HEPATITIS B SURFACE ANTIGEN (HBsAg) RAPID TEST

INTENDED USE

Nuvision HBsAg Rapid Test is a rapid immunochromatographic assay for the qualitative detection of Hepatitis B surface antigen in human Serum/Plasma samples. It is intended for professional use as a tool in the diagnosis of Hepatitis B infection.

SUMMARY

Hepatitis B virus (HBV) is partially double-stranded DNA that causes acute or chronic hepatitis. The viral particles are transmitted through exposure of infectious body fluids or blood, blood transfusion, and use of contaminated needles or syringes. Chronic hepatitis may progress to severe outcomes, including cirrhosis and liver cancer. Hepatitis B surface antigen (HBsAg) is the first marker to appear in the blood in acute hepatitis B, being detected 1 week to 2 months after exposure and 2 weeks to 2 months before the onset of symptoms. Three weeks after the onset of acute hepatitis almost half of all patients will still test positive for HBsAg. In the chronic carrier state, the HBsAg virus persists for long periods with no seroconversion to the corresponding antibodies. An individual positive for HBsAg is considered to be infected with HBV and is therefore potentially infectious.

PRINCIPLE OF THE ASSAY

Nuvision HBsAg test is an antigen-capture immunochromatographic assay, detecting the presence of HBsAg in serum/plasma samples. Monoclonal antibodies specifically against HBsAg are conjugated with colloidal gold and deposited on the conjugate pad and immobilized on the test line on the nitrocellulose membrane. When the serum/plasma sample is added, it rehydrates the gold antibody conjugate and the HBsAg, if any in the sample, interacts with the gold conjugated antibodies. The antigen-antibody-gold complex will migrate towards the test window until the Test Zone (T) where they are captured by immobilized antibodies, forming a visible pink line (Test band, indicates positive results). If HBsAg is absent in the sample, no pink line will appear in the Test Zone (T). To serve as an internal process control, a control line should always appear at Control Zone (C) after the test is completed. Absence of a pink control line in the Control Zone is an indication of an invalid result.

PACKAGE CONTENTS

- HBsAg Test pouches
- Pouch contents: Test Cassette, Sample dropper, Desiccant.
- 1 Test instruction per box

MATERIALS REQUIRED (BUT NOT PROVIDED)

- Clean, specimen collection container.
- Clock or timer.

WARNINGS AND PRECAUTIONS

- For professional *in vitro* diagnostic use only. NOT FOR MEDICINAL USE.
- Do not reuse.
- Do not use if the product seal or the packaging is compromised.
- Do NOT swallow Desiccant pouch, it can cause harm.
- Do not use after the expiration date shown on the pouch.
- Do not use if the Desiccant pouch's color is changed to pink or colorless when the test pouch is opened.
- Do not use if the Desiccant pouch's color is changed to pink or colorless when the test pouch is opened.
- Do not mix and interchange different specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious materials and performing the assay.
- Wash hands thoroughly after finishing the test.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Clean up spills thoroughly with appropriate disinfectants.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.
- Dispose of all specimens and used devices in a proper bio- hazard container. The handling and disposal of the hazardous materials should follow local, national or regional regulations.
- Keep out of children's reach.

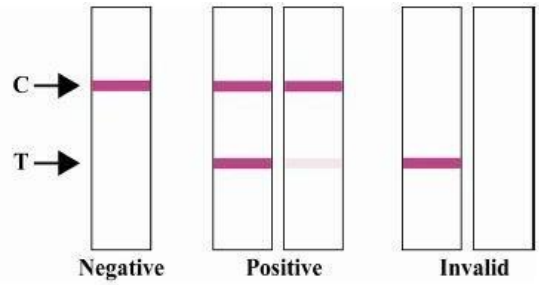
SPECIMEN PREPARATION AND STORAGE

- For serum samples, collect blood in a tube without anticoagulant and allow it to clot.
- For plasma samples, collect blood in a tube containing anticoagulant.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods.
- It is recommended that Fresh samples should be used for testing. However, the serum/plasma may be stored at 2°C to 8°C for up to three days and at -20°C for upto 2 months, if the tests cannot be performed immediately. Ensure that the samples are allowed to attain room temperature prior to use. Note: Hemolytic samples should not be used!
- Mix each specimen thoroughly prior to use. Do not heat or repeatedly freeze/thaw specimen.

PROCEDURE

- Bring the kit components to room temperature before testing.
- Open the pouch and remove the Test. Once opened, the test must be used immediately.
- Label the test card with patient's identity.
- Hold the sample dropper vertically. Add three full drops (120 µL) of serum/plasma without air bubbles into the sample well that is marked with arrow on the testing device.
- Read the results at the end of 10 minutes. Note:
  1. Some strong positive samples may show positive results before 5 minutes.
  2. DO NOT READ RESULTS AFTER 30 MINUTES. To avoid confusion, discard the test device after interpreting the results.

INTERPRETATION OF RESULTS



Negative

A pink colored band appears only at the control region (C), No band appears in Test region.

Positive

A clear pink control band (C) and a detectable test band (T) appears on their respective regions, indicating a positive result for Hepatitis B virus infections.

Invalid

No visible band at the control region (C). Repeat with a new test device. If the test still fails, please contact the distributor with the lot number.

STORAGE AND STABILITY

- **Test device in the sealed pouch should be stored at 2°-30°C. Do not freeze the test device.**
- **If stored at 2°-8°C, ensure that the device is brought to room temperature before opening.**
- **The test device should be kept away from direct sunlight, moisture and heat.**
- **Do not expose the kit over 30°C.**

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity studies were carried out in-house on fresh as well as frozen samples, from low risk as well as high risk groups.

HBsAg Samples	Positive	Negative	Total
Positive	120	01	121
Negative	00	142	142
Total	120	143	263

Relative Sensitivity: 99.17%, Relative Specificity: 100.00%, Overall agreement: 99.58%

LIMITATIONS

- **This product is an *in vitro* diagnostic test designed for professional use only.**
- **Humidity and temperature can adversely affect results.**
- **The instructions for the use of the test should be followed during testing procedures.**
- **There is always a possibility that false results will occur due to the presence of interfering substances in the specimen or factors beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.**
- **Although the test demonstrates superior accuracy in detecting Hepatitis B Surface Antigen, a low incidence of false results can occur. Therefore, other clinically available tests are required in case of questionable results. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.**

REFERENCES

1. **Blumberg, B.S. The Discovery of Australian Antigen and its relation to viral hepatitis. Vitro.1971; 7: 223**
2. **World Health Organization. Hepatitis B Surface Antigen Assays: Operational Characteristics (Phase I) report 1. 2001; 2 – 4**
3. **Krugman, S. Glies J.P. Viral Hepatitis, Type B (MS-2-Strain). Further Observations on Natural History and Prevention. New England Journal of Medicine. 288, 755.**
4. **Krugman, S. Overby L.R, et al. Viral Hepatitis Type B Studies On Natural History and Prevention Re-examined. New England Journal of Medicine. 300, 101**
5. **Caldwell C.W. etal., (1977) Clin. Chem. Acta: 31:305.**
6. **Peterson, D.L. etal., (1982) J. Biol. Chem., 257(17): 10414.**
7. **Robin, E (1979) Fed. Proc. 33 (13) 2665.**

MANUFACTURED BY: NUCLEUS DIAGNOSYS LLP, INDIA

Marketed By: ORCHARD MEDICAL,

DIAMOND ARCADE, 68 JESSORE ROAD,

1st FLOOR, UNIT No. 110 & 112, KOLKATA – 700 055

CUSTOMER CARE No: (033) 66202217