

CORTEZ DIAGNOSTICS, INC.

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HCV Serum InstaTest

Cat. No. 118771

INTRODUCTION

The ANTI-HCV Ab Rapid Test is a rapid, direct binding test for the detection of antibodies to hepatitis C (anti-HCV Ab) in serum. It is used as an aid in the diagnosis of hepatitis C infection. Test results are read visually without any instrument.

HCV test is based on the principle of inter-second antibody enzyme immunoassay for the determination of anti-HCV in serum or whole blood. Recombinant HCV antigens are employed to specifically identify anti-HCV antibodies specifically. The test is very sensitive and only takes 3 minutes.

The formation of a large dot (●) or a line of three smaller dots (●●●) provides an easy readout for positive and negative test results. The three smaller dots (●●●) also serve as an internal control. The center dot is a weak positive control and the two outer dots are the strong positive control. They only appear when all reagents are working and the sequence of adding reagents is performed correctly.

MATERIALS PROVIDED

1. Test devices (each device is for one single test)
2. Gold Conjugate solution

MATERIALS REQUIRED BUT NOT PROVIDED

1. Specimen collection containers
2. Pipettor
3. Pipette tips

STORAGE

After opening the package, it may be stored at room temperature for one week. Gold Conjugate must be stored at 2-8°C.

SPECIMEN COLLECTION

For serum, collect blood into a container without anticoagulant. Allow the blood to clot and separate the serum from the clot. Use the serum for testing.

If the specimen cannot be tested on the day of collection, store the serum specimen in a refrigerator or freezer. Do not freeze and thaw the specimen repeatedly. Mix samples thoroughly after thawing.

TEST PROCEDURE

Bring all reagents, test devices, specimens, references, and other materials to room temperature prior to testing. Do not mix the caps from different reagent vials.

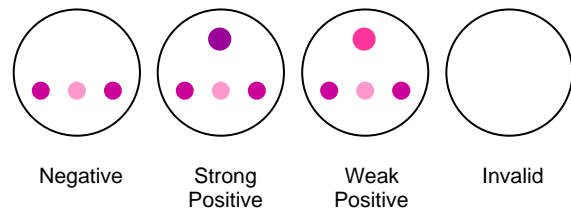
1. Add 10 drops of Gold Conjugate Solution into reaction well on the test device.
2. Using a pipettor, add 30 µL serum or whole blood sample to the reaction well and mix with Gold Conjugate Solution by pipetting the mixture up and down several times.
3. Using a dropper or pipette, transfer all the solution from the reaction well and add to the pre-filter well. Allow the specimen to soak completely through the pre-filter.
4. Add 10 drops of Gold Conjugate to the pre-filter. Allow the solution to soak through.
5. Remove and discard pre-filter. Read results.

INTERPRETATION OF RESULTS

- **Negative:** Only three small dots on the dot bar (●●●) are visible. Occasionally, the round test spot (●) may become visible where the round spot is lighter than all the dots on the dot bar.
- **Strong Positive:** Both the round spot (●) and the dot bar (●●●) are visible. The round spot is darker than all the dots on the dot bar.
- **Weak positive:** The round spot (●) is darker than or equal to the center dot on the dot bar (●●●) but weaker than other dots on the dot bar.
- **Invalid:** Only the round spot is visible or both the round spot and the three small dots are not visible. Repeat test with a new test kit.

PRECAUTION

1. For in vitro diagnostic use only.
2. Do not use test kit beyond expiry date.
3. The test device should not be reused.



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