Diagnostic Automation / Cortez Diagnostics, Inc.
IMMUNO DIAGNOSTICS

OneStep HCV (Serum) 3.5mm RapiDip™ InstaTest

Cat #118775-1
"Export Use Only"

IVD See external Label 2-30°C ∑=1 Test

Specificity	**97. 25%**
Sensitivity	**99. 43 %**

INTENDED USE

One Step Strip Style HCV Test is a rapid, direct binding test for the visual detection of hepatitis C antibodies (HCV) in serum."Export Use Only"

TEST PRINCIPLE

It is used as an aid in the diagnosis of hepatitis C infection. One Step HCV Test is based on the principle of double antigen sandwich immunoassay for determination of HCV in serum. Purified recombinant antigens are employed to identify HCV specifically. This one step test is very sensitive and only takes 10-20 minutes for the result to be read. Test results are read visually without any instrument.

SPECIMEN COLLECTION AND PREPARATION

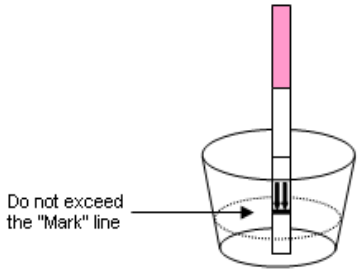
For serum, collect blood into a container without anticoagulant. Allow the blood to clot and separate the serum from the clot. Use the serum for testing.

If the specimen cannot be tested on the day of collection, store the serum specimen in a refrigerator or freezer. Stir and bring the

specimens to room temperature before testing. Do not freeze and thaw the specimen repeatedly.

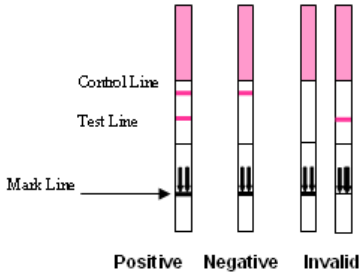
ASSAY PROCEDURE

1. When you are ready to begin testing, open the sealed pouch by tearing along the notch. Remove the test kit from the pouch and use it as soon as possible.
2. Following the illustration, dip the test strip with the arrow side pointing down into the vessel of serum for about 10 seconds. Do not immerse past the marker line. Take the strip out and lay it flat on a clean, dry and non- absorbent surface.
3. Wait for 10 minutes and read results. It is important that the background is clear before the result is read. Do not read results after 30 minutes.



RESULTS

- **Negative:** Only one colored band appears on the control (C) region. No apparent band on the test (T) region.
- **Positive:** In addition to a pink colored control(C) band, a distinct pink colored band will appear in the (T) test region.
- **Invalid:** A total absence of color in both (C) and (T) regions or no colored band appears on the control (C) region is an indication of procedure error and/or the test reagent has deteriorated. Repeat with a new test kit. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



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 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.

Diagnostic Automation/ Cortez Diagnostics, Inc.
21250 Califa St, Suite 102 and 116, Woodland Hills, CA 91367 USA Phone: 818-591-3030, Fax : 818-591-8383
Email: onestep@rapidtest.com Website: www.rapidtest.com

LIMITATIONS OF PROCEDURE

1. This test should be used for the antibodies to HCV in serum samples.
2. Only detect the presence of HCV, it should not be used as the sole criteria for the diagnosis of Hepatitis C viral infection.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician. A definite clinical diagnosis should only be made by the physician after all clinical and laboratory findings have been evaluated.
4. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is recommended. A negative result any time does not preclude the possibility of Hepatitis C Virus infection.

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.
4. The test kit can be stored at temperatures between 2 to 30ºC in the sealed pouch to the date of expiration. The test kit should be kept away from direct sunlight, moisture and heat.

ISO 13485
ISO 9001

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Cortez Diagnostics, Inc.
21250 Califa Street, Suite 102 and 116
Woodland Hills, California 91367 USA

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