Diagnostic Automation / Cortez Diagnostics, Inc.
IMMUNO DIAGNOSTICS

# OneStep HCV Serum/Plasma RapiFlo ™ InstaTest

**Cat#118771-1**

**"Export Use Only"**

IVD See external Label 2 - 30°C 1 Test

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| **Specificity** | **99.43%** |
| **Sensitivity** | **97.25%** |

## INTENDED USE

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

## TEST PRINCIPLE

MT HCV test is based on the principle of inter-second antibody enzyme immunoassay for the determination of anti-HCV in serum/plasma. 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 ( • ) (Test) or a line of three smaller dots (•••) (Control) 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.

## SPECIMEN COLLECTION AND PREPARATION

Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
If the specimen cannot be tested on the day of collection, store the specimen in a refrigerator or freezer. Do not freeze and thaw the specimen repeatedly. Mix samples thoroughly after thawing.

## MATERIALS AND COMPONENTS

### Materials provided with the test kits

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

### Materials required but not provided

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

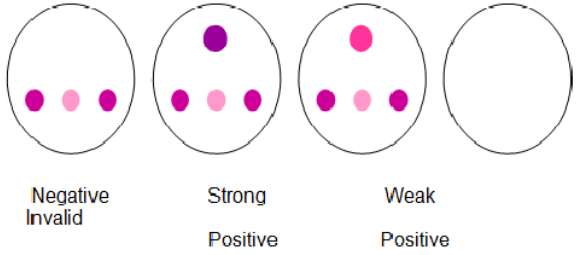
## ASSAY PROCEDURE

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 pipette, add 30 µL serum/plasma 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.

## RESULTS

- **Negative:** Only three small dots on the control dot bar (•••) are visible. Occasionally, the round test spot (•) may become visible where the color intensity of the round spot (Test Dot) is lighter than the center dot of the control dot bar.
- **Strong Positive**: Both the round spot (•) and the control dot bar (•••) are visible. The color intensity of the round spot is darker than all the dots on the control dot bar.
- **Weak Positive:** The round spot (•) is darker than or equal to the center dot on the control 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.




## PERFORMANCE CHARACTERISTICS

During mulch-centre performance evaluation, total of 1002 clinical samples were tested in parallel with ELISA test with well-established performance characteristics. 520 samples were positive by both HCV RAPID TEST and ELISA, 466 samples were negative by both tests, 3 samples were positive with ELISA but negative with the rapid test, and 13 samples were negative with ELISA, but positive with HCV RAPID TEST. Thus the positive and negative agreements of HCV RAPID TEST with ELISA were established as 99.43% and 97.25% respectively.

20 commercially available seroconversion panels were tested with both HCV RAPID TEST and HCV ELISA. The seroconversion detection of

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HCV RAPID TEST (28.96% , 53/183) was higher compare to the detection rate demmostrated by ELISA (24.59% , 45/183). In 9 seroconversion panels, seroconversion was detected earlier with the HCV RAPID TEST than with ELISA (average 4.89 days earlier). In 2 seroconversion panels, HCV RAPID TEST and ELISA detection of seroconversion was equal while in another two panels, ELISA demostrated earlier detection compared to the HCV RAPID TEST.

No cross- reactivity was observed when testing samples from patients infected with other hepatitis viruses, or suffering from sexuality transited diseases.

## PRECAUTIONS

1. For in vitro diagnostic use only.
2. Do not use test kit beyond expiry date.
3. The test device should not be reused.
4. The kit should be stored at 2-8°C.
5. Please bring the kit to room temperature before testing.
6. After opening the package, it may be stored at room temperature for one week. Gold Conjugate must be stored at 2-8°C.

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| ISO 13485<br>ISO 9001<br>**Diagnostic Automation/<br>Cortez Diagnostics, Inc.<br>21250 Califa Street, Suite 102 and 116<br>Woodland Hills, California 91367 USA** | |
| **Date Adopted** | **Cat # 118771-1** |
| **2006-07-01** | **CORTEZ- OneStep<br>HCV Serum/Plasma<br>RapiFlo™ InstaTest -2015** |
| Revision B Date: 2015-08-15 | |