AG- HEPATITIS B Ag RAPID TEST KIT

INSTRUCTION FOR USE

AstraGene – Hepatitis B Ag Rapid Test kit is a rapid and convenient immunochromatographic assay for the qualitative detection of HBsAg in human whole blood, 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

PRINCIPLE

AstraGene – Hepatitis B Ag Rapid Test kit 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. AstraGene – Hepatitis B Ag Rapid Test kit detects HBsAg for major serotypes (adr, adw, ayr, ayw) at concentrations of 1.0 ng/ml.

PACKAGE CONTENTS

Description	10 tests	1 test
Test Cassettes with desiccant	10	1
Sample Buffer Bottle	1	1
IFU	1	1

Catalogue Number	10 tests	1 test
Cassette Model	AG/RTK/HBsAg/21/01	AG/RTK/HBsAg/21/02

MATERIALS REQUIRED (BUT NOT PROVIDED)

- Clock or Timer
- Dropper
- Disposable Gloves

STORAGE &STABILITY

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

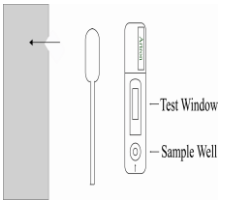
SPECIMEN COLLECTION & PREPARATION

- 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.
- For whole blood samples, collect blood in a tube containing anticoagulant.
- Whole blood samples should be tested immediately after sample collection.
- 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.

PROCEDURE

1

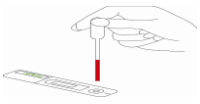
Remove the testing device from the sealed pouch by tearing at the notch and place the testing device on a leveled surface.



2

For Both Whole Blood Sample and Serum/plasma Sample:

- Hold the sample dropper vertically. Add one drop (approx. 35 µl) of the specimen without air bubbles into the Sample Well that is marked with an arrow on the testing device.



- Wait for 20-30 sec, then add 2 drops (approx. 100 µl) of the assay buffer to the same Sample Well of the testing device

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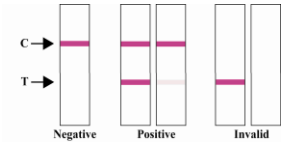
3

Read the results in 10-30 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 20-30 minutes.

DO NOT INTERPRET RESULTS AFTER 40 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 coloured 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.

LIMITATION OF THE PROCEDURE

- 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.

WARNING AND PRECAUTION

- 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..

SYMBOLS

Do not use if package is damaged Manufacturer LOT Batch Code

CE mark of Conformity Refer to the instructions ISO 13485:2016 ISO GMP

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