangzhou Economic & Technological Development Area, Hangzhou, 310018, P.R. China

*in vitro* diagnostic medical device referred to in List A in Annex II

**HBsAg Rapid Test Cassette (Whole Blood/Serum/Plasma)**
catalogue number: IHBSG-402

in term of the design conforms to the requirements of Annex IV section 4 to Directive 98/79/EC (as amended) implemented into Polish Law, as evidenced by the audit conducted by CeCert Sp. z o.o.

CE 2934

Validity date: 16.05.2022 – 26.05.2025

Issue date: 16.05.2022

Check it

Kamil Szczurowski
Director of *in Vitro* Diagnostic Medical Device
Certification Department

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00-515 Warszawa

www.cecert.pl
e-mail: biuro@cecert.pl

Certificate no: CeCert/101/W/E.1



# CERTIFICATE

DIRECTIVE 98/79/EC
FULL QUALITY ASSURANCE SYSTEM

CeCert Sp. z o.o. hereby confirms that
the quality assurance system in the organization

**Hangzhou AllTest Biotech Co., Ltd.**
#550, Yinhai Street, Hangzhou Economic & Technological Development Area, Hangzhou, 310018, P.R. China

with regard to the design, manufacture and final inspection
of *in vitro* diagnostic medical device referred to in List A in Annex II

**HBsAg Rapid Test Cassette (Whole Blood/Serum/Plasma)**
catalogue number: IHBSG-402

conforms to the requirements of Annex IV (excluding section 4 and 6) to Directive 98/79/EC (as amended) implemented into Polish Law, as evidenced by the audit conducted by CeCert Sp. z o.o.

CE 2934

Validity date: 16.05.2022 – 26.05.2025

Issue date: 16.05.2022

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Certificate no: CeCert/102/W/E.1

# CERTIFICATE

DIRECTIVE 98/79/EC
EC DESIGN-EXAMINATION

CeCert Sp. z o.o. hereby confirms that manufactured by

**Hangzhou AllTest Biotech Co., Ltd.**
#550, Yinhai Street, Hangzhou Economic & Technological Development Area, Hangzhou, 310018, P.R. China

*in vitro* diagnostic medical device referred to in List A in Annex II

**HCV Rapid Test Cassette (Whole Blood/Serum/Plasma)**
catalogue number: IHC-402

in term of the design conforms to the requirements of Annex IV section 4 to Directive 98/79/EC (as amended) implemented into Polish Law, as evidenced by the audit conducted by CeCert Sp. z o.o.

CE 2934

Validity date: 17.05.2022 – 26.05.2025

Issue date: 17.05.2022

Check it

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Certificate no: CeCert/106/W/E.1



# CERTIFICATE

DIRECTIVE 98/79/EC
FULL QUALITY ASSURANCE SYSTEM

CeCert Sp. z o.o. hereby confirms that the quality assurance system in the organization

**Hangzhou AllTest Biotech Co., Ltd.**
#550, Yinhai Street, Hangzhou Economic & Technological Development Area, Hangzhou, 310018, P.R. China

with regard to the design, manufacture and final inspection of *in vitro* diagnostic medical device referred to in List A in Annex II

**HCV Rapid Test Cassette (Whole Blood/Serum/Plasma)**
catalogue number: IHC-402

conforms to the requirements of Annex IV (excluding section 4 and 6) to Directive 98/79/EC (as amended) implemented into Polish Law, as evidenced by the audit conducted by CeCert Sp. z o.o.

CE 2934

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