HBsAg Test Strip (2-30°C)

CATALOGUE NUMBER	KIT SIZE (TESTS)
RADHBG1	50 Tests

Intended Use:
The HBsAg Rapid Test Strip (Whole Blood/Serum/Plasma) is a rapid visual immunoassay for the qualitative presumptive detection of Hepatitis B Surface Antigen in human whole blood, serum, or plasma samples. This kit is intended to be used as an aid in the diagnosis of HBV infection.

Summary:
Hepatitis B virus (HBV) is the prototypic member of the hepadnaviruses. Hepatitis B surface antigen (HBsAg) is located in the lipid envelope of the small DNA virus. During the replicative phase of the virus, this surface antigen is produced in excess and is detectable in the blood of infected individuals. The incubation period of HBV is 6 weeks to 6 months.

Test Principle:
The HBsAg Rapid Test Strip (Whole Blood/Serum/Plasma) detects HBsAg through visual interpretation of colour development on the internal strip. Anti-HBsAg antibodies are immobilized at the test line on the membrane. During testing, the sample reacts with anti-HBsAg antibodies conjugated to particles and precoated onto the sample pad of the test. The mixture then migrates through the membrane by capillary action and interacts with reagents on the membrane. If there is sufficient HBsAg in the sample, a coloured band will form at the test line of the membrane. The presence of this coloured band indicates a positive result, while its absence indicates a negative result. The appearance of a coloured band at the control line serves as a procedural control, indicating that the correct volume of sample has been added and membrane wicking has occurred properly.

Materials Provided

Individually pouched test strips
Disposable pipettes
Buffer
Instructions For Use sheet

Materials not provided: Timer, specimen collection container, centrifuge

Precautions:
- For professional *in vitro* diagnostic use only.
- Do not use after the expiry 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 samples by using a new specimen collection container for each sample obtained.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in the area where the samples and kits are handled. Handle all samples as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of samples. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when samples are assayed.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded according to local regulations.

Reagent Preparation 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**.**
- 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 equipment, containers or reagents can lead to false results.

Sample Collection and Storage:
- The HBsAg Rapid Test Strip (Whole Blood/Serum/Plasma) is intended for use with human whole blood, serum, or plasma samples only.
- Only clear, non-haemolyzed samples are recommended for use with this test. Serum or plasma should be separated as soon as possible to avoid haemolysis.
- Perform testing as soon as possible after sample collection. Do not leave samples at room temperature for prolonged periods. Serum and plasma samples may be tested within 3 days if stored at 2 - 8°C. For long term storage, serum and plasma may be kept below -20°C. Whole blood collected by venepuncture should be stored at 2 - 8°C and tested within 2 days of collection. Do not freeze whole blood samples. Whole blood collected by fingerstick must be tested immediately.
- Containers containing anticoagulants such as EDTA, citrate, or heparin should be used for whole blood storage.
- Bring samples to room temperature prior to testing. Frozen samples must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of samples.
- If samples are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.
- Icteric, lipemic, haemolysed, heat treated and contaminated sera may cause erroneous results.

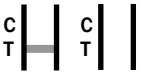
Assay Procedure:

Bring tests, samples, and/or controls to room temperature (15 - 30°C) before use.
Remove the Test Strip from its sealed pouch and perform the test within one hour.
Transfer 3 drops (approximately 75 µl) of serum or plasma to the sample pad of the strip from the disposable pipette provided and start the timer.
Or
Transfer 3 drops (approximately 75 µl) of venepuncture whole blood or 3 hanging drops fingerstick whole blood to the centre of the sample pad of the strip, add 1 drop of buffer (approximately 40 µl) and start the timer.
Avoid trapping air bubbles on the sample pad, and do not allow any buffer or sample to fall on the result window.
As the test begins to work, liquid will migrate across the membrane.
Wait for the coloured band(s) to appear. The result should be read between 15 and 30 minutes. Do not interpret the result after 30 minutes.

Interpretation of Results:

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

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



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 at the test line may vary depending on the concentration of analytes present in the sample. Therefore, any shade of colour at the test line should be considered positive. Note that this is a qualitative test and cannot determine the concentration of analytes in the sample.
2. Insufficient sample volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

Quality Controls:

- Internal procedural controls are included in the test. A coloured band appearing at the control line 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 HBsAg Rapid Test Strip (Whole Blood/Serum/Plasma) is for professional *in vitro* diagnostic use and should only be used for the qualitative detection of HBsAg.
2. The HBsAg Rapid Test Strip (Whole Blood/Serum/Plasma) will only indicate the presence of HBsAg in the sample and should not be used as the sole criteria for the diagnosis of Hepatitis B viral infection.
3. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time rule out the presence of HBsAg in blood, as HBsAg may be present below the minimum detection level of the test.
4. The packed cell volume of whole blood used should be between 25% and 65%.
5. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

Performance Characteristics:

Sensitivity
The HBsAg Rapid Test Strip was tested against a sensitivity panel including both ad and ay subtypes with concentration range 0 – 300 ng/ml. The test detects 1 ng/ml HBsAg in whole blood, serum and plasma in 15 minutes.

Specificity
The specificity of the HBsAg Rapid Test Strip was tested with laboratory strains of Hepatitis A and Hepatitis C. All results were negative.

Serum or Plasma samples:

Method		HBsAg ELISA		Total Results
	Result	Positive	Negative	
HBsAg Rapid Test Strip	Positive	180	2	182
	Negative	0	550	550
Total Results		180	552	732

Relative Sensitivity: >99.9% (95%CI*: 98.3 – 100 %) *Confidence Intervals
Relative Specificity: 99.6% (95%CI*: 98.7 - 99.9 %)
Overall Accuracy: 99.7 % (95%CI*: 99.0 - 99.9 %)

Whole blood samples:

Method		HBsAg ELISA		Total Results
	Result	Positive	Negative	
HBsAg Rapid Test Strip	Positive	180	1	181
	Negative	0	200	200
Total Results		180	201	381

Relative Sensitivity: >99.9% (95%CI*: 98.3 – 100 %) *Confidence Intervals
Relative Specificity: 99.5% (95%CI*: 98.7 - 99.9 %)
Overall Accuracy: 99.7 % (95%CI*: 98.5 - 99.9 %)

Precision
Intra-Assay precision was determined using 10 replicates of six samples containing 0, 2, 5, 12 and 20 ng/ml HBsAg. The negative and positive samples were correctly identified >99 % of the time.

Inter-Assay precision was determined by running six samples containing 0, 2, 5, 12 and 20 ng/ml HBsAg in separate assays using three different lots of the HBsAg Rapid Test Strip. The samples were correctly identified > 99 % of the time.

Cross-Reactivity

The HBsAg Rapid Test Strip was tested using anti-HAV IgM, anti-HEV IgG, anti-HCV IgG, anti-HIV IgG, anti-RF IgG, anti-Syphilis IgG, anti-HAMA IgM, anti-*H. pylori* IgG, CMV IgG, anti-CMV IgM, anti-Toxo IgG, anti-Toxo IgM, anti-Rubella IgG and anti-Rubella IgM positive samples and the results showed no cross-reactivity in the test.

Interfering Substances

There was no interference in the HBsAg Rapid Test Strip from visibly haemolysed and lipemic samples. Specifically, there was no interference using samples containing up to 2000 mg/dl haemoglobin, 1000 mg/dl bilirubin and 2000 mg/dl albumin.

References:

1. Blumberg BS, Sutnick AI, London WT, Millman I. The discovery of Australia antigen and its relation to viral hepatitis. Perspectives in Virology. 1971; 7: 223-240.

GLOSSARY OF SYMBOLS

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