Hepatitis C virus Antibody Rapid Test User Instruction

REF Catalog No. HCV-test
IVD In Vitro Diagnostic

Intended use

For the rapid qualitative determination of hepatitis C virus antibody in human blood as an aid in the diagnosis of hepatitis C virus infection. This test is intended for professional use and is a preliminary screening test and final diagnosis should be based after examination with other assays.

Introduction

Assay+ one step anti-HCV test is a lateral flow immunoassay device for the visual detection of hepatitis C antibodies (anti-HCV) in serum or plasma. It is used as an aid in the diagnosis of hepatitis C infection. The assay is based on the principle of double antigen sandwich immunoassay for determination of anti-HCV in serum or plasma. Purified recombinant antigens are employed to identify anti-HCV specifically. This one step test is very sensitive and only takes 20 minutes for the result to be read. Test results are read visually without any instrument.

Assay principle

Serum or plasma sample is used for the test. After a specimen is loaded to the device, the specific antibodies, HCV IgG in the specimen sample react to the gold-conjugated HCV antigen. As HCV antibody - HCV antigen-gold conjugated complex migrates along nitrocellulose membrane, anti-HCV antibody in the complex is captured by the test line coated with recombinant HCV antigen causing a pink to deep pink band. The intensity of the band is variable depending on the amount of antibody present in the blood sample. A red control line should always develop on the test strip to indicate the proper performance.

Components in pouch

1. One HCV antibody test strip
2. One desiccate

Material Required (but not provided)

- Glove.
- Clock or timer

General Precautions

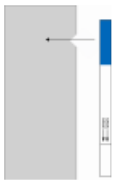
- The test is for In Vitro Diagnostic Use only.
- Appropriate infection control and handling procedures should be followed – do not smoke, eat or drink in the area where the test is to be performed. Use suitable clothing and gloves when handling samples and when performing the test.
- Do not pipette any samples or reagents by mouth.
- All materials should be considered as potentially infectious. To disinfect, either autoclave materials at 121.5'C for 1 hour or treat with Sodium hypochlorite (1 percent solution).
- Do not use test beyond the expiration date indicated.

Sample Collection

- 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.

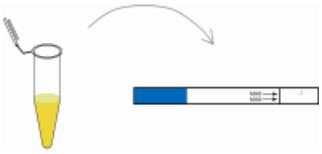
Test Procedure

1. Remove test cards from the pouches as needed. Lay on a clean flat surface



2. Holding the strip vertically, immerse the strip into the specimen with the arrow end pointing towards the specimen. Do not immerse past the MAX line.

3. Take the strip out when the sample has migrated to the test window (about 10 seconds). Lay the strip (MAX side facing up) flat on a clean, dry, non- absorbent surface.



4. Read the result in 10 minutes, following instructions under the "Results Interpretation" section

NOTE: Specimens with high concentrations of HCV antibodies may produce positive results in as little as 1 minute. Confirm negatives in 20 minutes.

Result Interpretation

Negative
A pink colored line appears only in the control region (C), indicating a negative result for HCV infections.

Positive
A clear pink control line (C) and a detectable test line (T) appear, indicating a positive result for HCV infections.

Invalid
No visible line in the control region. Repeat with a new test device. If the test still fails, please contact the distributor with the lot number.

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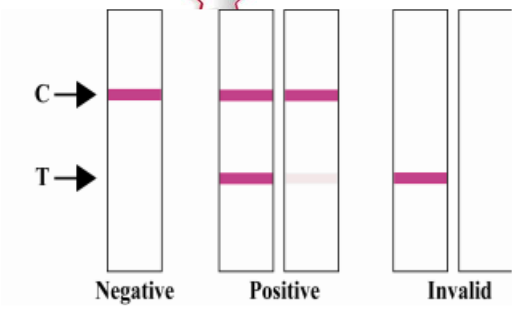

Quality Control

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.

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.

Limitation

- 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.

Inquires and general information

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