Hepatitis B Virus Core Antibody (HBcAb) Test Kit

Format: Cassette
Specimen: Serum/Plasma
Catalog Number: A02-05-222

Instructions For Use

Please carefully read the instructions before use

INTENDED USE

The Hepatitis B Virus Core Antibody (HBcAb) Test Kit is a rapid and convenient immunochromatographic *in vitro* assay for detection of HBcAb in human serum or plasma.

The test provides a visual, qualitative result, and all positive specimens are advised to be confirmed with other qualified assays.

SUMMARY AND PRINCIPLE OF THE ASSAY

The HBV core antigen (HBcAg) is a protein of 185 amino acids that constitutes together with the antigen e (HBeAg), the inner core of HBV. The HBcAg has a strong immunogenicity and it induces the production of antibodies (anti-HBC) that persist generally for lifetime. Anti-HBc appears shortly after the onset of infection with HBV and can usually be detected in serum soon after the appearance of circulating HBsAg and HBeAg. Testing for anti-HBc is currently being introduced at different blood banks worldwide to reduce HBV related post-transfusion hepatitis.

The principle of the HBcAb Test Kit is a competitive immunochromatographic assay. When serum is added to sample pad, it moves through the conjugate pad and dissolve the solid gold-anti-HBcAg antibody conjugate that is coated on the conjugate pad. The mixture moves along the membrane by capillary action and competes with each other to bind to HBcAg that is coated on the test region. If anti-HBcAg antibody is present, the result is no color band in T line. If there is no anti-HBcAg antibody in the sample, the T line will show a color band. The sample continues to move to the control area and forms a pink color. To serve as an internal process control, a control band should always be seen after test is completed. Absence of a colored control line in the control region is an indication of an invalid result.

PACKAGE CONTENTS

- Pouch Contents: Cassette, Sample Dropper, Desiccant
- Test instruction

MATERIALS REQUIRED BUT NOT PROVIDED

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

PRECAUTIONS

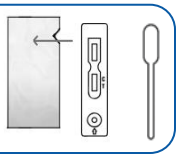
- For *in vitro* diagnostic use only.
- Do not reuse.
- Test device should remain sealed until use.
- Do not use after the expiration date shown on the pouch.
- Keep out of children's reach.

SPECIMEN PREPARATION

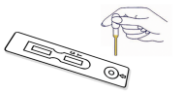
- For serum samples, collect blood in a tube without anticoagulant and allow it to clot.
- For plasma samples, collect blood in a tube containing anticoagulant.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods.

TEST PROCEDURES

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



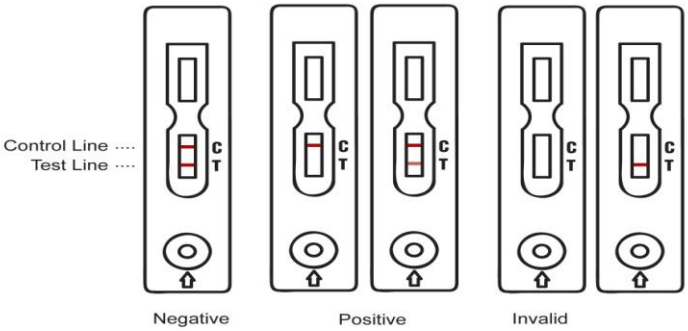
2. Holding the sample dropper vertically, add four full drops (0.2ml) of specimen without air bubbles into the sample well that is marked with an arrow on the testing device.



3. Read the result in 15 minutes. Ensure that the background of the test area is white before interpreting the results.

DO NOT INTERPRET RESULTS AFTER 30 MINUTES

RESULT INTERPRETATIONS



Negative
Two distinct color bands appear at the control and test regions.

Positive
A pink colored band appears only at the control region or the test band is much lighter than the control band.

Invalid
No visible band at the control region. Repeat with a new test kit. If 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 can be stored at 2-30ºC up to the expiration date. Do not freeze the test device.
- The test device should be kept away from direct sunlight, moisture and heat.

LIMITATIONS

- This product is designed for use with human blood only.
- There is always a possibility that false results will occur due factors beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.
- 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

Artron Laboratories Inc.
3938 North Fraser Way Burnaby, BC
V5J 5H6 Canada
REVISION 2009

Ph: 604.415.9757 Fax: 604.415.9795
www.artronlab.com
info@artronlab.com