HIV, HBsAg & HCV Combo Test

Instructions For Use

Format: Cassette
Specimen: Serum/Plasma
Catalog Number: A02-20-222

CE 2265

* Please read the instructions carefully before use

INTENDED USE

Artron One-Step HIV, HBsAg & HCV Combo Test is a rapid and convenient immunochromatographic assay for the qualitative detection of HBsAg, HCV antibodies and/or HIV1/2 virus- antibodies, respectively, in human serum or plasma samples. It is intended for professional use as an aid in diagnosing HCV, HIV, and/or HBV infections. This assay provides only a preliminary result and all positive specimens should be confirmed with other qualified assays.

SUMMARY AND PRINCIPLE OF THE ASSAY

The human immunodeficiency virus (HIV) is an etiological agent for acquired immunodeficiency syndrome (AIDS). The viral particles are transmitted by sexual contact, sharing needles among drug abusers, blood transfusion, and from mother to child. The disease is characterized by a chronic, progressive illness that leads to life-threatening opportunistic infections. The Hepatitis B virus (HBV) and Hepatitis C virus (HCV) are pathogenic agents that cause acute or chronic hepatitis. The viral particles are transmitted through the exposure of infectious body fluids or blood, blood transfusions, and use of contaminated needles or syringes. Chronic hepatitis may progress to severe outcomes without prompt medical intervention, including cirrhosis and liver cancer (heptatocellular carcinoma).

Artron One-Step HIV, HBsAg & HCV Combo Test is a double sandwich immunochromatographic assay, detecting the presence of HBsAg, HCV antibodies and HIV 1/2 virus antibodies, respectively, in human serum/plasma samples. Specific HIV and HCV antigens and monoclonal antibodies specifically against HBsAg are 1) conjugated with colloidal gold and deposited on a conjugate pad, and 2) immobilized on the test line of the Test Zone (Line T1 for HIV, line T2 for HbsAg, line T3 for HCV) on the nitrocellulose membrane. When a serum/plasma sample is added, the gold-antigen / antibody conjugates are rehydrated and the HBsAg, HCV antibodies and/or HIV1/2 virus antibodies, if any in the sample, will interact with the gold conjugates. The antigen-antibody-gold complex will migrate towards the test window until the Test Zone (T) where they will be captured by immobilized specific antigen/antibodies, forming visible pink line(s) (T1, T2 and/or T3); indicating positive result(s). If HBsAg, HCV antibodies and/or HIV1/2 virus antibodies are absent in the sample, no pink line will appear in the Test Zone (T), indicating a negative result.

To serve as an internal process control, a control band should always appear after the test is completed. Absence of a pink control line in the control region is an indication of an invalid result.

PACKAGE CONTENTS

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

MATERIALS REQUIRED (BUT NOT PROVIDED)

- Glove.
- Clock or timer.

WARNINGS AND PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not reuse.
- Do not use if the product sealed barrier 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 material 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.

LIMITATIONS

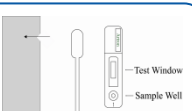
- This product is an *in vitro* diagnostic test designed for professional use only.
- Humidity and temperature can adversely affect results.
- The instructions for the use of the test should be followed during testing procedures.
- Anti-coagulants such as heparin, EDTA, and citrate do not affect the test result.
- 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 HCV, HIV, and/or HBV infections, 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.

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 and place the testing device on a leveled surface.



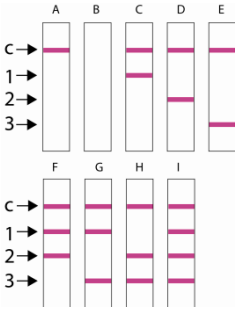
2. Hold the sample dropper vertically. Add three full drops (120 µl) of the specimen without air bubbles into the sample well that is marked with an arrow on the testing device.

3. Read the results in 10-20 minutes. Read results as shown under interpretation of Results.

NOTE: Strong positive specimens 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 HIV, HBV and/or HCV infections.

Positive
A pink control band (C) and detectable test band(s) (T1-T3) appears, indicating positive result for HIV, HBV and/or HCV infections.

Band T1: HIV Positive,

Band T2: HBsAg Positive,

Band T3: HCV Positive.

Invalid
No visible band appears 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 bottle containing the buffer should be stored at 2-30ºC.
- The test device should be kept away from direct sunlight, moisture and heat.

MANUFACTURER CONTACT INFORMATION

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