HBV Combo Rapid Test Cassette (Serum/Plasma)

English

IVD

CITEST DIAGNOSTICS INC.
170-422 Richards Street
Vancouver BC, V6B 2Z4, Canada

A rapid test for the qualitative detection of Hepatitis B Surface Antigen (HBsAg), Hepatitis B Surface Antibody (HBsAb), Hepatitis B Envelope Antigen (HBeAg), Hepatitis B Envelope Antibody (HBeAb) and Hepatitis Core Antibody (HBcAb) in human serum or plasma.

For professional in vitro diagnostic use only.

INTENDED USE

The HBV Combo Rapid Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of HBsAg, HBsAb, HBeAg, HBeAb and HBcAb in serum or plasma.

SUMMARY

Chronic hepatitis B is a serious, debilitating illness that can cause cirrhosis of the liver, liver cancer and death. Chronic hepatitis B is the main cause of liver cancer and the tenth leading cause of death worldwide, with 400,000,000 people infected with the virus. Every year, one million people worldwide are expected to die from this infection.

Most people fight off the infection themselves, but approximately 5-10 percent of those infected with the virus become carriers, and an additional 5-10 percent of those infected each year will progress to chronic liver disease, cirrhosis and possibly liver cancer.

The HBV Combo Rapid Test Cassette (Serum/Plasma) is a rapid test to qualitatively detect the presence of HBsAg, HBsAb, HBeAg, HBeAb and HBcAb in serum or plasma without the use of an instrument.[1]

PRINCIPLE

HBsAg and HBeAg

The HBsAg and HBeAg tests are qualitative, two-site sandwich immunoassays for the detection of HBsAg or HBeAg in serum or plasma. The membrane is pre-coated with anti-HBsAg or anti-HBeAg antibodies on the test line region of the strip. During testing, the serum or plasma specimen reacts with the particle coated with anti-HBsAg or anti-HBeAg antibodies.[2] The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-HBsAg or anti-HBeAg antibodies on the membrane and generate a colored line. The presence of this colored line in the test line region indicates a positive result, while its absence indicates a negative result.

HBsAb

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

HBeAb and HBcAb

Hepatitis B envelope Antibody (HBeAb) is also known as anti-Hepatitis B envelope Antigen (anti-HBe). Hepatitis B core Antibody (HBcAb) is also known as anti-Hepatitis B core Antigen (anti-HBc). These tests are immunoassays based on the principle of competitive binding.

During testing, the mixture migrates upward on the membrane chromatographically by capillary action. The membrane is pre-coated with HBeAg or HBcAg on the test line region of the strip. During testing, anti-HBe antibody or anti-HBc antibody, if present in the specimen, will compete with particle coated anti-HBe antibody or anti-HBc antibody for limited amount of HBeAg or HBcAg on the membrane, and no line will form in the test line region, indicating a positive result. A visible colored line will form in the test line region if there is no anti-HBe antibody or anti-HBc antibody in the specimen because all the antibody coated particles will be captured by the antigen coated in the test line region.

To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test cassette contains anti-HBsAg particles, HBsAg particles, anti-HBeAg particles, HBcAg particles respectively and anti-HBsAg, HBsAg, anti-HBeAg, Anti-HBcAg coated on the membrane respectively.

PRECAUTIONS

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

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

STORAGE AND STABILITY

Store as packaged at room temperature or refrigerated (2-30 °C). The test 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 HBV Combo Rapid Test Cassette can be performed using either serum or plasma.
- 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 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.
- 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

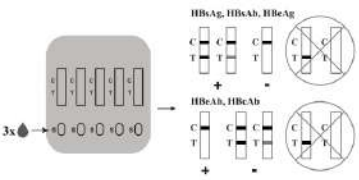
- Test cassettes
- Droppers
- Package insert

Materials required but not provided

- Specimen collection containers
- Centrifuge
- Timer

DIRECTIONS FOR USE

1. Remove the test cassette from the sealed 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 clean and level surface. Hold the dropper vertically and transfer **3 full drops of serum or plasma** (approx.75μL) to each sample well of the test cassette respectively, and then start the timer. Avoid trapping air bubbles in the specimen well. See the illustration below.
3. Wait for the red line to appear. **The result should be read at 15 minutes.** Do not interpret the results after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

Warning: Do not interpret all 5 tests with the same criterion. Carefully follow the directions below.

HBsAg, HBsAb, HBeAg

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, HBsAb, HBeAg 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 cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

HBeAb, HBcAb

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

***NOTE**. The intensity of the color in the test line region (T) may vary. But it should be considered negative whenever there is even a faint pink line.

Positive: One colored line appears in the control region (C). No 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 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 line region (**C**) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The HBV Combo Rapid Test Cassette is for professional *in vitro* diagnostic use only. The test should be used for the detection of HBsAg, HBsAb, HBeAg, HBeAb and HBcAb in serum or plasma specimen. Neither the quantitative value nor the rate of HBsAg, HBsAb, HBeAg, HBeAb, HBcAb concentration can be determined by this qualitative test.
2. The HBV Combo Rapid Test Cassette will only indicate the presence of HBsAg, HBsAb, HBeAg, HBeAb and HBcAb in the specimen and should not be used as the sole criteria for the diagnosis of Hepatitis B viral infection.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The HBV Combo Rapid Test Cassette (Serum/Plasma) was compared with leading commercial EIA/RIA HBsAg, HBsAb, HBeAg, HBeAb, HBcAb tests, the results show that the HBV Combo Rapid Test Cassette (Serum/Plasma) has a high sensitivity and specificity.

HBsAg

Method		EIA		Total Results
HBsAg Rapid Test Cassette (Serum/Plasma)	Results	Positive	Negative	
	Positive	241	2	243
	Negative	0	359	359
Total Results		241	361	602

Relative Sensitivity: >99.9% (95%CI*: 98.8%-100%)
Relative Specificity: 99.4% (95%CI*: 98.0%-100%)
Accuracy: 99.7% (95%CI*: 98.8%-100%) *Confidence Intervals

HBsAb

Method		RIA		Total Results
HBsAb Rapid Test Cassette (Serum/Plasma)	Results	Positive	Negative	
	Positive	194	9	203
	Negative	7	391	398
Total Results		201	400	601

Relative Sensitivity: 96.5% (95%CI*: 93.0%-98.6%)
Relative Specificity: 97.8% (95%CI*: 95.8%-99.0%)
Accuracy: 97.3% (95%CI*: 95.7%-98.5%) *ConfidenceIntervals

HBeAg

Method		RIA		Total Results
HBeAg Rapid Test Cassette (Serum/Plasma)	Results	Positive	Negative	
	Positive	154	9	163
	Negative	6	429	435
Total Results		160	438	598

Relative Sensitivity: 96.3% (95%CI*: 92.1%-98.6%)
Relative Specificity: 97.9% (95%CI*: 96.1%-99.1%)
Accuracy: 97.5% (95%CI*: 95.9%-98.6%) *Confidence Intervals

HBeAb

Method		EIA		Total Results
HBeAb Rapid Test Cassette (Serum/Plasma)	Results	Positive	Negative	
	Positive	146	7	153
	Negative	4	329	333
Total Results		150	336	486

Relative Sensitivity: 97.3% (95%CI*: 93.3%-99.3%)
Relative Specificity: 97.9% (95%CI*: 95.8%-99.2%)
Accuracy: 97.7% (95%CI*: 96.0%-98.9%) *Confidence Intervals

HBcAb

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

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

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Precision

Intra-Assay

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

Inter-Assay

Between-run precision has been determined by using the same three specimens of negative, low positive, high positive of HBsAg, HBsAb, HBeAg, HBeAb, HBcAb in15 independent assays. Three different lots of the HBV Combo Rapid Test Cassette (Serum/Plasma)has been tested over a 10 days period using negative, low positive and high positive specimens. The specimens were correctly identified 99% of the time.

Cross-reactivity

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

Interfering Substances

The HBV Combo Rapid Test Cassette (Serum/Plasma) has been tested for possible interference from visibly hemolyzed and lipemic specimens. No interference was observed.

In addition, no interference was observed in specimens containing up to 2,000 mg/dL Hemoglobin, 1000 mg/dL Bilirubin, and 2000 mg/dL human serum Albumin.

BIBLIOGRAPHY

1. Chizzali-Bonfadin C., Addlassnig K.P., Krethsl M., Hatvan A., Horak W., Knowledge-based interpretation of serologic tests for hepatitis on the World Wide Web. Clin Perform Qual HealthCare 1997 Apr-Jun 5:61-3
2. ter Bog F., ten Kate F.J., Cuypers H.T., Leentvaar-KuipersA., Oosting J., Wertheim-van Dillen P.M., Honkoop P., Rasch M.C., de Man R.A., vabHattum J., Chameleau R.A., Reesink H.W., Jones E.A., Relation between laboratory results and histological hepatitis activity in individuals postive for hepatitis B surfaceantigen and antibodies to hepatitis B e antigen. Lancet 1998 June 351:1914-8

INDEX OF SYMBOLS

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

REF: IHB-355
Number: 145071302
Date: 2023-07-04

Procedo
INTERNATIONAL CERTIFICATION

SNAS
Reg. No. 672/Q-084

Quality management system

CERTIFICATE

This is to certify that the Quality management system for medical devices of the company

CiTEST DIAGNOSTICS INC.
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has been found in compliance with requirements of the standard

ISO 13485: 2016 /
EN ISO 13485: 2016 + A11: 2021

for the following scope:

Design and Development, Production and Distribution of In Vitro Diagnostic Reagents,Control Material and Instruments for Clinical Chemistry, Immunochemistry (Immunology),Haemostasis, Infectious Diseases and Immunohaematology, including Professional Laboratory Use, Near Patient and Self Testing

Certificate no.: QMS-13-001-2022/A
Initial certificate issue: 12/04/2022

Date of issue: 07/04/2025
Valid from: 12/04/2025

On condition that the organisation will maintain an effective quality management system for medical devices, this certificate remains valid until ***11/04/2028.***

Procedo
INTERNATIONAL CERTIFICATION
Certification Body

Ľubica Škrovanová
Head of Certification Body

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