AG-HCV Ab RAPID TEST KIT

INSTRUCTIONS FOR USE

AstraGene HCV Ab rapid test kit is a rapid and convenient immunochromatographic assay for the qualitative detection of antibodies against HCV in human whole blood, serum or plasma samples. It is intended for professional use as an aid in diagnosis of HCV 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 HCV Ab rapid test kit is an antibody-capture immunochromatographic assay, detecting the presence of HCV antibodies in either serum or plasma. Specific HCV antigens are 1) conjugated with colloidal gold and deposited on the conjugate pad, and 2) immobilized on the test line of the nitrocellulose membrane. When a serum or plasma sample is added, it rehydrates the gold-antigen conjugate and the HCV antibodies, if present in the sample, interacts with the gold conjugated antigen. The antigen-antibody-gold complex will migrate towards the test window until the test region (T) where they are captured by the immobilized antigens, forming a visible pink line (test line), indicating a positive result). If HCV antibodies are absent in the sample, no pink line will appear in the test region. To serve as an internal process control, a control line should always appear in the control region (C) after the test is completed. Absence of a pink control line in the control region is an indication of an invalid result.

PACKAGE CONTENTS

Description	**10 tests**	1 test
Test Cassette and Desiccant	10 Cassette's	1 Cassette
Sample Dropper	10 No's	1 No.
Sample Buffer	1.2 mL per box	0.12mL per box
IFU	1 No.	1 No.

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

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.

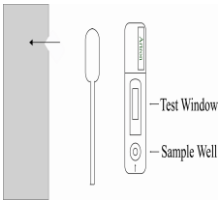
SPECIMEN COLLECTION & PREPARATION

- 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.before beginning the assay.

PROCEDURE

1

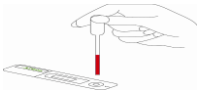
Remove the testing device from the sealed pouch by tearing at the notch and place the testing device on a leveled surface.



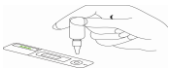
2

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 minutes. Following instructions under the "Result Interpretation"

NOTE: Specimens with high concentrations of HCV antibodies may produce positive results in as little as 1 minute. Confirm negatives in 10 - 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 HCV infections.

Positive
A clear pink control band (C) and a detectable test band (T) appear, indicating a positive result for HCV 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 control (pink colored line in the control region), good laboratory practice recommends the 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 HCV 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.

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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