ImmunoScience INDIA

ImmunoQuick

HBsAg

Rapid test for detection of HBsAg - Device/Cassette

For *In-Vitro* Diagnostic Use Only **Store at 4°C to 30°C**

INTENDED USE

"Rapid test for detection of HBsAg - Device/Cassette" is an immunoassay for the rapid and visual detection of Hepatitis B Surface Antigen in human serum/ plasma/whole blood for the diagnosis of Hepatitis B virus Infection.

PRINCIPLE

After addition of the serum/plasma/whole blood sample and Assay buffer (for whole blood) to the sample well of the device containing a test strip, the sample moves on to the conjugate pad containing colloidal gold particles conjugated with HBsAg specific Antibody and Rabbit IgG Antibody. If the sample contains detectable levels of the HBsAg, it reacts with the gold conjugated HBsAg specific Antibody to form a complex. This complex moves further and reacts with HBsAg specific Antibody coated as test line on the nitrocellulose membrane to form colored band (test line). The unbound complex and the rabbit IgG conjugated colloidal gold particles move further to the goat anti-rabbit IgG coated control area to form a colored band (Control line). The appearance of test line and control line in respective area indicates the positive result. Appearance of only control line indicates a negative result. The control line acts as a procedural control. Control line should always appear if the test is performed as per the procedure and

CONTENTS OF KIT

1. Pouches of Test device With Desiccant
2. Plastic Dropper
3. Package Insert
4. Assay Buffer

OPTIONAL MATERIAL REQUIRED

1. Stop Watch
2. Sample Container
3. Disposable gloves

PRECAUTIONS/KIT STORAGE AND STABILITY

1. Please read all information in the pack insert carefully before performing the test. Pay particular attention to the position of the Control and Test lines.
2. Do not use expired test, Expiry date is printed on the foil pouch and kit.
3. Store kit in a dry place at temperature 4°C to 30°C. Do not freeze.
4. Do not use if pouch is torn or damaged.
5. Do not open the foil pouch until you are ready to start the test.
6. Keep out of reach of children.

WARNINGS

1. Do not reuse the test.
2. Follow the instruction to get accurate results.
3. Use appropriate personal protective equipments.
4. Dispose off hygienically in Biohazard waste container.
5. Do not touch the membrane.
6. Treat used samples and tests as potentially infectious. Avoid contact with skin.
7. For in vitro diagnostic use. Not to be taken internally.
8. Do not eat the desiccant in the package.
9. Do not mix the specimen sample or interchange the different specimen.
10. The manufacturer and distributor of this product shall not be liable for any loses, liability, claims, costs or damages whether direct or consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.

SPECIMEN COLLECTION

1. This test can be performed using serum/plasma/whole blood.
2. Do not leave the specimen at room temperature for prolonged periods.
3. For whole blood, Fresh anti coagulated whole blood should be used as a test sample. EDTA or Heparin or Oxalate or Tri-sodium Citrate can be used as suitable anticoagulants.
4. The specimen should be collected in a clean glass or plastic container. If immediate testing is not possible then store the specimen at 2°C to 8°C for up to maximum three days.
5. Do not use hemolyzed, turbid or contaminated samples. Turbid samples should be centrifuged and only clear supernatant must be used for testing.

TEST PROCEDURE

1. **Allow the kit components and samples to reach room temperature (20°C to 30°C).**
2. **Tighten the vial cap of the assay buffer provided with the kit in the clockwise direction to pierce the dropper bottle nozzle.**
3. **Open the pouch and remove the test device, plastic dropper and desiccant pouch. Check the color of desiccant, it should be blue, if it has turned colorless or pink, discard the test and use another test. Once opened, test should be used immediately.**
4. **Label the test with patient's identity.**
5. **Place the device on plane surface & add 2 drops (Approx. 60 µl) of serum or plasma sample in well "S".**

   OR

   Add 2 drops (Approx. 60 µl) of whole blood sample and one drop (Approx. 30 µl) Assay Buffer in well "S".
6. **Start the timer.**
7. **Read the result at 15 minutes. Do not read the result after 20 minutes.**

Note: Use assay buffer for whole blood samples only.

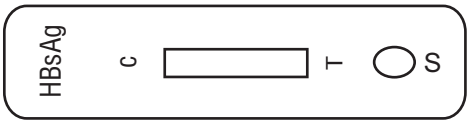
INTERPRETATION OF RESULTS

Negative: If colored line appears at the control side 'C' only.

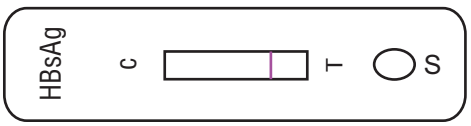
Positive: A distinct colored lines appears at the control side 'C' and at the test side 'T'.

Invalid: The test should be considered invalid if,

A) No line appears at 'C' and 'T' side.



B) No line appears at 'C' side and line appear only at 'T' side.



NOTE: The intensity of the color in the test line region (T) will vary depending on the levels of the HBsAg in the specimen. However, neither the quantitative value nor the rate of increase in level of antigen in the specimen can be determined by this qualitative test. Positive results may appear as early as five minutes. Negative results must be confirmed only at the end of 15 minutes.

PERFORMANCE CHARACTERISTICS

Internal Evaluation:

In an in-house study, total 245 samples were evaluated for sensitivity and specificity. We found the relative sensitivity was 100 % (i. e. 45/45) and the relative specificity was 100 % (i. e. 200/200).

The results are summarized in the following table:

Sample	Total Number of Samples Tested	ImmunoQuick HBsAg Test Device		Sensitivity (%)	Specificity (%)
		Positive	Negative		
HBsAg Positive Serum Samples	25	25	0	100	-
HBsAg Positive Plasma Samples	10	10	0	100	-
HBsAg Positive Blood Samples	10	10	0	100	-
Negative Human Serum Samples	150	0	150	-	100
Negative Human Plasma Samples	25	0	25	-	100
Negative Human Blood Samples	25	0	25	-	100

Cross reactivity was studied with HIV 1 positive, HIV 2 positive and HCV positive samples. No cross reactivity was observed.

External Evaluation:

ImmunoQuick HBsAg Test Device were evaluated at NIB (National Institute of Biologicals) Ministry of Health & Family welfare, Government of India. Sensitivity was found 100 % and the specificity was found 100 %.

LIMITATIONS

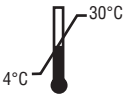
This test provides presumptive diagnosis of Hepatitis B. A confirmed HBsAg diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

DISCLAIMER

The all precaution shall be taken to ensure the diagnostic ability and accuracy of this product. This product is utilized outside the control of manufacturer and distributors. The various factors including storage temperature, environmental conditions and procedure error may affect the results.

REFERENCES

1. Kim, C. Y., Tillis, J. G. 1973, Purification of Biophysical characterization of Hepatitis A antigen, J. Clin. Invest, 52, May 1973, Pgs. 1176-1186.
2. Kee Myung Lee et.al., Emergence of Vaccine- induced escape mutant of Hepatitis B Virus with Multiple surface gene mutations in a Korean child, J.Korean. Med.Sci., 2001, 16, Pgs 356-361.
3. Koyanagi T et al. Analysis of HBs antigen negative variant of hepatitis B virus: Unique Substitutions, Glu 129 to Asp and Gly 145 to Ala in the surface antigen gene. Med Sci Monit, 2000; 6(6): Pgs1165-1169.

IVD	In Vitro Diagnostic Use
	Manufacturer
	Manufacturing Date
	Expiry Date
LOT	Lot Number
	Store at 4°C to 30°C
	Single Use
	Number of tests in the pack
	Do not use if pouch or kit damaged
	This side Up
	Read package insert before use

MANUFACTURED BY

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