AG- HIV/HBs/HCV Ag RAPID TEST KIT

INSTRUCTIONS FOR USE

AstraGene HIV/HBs/HCV Ag rapid test kit 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.

PRINCIPLE

AstraGene HIV/HBs/HCV Ag rapid test is a qualitative, solid phase, two-site sandwich immunoassay for the detection of HBsAg in serum or plasma. The membrane is pre-coated with anti-HBsAg antibodies on the test line region of the cassette. During testing, the serum or plasma specimen reacts with particles coated with anti-HBsAg antibodies. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-HBsAg antibodies on the membrane and generate a colored line. This test is for in vitro diagnostic use only, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

The HCV Rapid Test is a qualitative, membrane-based immunoassay for the detection of antibody to HCV in serum or plasma. The membrane is pre-coated with recombinant HCV antigen on the test line region of the cassette. During testing, the serum or plasma specimen reacts with recombinant HCV antigen conjugated colloid gold. The mixture migrates upward on the membrane chromatographically by capillary action to react with recombinant HCV antigen on the membrane and generate a colored line. The presence of this colored line indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

The HIV 1.2 Rapid Test is a qualitative, membrane-based immunoassay for the detection of antibodies to HIV 1.2 in serum or plasma. The membrane is pre-coated with recombinant HIV antigens. During testing, the serum or plasma specimen reacts with HIV antigen coated particles in the test cassette. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with recombinant HIV antigen on the membrane in the test line region. If the specimen contains antibodies to HIV 1 and/or HIV 2, a colored line will appear in the test line region, indicating a positive result. If the specimen does not contain HIV 1 and/or HIV 2 antibodies, a colored line will not appear in the test line region, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

PACKAGE CONTENTS

Description	**10 tests**	1 test
Test Cassette and Desiccant	10	1
Sample Dropper	10	1
Buffer	1	1
IFU	1	1

Catalogue Number	**10 tests**	**1 test**
Cassette Model	AG/RTK/HHHAg/24/01	AG/RTK/HHHAg/24/02

MATERIALS REQUIRED (BUT NOT PROVIDED)

- Clock or timer.
- Pipette
- Latex gloves

STORAGE &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.

SPECIMEN COLLECTION & PREPARATION

- AstraGene HIV/HBs/HCV Ag rapid test can be performed using either serum or plasma
- Separate the serum or plasma from blood as soon as possible to avoid hemolysis.
- Only clear, non-hemolyzed specimens can be used.
- Testing should be performed immediately after the specimens have been collected.
- Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with federal regulations for transportation of etiologic agents.

PROCEDURE

- Allow the test, specimen, buffer and/or controls to room temperature (15-30°C) prior to testing.
- Remove the test cassette from the foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
- Place the test cassette on a clean and level surface. Hold the dropper vertically and transfer 2 drops of serum or plasma (approximately 50 uL) to the each sample well, then add 1 drop of buffer (approximately 40 uL) to each sample well and start the timer. See the illustration below.
- Wait for the colored line(s) to appear. The test result should be read at 10 minutes. Do not interpret the result after 20 minutes.

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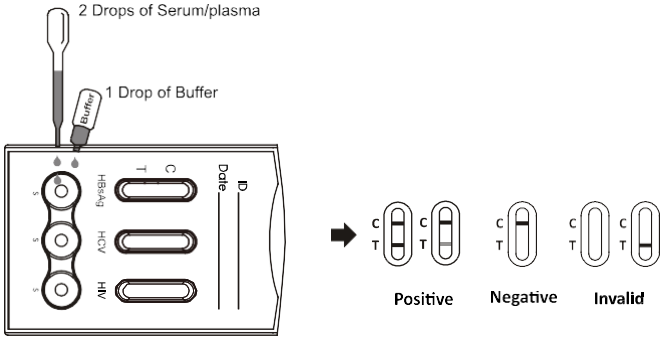

RESULT INTERPRETATIONS

- POSITIVE: * Two colored lines appear. One colored line should be in the control region (C) and another colored line should be in the test region (T).
- *NOTE: The intensity of the color in the test line region (T) will vary depending on the concentration of HBsAg antigen, HCV antibody and HIV antibody present in the specimen. Therefore, any shade of red in the test region should be considered positive.
- NEGATIVE: One colored line appears in the control region (C). No colored line appears in the test region (T).
- INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATION OF THE PROCEDURE

- This test is for in vitro diagnostic use only.
- This test has been developed for testing serum or plasma specimens only. The performance of the test using other specimens has not been substantiated.
- This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of HBsAg, HCV antibody or HIV 1.2 antibody
- The HBsAg Rapid Test cannot detect less than 1 PEI ng/mL of HBsAg in specimens.
- As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
- If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is recommended. A negative result at any time does not preclude the possibility of HBsAg and/or Hepatitis C Virus and/or HIV 1.2 infection.

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 being handled.
- Clean up spills thoroughly with appropriate disinfectants.
- Handle all specimens as if they contain infectious agents. Observe established precautions magainst 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 | GMP

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