HBsAb RAPID TEST DEVICE (2-30°C)

CATALOGUE NUMBER	KIT SIZE (TESTS)
RADHBS1	20 Tests

Intended Use:
The HBsAb Rapid Test Device (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of antibody to Hepatitis B Surface antigen in whole blood, human serum and plasma samples.

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. There is a complex antigen found on the surface of HBV named Surface antigen (HBsAg). The presence of HbsAg in whole blood, serum or plasma is an indication of an active Hepatitis B infection, either acute or chronic. The antibody to HbsAg, HbsAb, may not become detectable for 3-6 months after acute infection. It is associated with resolution of the illness. The antibody is recognized as the marker of immunity to HBV. As a result, vaccination against HBV was introduced to control the morbidity and mortality associated with the virus. As part of the World Health Organization (WHO) program for the control of Hepatitis B, many people, especially new born infants, receive vaccination. The minimum standard titer of HbsAb is 10mIU/ml for protective immunity to HBV. Unfortunately, approximately 5-15% of healthy immune competent individuals either do not exhibit an antibody response to the existing recombinant vaccination or respond poorly. The HbsAb Rapid Test Device (Whole Blood/Serum/Plasma) is a rapid test to qualitatively detect the presence of HbsAb in whole blood, serum or plasma samples. The test involves a double antigen sandwich system to detect as low as 10mIU/ml of HbsAb in whole blood, serum or plasma.

Test Principle:
The membrane is pre-coated with HbsAg on the test line region. During testing, whole blood, serum or plasma samples which contain HBsAb react with particles coated with HbsAg. The mixture migrates upward on the membrane by capillary action to react with the HbsAg at the test line. If a coloured line develops at the test region this indicates a positive result, while its absence indicates a negative result. 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.

Reagents
The test device contains HBsAg coated particles and HBsAg coated on the membrane.

Materials Provided
Individually pouched test devices
Disposable pipettes
Buffer
Instructions For Use sheet

Materials not provided: Blood collection tubes, centrifuge, timer,

Precautions:

For *in vitro* diagnostic use by trained professionals only.

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

Handle all the 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 at room temperature or refrigerated (2 - 30°C). The test is stable 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 Preparation:

The HBsAb Rapid Test Device can be performed using whole blood (from venepuncture or fingerstick), serum or plasma.

To collect Fingerstick Whole Blood samples: 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, towards the fingertip. Puncture the skin with a sterile lancet and wipe away the first sign of blood. Continue to massage the hand and finger to form a rounded drop of blood over the puncture site. Collect the fingerstick blood into a capillary tube

To collect venepuncture whole blood: Collect serum and plasma by standard venepuncture technique. Separate the serum or plasma from blood as soon as possible to avoid haemolysis. Use only clear non-haemolysed samples.

Testing should 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. Whole blood collected by venepuncture can be stored at 2 - 8°C for testing within 48 hours. Do not freeze whole blood samples. Whole blood collected by fingerstick must be tested immediately.

Bring samples to room temperature prior to testing. Frozen samples must be completely thawed and mixed well prior to testing. Avoid repeated freeze / thaw cycles.

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

Assay Procedure:

Bring tests, samples, and/or controls to room temperature (15-30°C) before use.
1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. For best results the assay should be performed within one hour.
2. For Serum or Plasma sample:

   Hold the dropper vertically and transfer 3 drops of serum or plasma (approximately 75µl) to the sample well of the test device and start the timer.

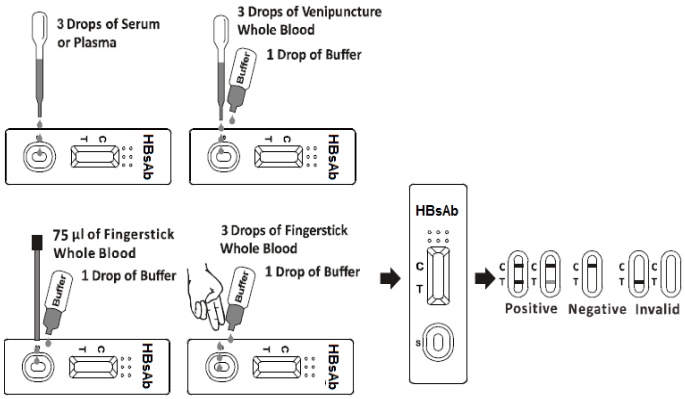
   For Venipuncture Whole Blood sample:

   Hold the dropper vertically and transfer 3 drops of whole blood (approximately 75µl) to the sample well, then add 1 drop of buffer (approximately 40 µl) and start the timer.

   For Fingerstick Whole Blood sample:

   Using a capillary tube: Touch the end of a capillary tube to the blood droplet until filled. Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood onto the test device. Transfer approximately 75 µl of fingerstick whole blood to the sample well of the test device, then add 1 drop of buffer (approximately 40 µl) and start the timer.
   Using hanging drops: Allow 3 hanging drops of fingerstick whole blood (approximately 75 µl) to fall onto the centre of the sample well of the test device, then add 1 drop of buffer (approximately 40 µl) and start the timer.

3. Wait for coloured band(s) to appear. The result should be read at 15 minutes. Do not interpret any result after 20 minutes.



Interpretation of Results:

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

NEGATIVE: Only one coloured band appears, in the control region (C). No coloured band develops 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.

Quality Control:
Internal procedural controls are included in the test. A coloured band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient sample volume and correct procedural technique.
External controls are not supplied with this kit. 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 of the Test:

1. The HBsAb Rapid Test Device (Whole Blood/Serum/Plasma) is for professional in vitro diagnostic use and should only be used for the qualitative detection of HBsAb.
2. A negative result does not at any time preclude the presence of HBsAb in blood, as HBsAb may be present below the minimum detection level of the test (10 mIU/ml).
3. 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 HBsAb Rapid Test Device (Whole Blood/Serum/Plasma) has been compared with a leading commercial HBsAb EIA test. The correlation between these two systems is > 99%.

Performance:
Sensitivity
The HBsAb Rapid Test Device (Whole Blood/Serum/Plasma) has been tested with a sensitivity panel ranging from 1mIU/ml to 40mIU/ml. The sensitivity was found to be 10mIU/ml of HBsAb in 15 minutes.

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Specificity
Antigen used for the HBsAb Rapid Test Device (Whole Blood/Serum/Plasma) is highly specific for detecting HBsAb in whole blood, serum or plasma. The specificity was comparable to EIA.

Method		EIA		Total Results
HBsAb Rapid Test Device	Results	Positive	Negative	
	Positive	189	2	191
	Negative	0	341	341
Total Results		189	343	532

Relative Sensitivity: >99.9% (95% CI*: 98.4%-100%)
Relative Specificity: 99.4% (95%CI*: 97.9%-99.9%)
Accuracy: 99.6% (95% CI*:98.6%-100%) *Confidence Intervals

Precision
Intra-Assay
Intra Assay precision was determined using 15 replicates of three samples negative, low positive and high positive for HBsAb. 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 HBsAb in 15 independent assays. Three different lots of the HBsAb Rapid Test Device (Whole Blood/Serum/Plasma) were tested. The samples were correctly identified 99% of the time.

Cross-reactivity
The HBsAb Rapid Test Device (Whole Blood/Serum/Plasma) has been 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 HBsAb Rapid Test Device (Whole Blood/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.

References:

1. David Siebert. Aust Prescr. 1998;21;72-5

2. Zuckerman JN, Sabin C, Craig FM, Wiliams A, Zuckerman AJ. Immune response to a new hepatitis B vaccine in healthcare workers who had not responded to standard vaccine: randomised double blind dose-response study. Br. Med J 1997; 314:329-33.

REF	Catalogue number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by Date
	Manufacturer	2	Do not reuse

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