

CORTEZ DIAGNOSTICS, INC.

23961 Craftsman Road, Suite E/F,
Calabasas, CA 91302 USA

Tel: (818) 591-3030 Fax: (818) 591-8383

E-mail: onestep@rapidtest.com

Web site: www.rapidtest.com

OneStep HCV RapiDip InstaTest

Cat. No. 118774-1 Cat. No. 118775-1

INTRODUCTION

One Step Strip Style ANTI-HCV Test is a rapid, direct binding test for the visual detection of hepatitis C antibodies (anti-HCV) in serum. It is used as an aid in the diagnosis of hepatitis C infection. One Step ANTI-HCV Test is based on the principle of double antigen sandwich immunoassay for determination of anti-HCV in serum. Purified recombinant antigens are employed to identify anti-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.

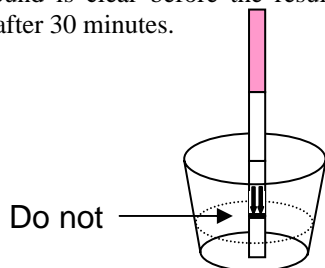
SPECIMEN COLLECTION & PREPARATION

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.

TEST 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.



PRECAUTION

1. For in vitro diagnostic use only.
2. Do not use test kit beyond expiry date.

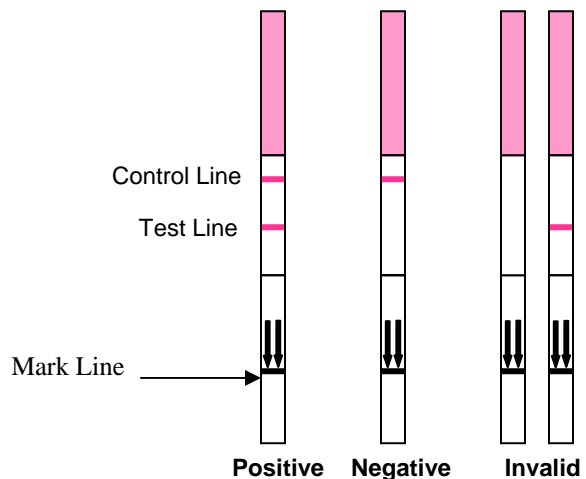
3. The test device should not be reused.

INTERPRETATION OF RESULTS

➤ **Negative:** Only one color 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 also appear in the test (T) 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.



STORAGE AND STABILITY

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

LIMITATIONS

1. This test should be used for the detection of antibodies to HCV in serum samples.
2. Only detect the presence of Anti-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.



CORTEZ DIAGNOSTICS, INC.

23961 Craftsman Road, Suite E/F,

Calabasas, CA 91302 USA

Tel: (818) 591-3030 Fax: (818) 591-8383

ISO 13485-2003

Revision Date: 6-5-06