Certificate of Analysis

Product Name: HBcAb Rapid Test Cassette (S/P)

Catalog No.: IHBCB-302

Batch No.: 1225I5014

Quantity:1000PCS

Expiry Date:11-2027

Date of Sampling:2026-01-04

Date of Analysis: 2026-01-04

Other information:/

QC Item		**QC Criterion**	**QC Result**	**Conclusion**
Physical	Appearance	Good	Good	Pass
Functional Performance	Low Positive	Low Positive	100% Positive	Pass
	High Positive	High Positive	100% Positive	Pass
	Negative Sample	Negative	100% Negative	Pass

Others	/

Final QC Conclusion:	This batch of product met the QC Criteria.

QC supervisor: Eva zhang

Date: 2026.01.04

APPROVED
CITEST DIAGNOSTICS INC.
QUALITY CONTROL

Digitally signed by Dolgopol Iulian
Date: 2026.04.03 10:43:28 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

HBcAb 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 Core Antibody (HBcAb) in serum or plasma.
For professional in vitro diagnostic use only.

INTENDED USE

The HBcAb Rapid Test Cassette (Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of *Hepatitis B Core Antibody (HBcAb) in serum or plasma.*

SUMMARY

Viral hepatitis is a systemic disease primarily involving the liver. Most cases of acute viral hepatitis are caused by Hepatitis A virus (HAV), Hepatitis B virus (HBV) or Hepatitis C virus (HCV). Hepatitis B core antibody is a viral protein secreted by HBV infected cells.[1] Its presence indicates high levels of virus in the blood, and it is an indicator of the infectiousness of the carrier. If this test is negative, but a person is known to be HBcAb positive, then it indicates low levels of virus in the blood or an "integrated phase" of HBV in which the virus is integrated into the host's DNA.[2]

The HBcAb Rapid Test Cassette (Serum/Plasma) is a rapid test to qualitatively detect the presence of HBcAb in serum or plasma specimen. The test utilizes a combination of monoclonal antibodies and antigen to selectively detect elevated levels of HBcAb in serum or plasma. This one step test is very sensitive and only takes about 15-20 minutes. Test results are read visually without any instrument.

PRINCIPLE

The HBcAb test is immunoassay 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 anti-HBcAg on the test line region of the strip. During testing, if HBcAb presents in the specimen, it will compete with particle coated HBcAg antibody for limited amount of recombine HBcAg on the membrane. No line will form in the test region. And a visible colored line will form in the test region if there is no HBcAb in the specimen because all the antigen coated particles will be captured by the anti-HBcAg 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 device contains HBcAg particles and anti-HBcAg coated on the membrane.

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 specimen or kits are handled.
3. Handle all the 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 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

1. The HBcAb Rapid Test Cassette (Serum/Plasma) can be performed using serum or plasma.
2. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
3. 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.
4. 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.
5. If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

MATERIALS

Materials provided

• Test cassettes
• Droppers
• Package insert

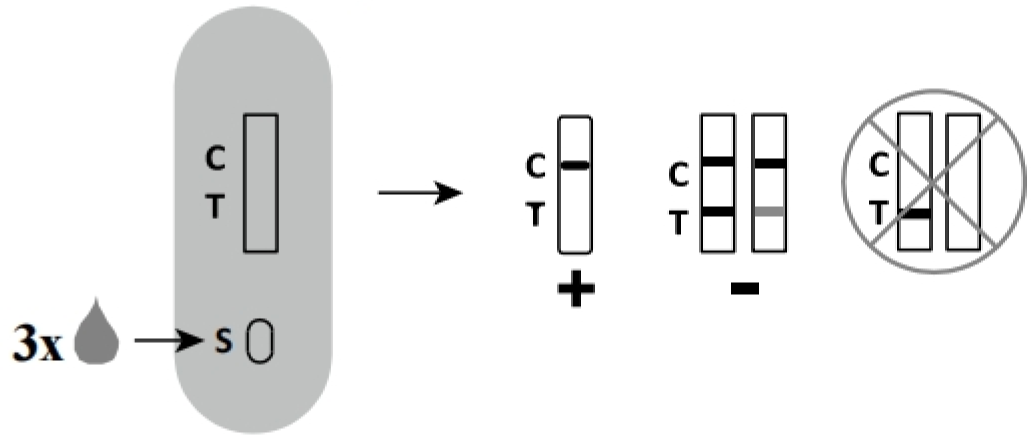
Materials required but not provided

• Specimen collection containers
• Centrifuge
• Timer

DIRECTIONS FOR USE

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

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 immediately after opening the foil pouch.
2. Hold the dropper vertically and transfer **3 drops of serum or plasma (approximately 75µL)** to the specimen well of test device and start the timer. Avoid trapping air bubbles in the specimen well. See illustration below.
3. Wait for the colored line is appeared. The result should be read **at 15 minutes.** Do not interpret the result after **20 minutes**.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

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 shade of red 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

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal positive 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 HBcAb Rapid Test Cassette (Serum/Plasma) is for *in vitro* diagnostic use only. This test should be used for the detection of HBcAb in serum or plasma specimen.
2. The HBcAb Rapid Test Cassette (Serum/Plasma) will only indicate the presence of 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 HBcAb Rapid Test Cassette (Serum/Plasma) was compared with a leading commercial ELISA HBcAb test, the result show that the HBcAb Rapid Test Cassette (Serum/Plasma) has a high sensitivity and specificity.

Method		ELISA		Total Results
	Results	Positive	Negative	
HBcAb Rapid Test Cassette(Serum/Plasma)	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

Precision

Intra-Assay

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

Inter-Assay

Between-run precision has been determined by using the same three specimens of negative, low positive and high positive of HBcAb in 15 independent assays. Three different lots of the HBcAb 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 HBcAb 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 HBcAb 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.Kobayashi E, Deguchi M, Kagita M, et al. Performance evaluation of four dominant anti-hepatitis B core antigen (HBcAb) kits in Japan for preventing de novo hepatitis B virus (HBV) infection. Clin Lab. 2015; 61 (1-2):77-85.
2.Li T, Wang SK, Zhou J, et al. Positive HBcAb is associated with higher risk of early recurrence and poorer survival after curative resection of HBV-related HCC. Liver Int. 2016; 36 (2):284-92.

INDEX OF SYMBOLS

IVD	*In vitro* diagnostic medical device
2°C – 30°C	Temperature limit
	Do not use if package is damaged and consult
REF	Catalogue number
Σ	Contains sufficient for <n> tests
	Use-by date

LOT	Batch code
	Manufacturer
	Do not re-use
i	Consult instructions for use or consult electronic
	Caution

REF: IHBCB-302
Number: 145071502
Date: 2023-08-28

Quality management system

Procedo
INTERNATIONAL CERTIFICATION

SNAS
Reg. No. 672/Q-084

CERTIFICATE

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

CiTEST DIAGNOSTICS INC.
170-422, RICHARDS ST, VANCOUVER, BC V6B 2Z4, CANADA

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