

HCV RAPID TEST

(Serum / Plasma / Whole Blood)

INTENDED USE

First View HCV Rapid Antibody Test is a double antigen lateral flow chromatographic immunoassay for the qualitative detection of anti-hepatitis C virus antibodies (IgG, IgM, IgA) in human serum / plasma or Whole blood. It is intended to be used as a screening test and as an aid in the diagnosis of infection with HCV.

SUMMARY AND EXPLANATION OF THE TEST

Hepatitis C virus (HCV), which was formerly described as the parentally transmitted form of non-A, non-B hepatitis (NANBH), causes chronic disease in 50% of patients. HCV can also be transmitted through intravenous drug abuse and sexual contact. Hepatitis C virus is a single-stranded RNA virus with structural similarities to the flavivirus family. Nucleic acid sequences of HCV cDNA clones provide the basis for the construction of recombinant peptides representing putative hepatitis C virus proteins. Anti-hepatitis C virus antibody screening of blood using synthetic or recombinant proteins helped to identify apparently healthy blood donors with anti-HCV antibodies who otherwise might have transmitted the virus.

First View HCV Rapid Antibody Test is a useful tool for blood bank screening safety. First View HCV Rapid Antibody Test has been developed to detect anti-HCV antibodies (IgG, IgM, IgA) in human serum / plasma or Whole blood. The test can be performed by minimally trained personnel and without cumbersome laboratory equipment.

TEST PRINCIPLE

First View HCV Ab Rapid Test is a double antigen lateral flow chromatographic immunoassay. The test cassette consists of:

1. A burgundy-colored conjugate pad containing recombinant HCV fusion antigens (core, NS3, NS4 and NS5) conjugated with colloidal gold (HCV Ag conjugates) and a control antibody conjugated with colloidal gold,
2. A nitrocellulose membrane strip containing a test line (T line) and a control line (C line). The T line is pre-coated with recombinant HCV fusion antigens (core, NS3, NS4 and NS5), and C line is pre-coated with a control line antibody.

When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the test cassette. HCV antibodies, if present in the specimen, will bind to the HCV Ag conjugates. The immunocomplex is then captured on the membrane by the pre-coated non-conjugated HCV antigen forming a burgundy colored T line, indicating an HCV positive test result. Absence of the T line suggests a negative result. The test contains an internal control (C line) which should exhibit a burgundy colored line of the immunocomplex of the control antibodies, regardless of any color development on the T line. If the C line does not develop, the test result is invalid, and the specimen must be retested with another device.

REAGENTS AND MATERIALS PROVIDED

HCV test cards contain the following:

- Test Device with activated silica gel
- Plastic Dropper.
- Assay Buffer Bottle
- Package Insert (Instruction for use)

MATERIALS MAY BE REQUIRED BUT NOT PROVIDED

- Positive Control
- Negative Control

MATERIALS REQUIRED BUT NOT PROVIDE

- Timer
- Digital Clock
- Specimen collection container Tube

WARNINGS AND PRECAUTIONS:

For in Vitro Diagnostic Use

- This package insert must be read completely before performing the test.
- The test device should remain in the sealed pouch until use
- Do not use expired devices.
- Do not use the kit if the cassette package is damaged or the seal is broken.

- Bring all reagent to room temperature (15-30°C) before use.
- Do not use hemolyzed blood specimens for testing.
- Wear personal protective equipment, such as gloves and lab coats when handling kit reagents. Wash hands thoroughly after performing the test.
- Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
- Dispose of all specimens and material used to perform the test as bio-hazardous waste.

REAGENT PREPARATION AND STORAGE

INSTRUCTIONS: All reagents are ready to use as supplied. Store unused test device unopened at 2-30 °C, ensure that the test device brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit to temperature 30°C.

SPECIMEN COLLECTION, STORAGE AND HANDLING

Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.

1. Plasma

- **Step 1:** Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively, in Vacutainer®) by venipuncture.
- **Step 2:** Separate the plasma by centrifugation.
- **Step 3:** Carefully withdraw the plasma into a new pre-labeled tube.

2. Serum

- **Step 1:** Collect blood specimen into a red top collection tube (containing no anti coagulants in Vacutainer®) by venipuncture.
- **Step 2:** Allow the blood to clot.
- **Step 3:** Separate the serum by centrifugation.
- **Step 4:** Carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. Store Specimens at 2-8°C if not tested immediately, for up to 5 days. The specimens should be frozen at -20°C for longer storage.

3. Whole Blood

- Drops of whole blood can be obtained by either finger tip puncture or venipuncture. Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®). Do not use hemolyzed blood for testing.
- Whole blood specimens should be stored in refrigeration (2-8°C), if not tested immediately. The specimens must be tested within 24 hours of collection.

DIRECTIONS FOR USE

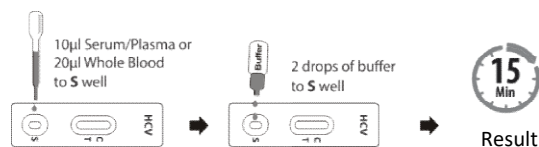
Allow test cassette, specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it.
2. Remove the test cassette from the sealed pouch and place it on flat dry surface.
3. **For Serum or Plasma Specimen:** Hold the dropper vertically and transfer **1 drop** of serum or plasma (**approximately 10µl**) to the specimen area, then add **2 Drops** of buffer (**approximately 80µl**), and start the timer, see illustration below.

For Whole Blood Specimen: Hold the dropper vertically and transfer **2 Drops** of whole blood (**approximately 20µl**) to the specimen area, then add **2 Drops** of buffer (**approximately 80µl**), and start the timer. See illustration below.

4. Wait for the colored line(s) to appear. The test result should be read at 15-20 minutes.

Note. Do not interpret the result after 20 minutes.



QUALITY CONTROL

- Internal Control:** This test contains a built-in control feature, the C line. The C line develops after adding the specimen. If the C line does not develop, review the entire procedure and repeat the test with a new device.
- External Control:** Good Laboratory Practice recommends using external controls, positive and negative, to ensure the proper performance of the assay, particularly under the following circumstances :
 - A new operator uses the kit prior to performing the testing of specimens.
 - A new lot of test kits issued.
 - A new shipment of kits issued.
 - The temperature used during storage of the kit falls outside of 2-30°C.
 - The temperature of the test area falls outside of 15-30°C.
 - To verifying her than expected frequency of positive or negative results.
 - To investigate the cause of repeated invalid results.

INTERPRETATION OF ASSAY RESULT

- NEGATIVE RESULT:** If only the C line is developed, the test indicates that the level of HCV antibodies in the specimen is undetectable. The result is negative or non-reactive.



- POSITIVE RESULT:** If both the C and the T lines are developed, the test indicates that the specimen contains HCV antibodies. The result is positive or reactive. Samples with reactive results should be confirmed with alternative testing method(s) and clinical findings before a positive determination is made.



- INVALID:** If no C line is developed, the assay is invalid regardless of color development on the T line as indicated below. Repeat the assay with a new device.



Remarks: Any reactive specimen with First View HCV Ab Rapid Test must be confirmed with alternative testing method(s) and clinical findings.

PERFORMANCE CHARACTERISTICS.

1. Clinical Performance.

A total of 733 samples from susceptible subject were tested with the First View HCV Rapid Test and with a commercial HCV ELISA KIT. Comparison for all subjects is shown in the following table.

| HCV ELISA | First View HCV Rapid Test | | |
|-----------|---------------------------|----------|-------|
| | Positive | Negative | Total |
| Positive | 325 | 3 | 328 |
| Negative | 2 | 403 | 405 |
| Total | 327 | 406 | 733 |

Relative Sensitivity: 99.1%

Relative Specificity: 99.5%,

Accuracy : 99.3%.

2. Acceptance Criteria.

| Sr. No. | Test(s) Conducted | As per CDSCO's Specifications for HCV Ab Rapid Test. |
|---------|-------------------|--|
| 1 | Sensitivity | >= 99% |
| 2 | Specificity | >= 98% |

3. Cross-reactivity.

The HCV Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested by HAMA, RF, HAV, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, Syphilis, HIV, Dengue , CMV IgG/IgM, Rubella IgG/IgM, Toxo IgG/IgM positive specimens. The results showed no cross-reactivity.

LIMITATIONS OF TEST

- The Assay Procedure and the Interpretation of Assay Result sections must be followed closely when testing for the presence of HCV Ab in serum/plasma or whole blood from individual subjects. Failure to follow the procedure may lead to inaccurate results.
- The First View HCV Rapid Test is limited to the qualitative detection of HCV Ab in human serum/plasma or whole blood. The intensity of the test line does not have a linear correlation with the HCV Ab titer in the specimen.
- A non-reactive test result does not preclude the possibility of exposure to or infection with HCV.
- A non-reactive result can occur if the quantity of HCV Ab present in the specimen is below the detection limits of the assay or the HCV Ab that is detected was not present during the stage of disease in which a sample is collected.
- If the symptoms persist when the result from First View HCV Rapid Test is non- reactive, it is recommended to re-sample the patient a few days later or to test with an alternative test method.
- Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor may affect expected results.
- The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

REFERENCES

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