HBcAb DEVICE (2-30°C)

CATALOGUE NUMBER	KIT SIZE (TESTS)
RADHBC2	20 Tests

Intended Use:
The HBcAb Rapid Test Device (Serum/Plasma) Is a rapid chromatographic immunoassay for the qualitative detection of Hepatitis B Core Antibody (HBcAb) in serum and 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 generated against the core of Hepatitis B virus during the active stage of infection. Its presence indicates high levels of virus in the blood, and it is an indicator of the infectivity of the carrier. If this test is negative, but a person is known to be HBV 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 test involves 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 with a result in less than 20 minutes. Test results are read visually with no requirement for an analyser.

Test Principle:
The HBcAb test is immunoassay based on the principle of competitive binding. During testing, serum or plasma sample reacts with HBc antigen coated particles loaded on the device strip near the sample well. The mixture migrates upward on the membrane by capillary action. The membrane is pre-coated with anti-HBcAg at the test line region and it will capture the labelled particles if there is any free HBc antigen. If HBcAb is present in the sample, it will have already reacted with a proportion or all of the HBcAg so none or fewer particles are captured on the membrane. Hence no line will form in the test region. A coloured line will form at the test region if there is no HBcAb in the sample because all the antigen coated particles will be captured by the anti-HBcAg at the test line region. To serve as a procedural control, a coloured line should always appear in the control line region indicating that proper volume of sample has been added and membrane wicking has occurred.

Materials Provided
Individually pouched test devices
Disposable sample droppers
Instructions For Use Sheet

Materials not provided: Timer, specimen collection tube, centrifuge

Precautions:
For professional *in vitro* diagnostic use only.

Do not eat, drink or smoke in the area where the samples or kits are handled.

Handle all samples as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of samples.

Wear protective clothing including laboratory coats, disposable gloves and safety glasses when samples are being tested.

Humidity and temperature can adversely affect results.

Storage and Stability:

Store as packaged in the sealed pouch either at room temperature or refrigerated (2 - 30°C).
The test is up to the expiry date printed on the sealed pouch.
The test must remain in the sealed pouch until use.
Do not freeze.
Do not use beyond the expiry date.

Sample Collection and Storage:
The HBcAb Test Device can be performed using either serum or plasma.

Collect serum and plasma by standard venepuncture technique. Separate the serum or plasma from red blood cells as soon as possible to avoid haemolysis. Only clear, non-haemolyzed samples can be used.

Testing should ideally be performed immediately after the samples have been collected. Do not leave the samples at room temperature for prolonged periods. Serum and plasma samples may be stored at 2 - 8°C for up to 3 days or for longer term storage, kept below -20°C. Bring samples to room temperature prior to testing. Frozen samples must be completely thawed and mixed well prior to testing. Samples should not be frozen and thawed repeatedly.

If samples are to be shipped, they should be packed in compliance with local regulations.

Assay Procedure:
Bring the test device, samples, and/or controls to room temperature (15 - 30°C) prior to testing.

1. Remove the test device 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 device on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of serum or plasma (approximately 75 µl) to sample well of the test device, and then start the timer. Avoid trapping air bubbles in the sample well.
3. Wait for the coloured line(s) to appear. The result should be read at 15 minutes. Do not interpret any result after 20 minutes.

Interpretation of Results:

POSITIVE: Only one coloured line appears, in the control region (C). No coloured line develops in the test region (T).

NEGATIVE: Two coloured lines 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 colour in the test region (T) may vary depending on the concentration of analytes present in the sample. Therefore, any visible evidence of colour in the test region should be considered negative.
2. Insufficient sample volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

Quality Controls:
A procedural control is included in the test. A coloured line appearing in the control region (C) is the internal procedural control. It confirms sufficient sample 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 of the Test:
1. The HBcAb Test Device (Serum/Plasma) is for in vitro diagnostic use only. This test should only be used for the detection of HBcAb in serum or plasma.
2. The result from this test should not be used as the sole criteria for the diagnosis of Hepatitis B infection, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

Expected Values:
The HBcAb Rapid Test Device (Serum/Plasma) has been compared with a leading commercial HBcAb EIA test. The correlation between these two systems is > 97%.

Performance Characteristics:
Sensitivity and Specificity
Comparison of the HBcAb Rapid Test Device (Serum/Plasma) with a leading commercial HBcAb ELISA test showed that the HBcAb Rapid Test Device has a high sensitivity and specificity.

Method		ELISA		Total Results
HBcAb Rapid Test Device	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

Precision
Intra-Assay
Intra Assay precision was determined using 15 replicates of three samples negative, low positive and high positive for HBcAb. The negative and positive values were correctly identified 99% of the time.

Inter-Assay
Inter Assay precision was determined using the same three samples of negative, low positive and high positive for HBcAb in 15 independent assays. Three different lots of the HBcAb Rapid Test Device (Serum/Plasma) were tested over 10 days. The samples were correctly identified 99% of the time.

Cross-reactivity
The HBcAb Rapid Test Device (Serum/Plasma) was tested using HAMA, Rheumatoid Factor, HAV, Syphilis, HIV, H. pylori, MONO, CMV, Rubella and TOXO positive samples. There was no cross-reactivity using these samples.

Interfering Substances
The HBcAb Rapid Test Device (Serum/Plasma) has been tested for possible interference from visibly haemolyzed and lipemic samples. No interference was observed in samples containing up to 2,000 mg/dl haemoglobin, 1,000 mg/dl bilirubin and 2,000 mg/dl human serum albumin.

REF	Catalogue number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by Date
	Manufacturer		Do not reuse

AMS UK Ltd., 42 Ballymena Business Centre, Galgorm, Co. Antrim, BT42 1FL. Tel: +44(0)28 25656268
www.amslabs.co.uk info@amslabs.co.uk

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