

HEALTH-CHEM DIAGNOSTICS LLC

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RAPIDTEST HCV® SCREEN – LATERAL FLOW

Serum or Plasma Only

For In-Vitro Diagnostic Use only

SUMMARY

The general method of detecting infection with HCV is to observe the presence of antibodies to the virus by an EIA method followed by confirmation with Western Blot. The Rapid Anti-HCV Test is a simple, visual qualitative test that detects antibodies in human serum or plasma. The test is based on immunochromatography and can give a result within 15 minutes.

INTENDED USE

The Rapid Anti-HCV Test is a Colloidal Gold enhanced, rapid Immunochromatographic Assay for the qualitative detection of antibodies to Hepatitis C Virus (HCV) in Human Serum or Plasma. This test is a screening test and all positives must be confirmed using an alternate test such as Western Blot. The test is intended for Healthcare Professional use only. Both the testing and the results of the testing are intended to be used by medical and legal professionals only, unless otherwise authorized by regulation in the country of use. Not intended for sale in the USA or its protectorates. The test should not be used without appropriate supervision.

PRINCIPLE OF THE PROCEDURE

The assay starts with a sample applied to the sample well and the addition of the provided sample diluent immediately. HCV antigen-Colloidal Gold conjugate embedded in the sample pad reacts with the HCV antibody present in serum or plasma, forming conjugate/HCV antibody complex. As the mixture is allowed to migrate along the test strip, the conjugate/HCV antibody complex is captured by an antibody-binding protein A immobilized on a membrane forming a colored band in the test region. A negative sample does not produce a test line due to the absence of Colloidal Gold conjugate/HCV antibody complex. The antigens used in the test are recombinant proteins corresponding to highly immunoreactive regions of HCV. A colored control band in the control region appears at the end of the test procedure regardless of the test result. This control band is the result of Colloidal Gold conjugate binding to an antibody immobilized on the membrane. The control line indicates that the Colloidal Gold conjugate is functional. The absence of the control band indicates that the test is invalid.

REAGENTS AND MATERIALS SUPPLIED

Test device individually foil pouched with a desiccant

- Plastic dropper.
- Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Positive and negative controls (available as a separate item)

STORAGE & STABILITY

- The test should be stored at 2-8°C. The test will withstand storage at temperatures up to 30°C, but long term shelf life may be affected.

WARNINGS AND PRECAUTIONS

- 1) All positive results must be confirmed by an alternative method.
- 2) Treat all specimens as though potentially infectious. Wear gloves and protective clothing when handling specimens.
- 3) Devices used for testing should be autoclaved before disposal.
- 4) Do not use kit materials beyond their expiration dates.
- 5) Do not interchange reagents from different lots.

SAMPLE COLLECTION AND STORAGE

- 1) Collect serum or plasma specimens following regular clinical laboratory procedures.
- 2) Storage: A specimen should be refrigerated if not used the same day of collection. Specimens should be frozen if not used within 3 days of collecting. Avoid freezing and thawing the specimens more than 2-3 times before using. 0.1% of Sodium Azide can be added to specimen as a preservative without affecting the results of the assay.

BEFORE TESTING

- 1) Bring the device and specimens to room temperature.
- 2) Remove the device from the sealed pouch.

ASSAY PROCEDURE

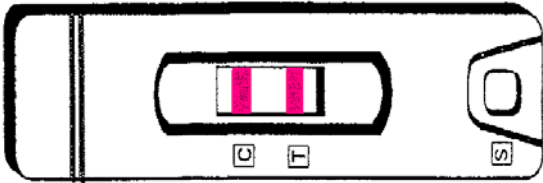
- 1) Using the enclosed plastic dropper for the sample, dispense 2 drops of serum or plasma to the circular sample well of the test card (marked "S"), according to the figure. Allow the first drop to be absorbed before adding the second drop.
- 2) Interpret test results at 12-20 minutes.

Notes:

- 1) The positive results could appear as soon as one minute for a sample with high levels of HCV antibodies.
- 2) **Do Not Interpret results after 20 minutes**

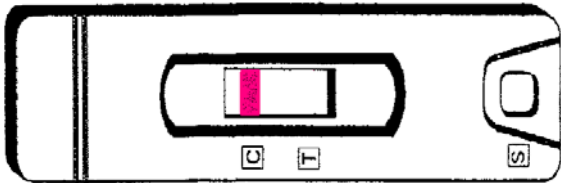
READING THE TEST RESULTS

1. Positive: Both a purplish red test band and a purplish red control band appear on the membrane. The lower the antibody concentration, the weaker the test band.



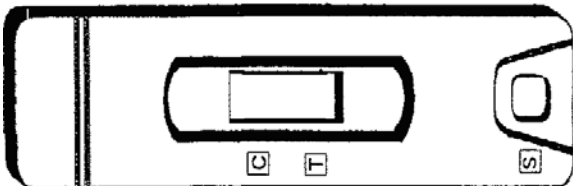
POSITIVE RESULT

2. Negative: Only the purplish red control band appears on the membrane. The absence of a test band indicates a negative result.



NEGATIVE RESULT

3. Invalid result: There should always be a purplish red control band in the control region, regardless of the test result. If a control band is not seen, the test is considered invalid. Repeat the test using a new test device.



INVALID RESULT

Note: It is normal to have a slightly lightened control band with very strong positive samples, as long as it is distinctly visible.

PERFORMANCE CHARACTERISTICS

1: Specificity: The specificity of the Rapid Anti-HCV Test is based on clinical studies using 156 confirmed negative serum samples from blood bank and hospital patients. The studies were performed comparing the results from Rapid Anti-HCV test and that from Abbott’s ELISA as a reference test. The overall specificity was found to be 97-99%.

2: Sensitivity: In the same studies mentioned above, Rapid Anti-HCV Test was evaluated with 61 confirmed positive serum samples. All 61 samples were found reactive. The overall sensitivity was found to be 99%+.

In another study, using 182 patient samples, 74 positive and 103 negative had been assayed by ELISA and Rapid-Test kit. The correlation is 97.25%.

| | | RapidTest | |
|-------|---|-----------|-----|
| | | + | - |
| ELISA | + | 74 | 0 |
| | - | 5 | 103 |

LIMITATION

- 1) Only clear, fresh, free flowing Serum or Plasma can be used in this test.
- 2) Fresh samples are best but frozen samples can be used. If a sample has been frozen, it should be allowed to thaw in a vertical position and checked for fluidity.
- 3) Do not agitate the sample. Insert a pipette just below the surface of the sample to collect the Specimen.

BIBLIOGRAPHY

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