Rapid Response™

Hepatitis B core Antibody Test Cassette

(Serum/Plasma)

REF HBcAb -12C40 Product Insert

For professional *in vitro* diagnostic use only.

Intended Use

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

Introduction

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. 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.

The Rapid Response™ HBcAb 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. 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 HBcAg on the test line region of the strip. During testing, if anti-HBc antibody, present in the specimen, will compete with particle coated anti-HBc antibody for limited amount of 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 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.

Materials

Materials provided

- Test cassette
- Disposable specimen dropper
- Package insert

Materials required but not provided

- Specimen collection container
- Centrifuge
- Timer

Precautions

- For professional in vitro diagnostic use only.
- Read these instructions carefully before performing the test.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled by observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Avoid splashes and clean up spills immediately with appropriate disinfectant.
- Do not use any other specimen than those specified. For plasma, EDTA, sodium citrate, sodium heparin or potassium oxalate can be used as anticoagulant.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded according to local regulations

Storage and Stability

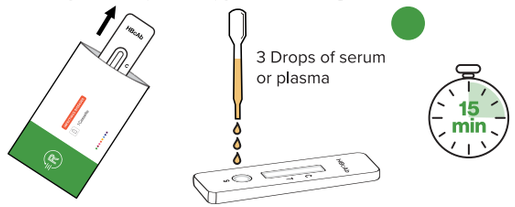
- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- Do not freeze the kit.
- Protect the kit from humidity.
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipments, containers or reagents can lead to false results.

Specimen Collection and Storage

- The Rapid Response™ HBcAb Test Cassette (Serum/Plasma) can be performed using either serum or plasma.
- Collect specimens according to safe phlebotomy procedure.
- Only clear, non-hemolyzed specimens are recommended for use with this test. Serum or plasma should be separated as soon as possible to avoid hemolysis.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 7 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. Avoid repeated freezing and thawing of specimens.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.
- Icteric, lipemic, hemolysed, heat treated and contaminated specimens may cause erroneous results.

Procedure

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

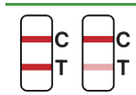


1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Put the test cassette on a clean and level surface. Hold the dropper vertically and transfer 3 drops of serum or plasma (approximately 75 µL) to specimen well (S) of the test cassette, and then start the timer. Avoid trapping air bubbles in the specimen well (S), and do not add any solution to the result window. As the test begins to work, color will migrate across the membrane.
3. Wait for the colored line(s) to appear. The result should be read at 15 minutes. Do not interpret the results after 20 minutes.

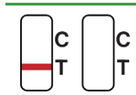
Results Interpretation

HBsAg, HBsAb, HBeAg

POSITIVE: Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (T).



NEGATIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).



INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the 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 negative. Note that this is a qualitative test only, and 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

- A procedural control is included in the test. A colored 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 control be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

Limitations

1. The Rapid Response™ HBcAb 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. Neither the quantitative value nor the rate of increase in the concentration of HBcAb can be determined by this qualitative test.
2. The Rapid Response™ HBcAb 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.
4. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested. A negative result at any time does not preclude the possibility of Hepatitis B Virus infection

Performance Characteristics

The performances of the Rapid Response™ HBcAb Rapid Test Cassette (Serum/Plasma) have been established in comparison with EIA. The testing results are shown in the table below:

Table: HBcAb Rapid Test vs. EIA

Relative Sensitivity:
96.3%(99.3%-100.0%)*
Relative Specificity:
96.8% (99.7%-99.9%)*
Overall Agreement:
96.4% (99.8%-99.9%)*
***95% Confidence Interval**

		EIA		
		+	-	Total
HBcAb Rapid Test	+	443	17	460
	-	4	120	124
Total		447	137	584

Glossary of Symbols

Consult instructions for use	Test per Kit	REF	Catalogue #
Store between 35.6°F to 86°F	Use by		Do Not Reuse
LOT Lot Number	IVD For *in vitro* diagnostic use only		Manufacturer

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