Hepatitis B Surface Antigen（HBsAg）Test

Instructions For Use

Format: Cassette
For:
Catalog Number: A02-01-222
Specimen: Serum/Plasma

* Please read the instructions carefully before use

INTENDED USE

Artron One Step Hepatitis B Surface Antigen (HBsAg) Test is a rapid and convenient immunochromatographic assay for the qualitative detection of HBsAg in human serum or plasma samples at or above a level of 1 ng/ml. It is intended for professional use as an aid in the diagnosis of Hepatitis B virus (HBV) infection. This assay provides only a preliminary result. Clinical expertise and professional judgment should be sought to further evaluate the result of the test

SUMMARY AND PRINCIPLE OF THE ASSAY

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 (heptatocellular carcinoma). The virus is divided into four major serotypes (adr, adw, ayr, ayw) based on antigenic epitopes presented on its envelope proteins.

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. The most commonly used diagnostic and blood screening markers sought is HBsAg. An individual positive for HBsAg is considered to be infected with HBV and is therefore potentially infectious.

Artron One Step HBsAg test is an antigen-capture immunochromatographic assay, detecting the presence of HBsAg in blood samples. Monoclonal antibodies specifically against HBsAg are 1) conjugated with colloidal gold and deposited on the conjugate pad and 2) immobilized on the test line on the nitrocellulose membrane. When the blood 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.

Artron One Step HBsAg Test detects HBsAg for major serotypes (adr, adw, ayr, ayw) at concentrations of 1.0 ng/ml.

PACKAGE CONTENTS

- Pouch contents: Test Cassette, Sample dropper, Desiccant.
- Test instruction.

MATERIALS REQUIRED (BUT NOT PROVIDED)

- Gloves.
- Clock or timer.

WARNINGS AND PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not reuse.
- Do not use if the pouch seal or its packaging is compromised.
- Do not use after the expiration date shown on the pouch.
- 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 tests.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.

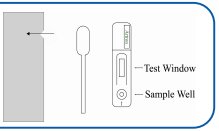
- Clean up spills thoroughly with appropriate disinfectants.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.
- Dispose of all specimens and used devices in a proper bio-hazard container. The handling and disposal of the hazardous materials should follow local, national or regional regulations.
- Keep out of children's reach.

SPECIMEN PREPARATION

- Blood samples may be collected by fingerstick or venipuncture, following routine facility procedures.
- 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.
- The blood may be stored at 2ºC to 8ºC for up to three days if the tests cannot be performed immediately. Ensure that the blood samples should be allowed to attain room temperature prior to use.

TEST PROCEDURES

1. Remove the testing device from the sealed pouch by tearing at the notch and place the testing device on a leveled surface.



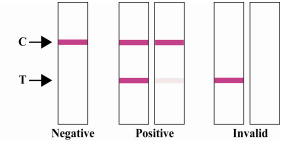
2. Hold the sample dropper vertically. Add 3 full drops (120 µl) of specimen without air bubbles into the sample well that is marked with an arrow on the testing device.

3. Read the result in 10 minutes. Read results as shown under interpretation of results.

NOTE: Specimens with high concentrations of HBsAg may produce positive results in as little as 1 minute. Confirm negatives in 20 minutes.

DO NOT INTERPRET RESULTS AFTER 30 MINUTES

RESULT INTERPRETATIONS



Negative
A pink colored band appears only at the control region (C), indicating a negative result for HBV infections.

Positive
A clear pink control band (C) and a detectable test band (T) appear, indicating a positive result for HBV 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

QUALITY CONTROL

Although the testing device contains an internal quality control (pink colored band in the control region), good laboratory practice recommends the daily use of an outside control to ensure proper testing device performance. Quality control samples should be tested according to the standard quality control requirements established by your laboratory.

STORAGE AND STABILITY

- Test device in the sealed pouch should be stored at 2-30ºC. Do not freeze the test device.
- The test device should be kept away from direct sunlight, moisture and heat.

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 HBsAg, 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.

MANUFACTURER CONTACT INFORMATION

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