HCV Ab cassette (serum/plasma) (RAP-4726)

RUO in the USA

Revised 18 June 2007

IVD

INTENDED USE

This HCV test is a rapid, one-step test for the qualitative detection the HCV *antibody* in human blood, serum and plasma. This test is intended primarily as an initial screening test and reactive samples should be confirmed by a supplemental assay such an ELISA test or Western Blot or RIBA blot assays.

PRINCIPLE MATERIALS USED IN THE TEST

The capture and label reagents are recombinant proteins of HCV, corresponding immunodominant regions of Core (C-123 aa), NS3 (275 aa), and NS5 (180 aa).

PRINCIPLE OF THE TEST

This HCV test consists of a chromatographic absorbent membrane strip with immobilized recombinant HCV antigen. The antibody in sample reacts with a colored conjugate antigen, which pre-dried on the strip, and an antigen-antibody complex is formed when antibody is present in the sample. The mixture then moves upward and the immuno complex labeled with dye will be captured by the antigen immobilized on the membrane, then a color band can be seen.

In the test procedure, the samples is added to the sample well with the aid of a dropper, and allowed to migrate through the absorbent device. The labeled antigen-dye conjugate binds to HCV antibody in the serum and migrates along the chromatographic membrane through capillary action. If there is *HCV antibody* present in the sample, a rose color band appears in the test window. In the absence of HIV antibody, there is no formation of a rose-pink color band in the positive reaction zone. The reaction mixture continues flowing through the absorbent device past the positive reaction zone to the control zone. Unbound conjugate binds to the reagents in the control zone, producing a rose-pink color band, demonstrating that the reagents and device are functioning correctly.

MATERIALS PROVIDED

1. Test Devices
2. Instructions for use

STORAGE AND STABILITY

The test device may be stored at ambient temperature of 20 - 30ºC (50-85°F) in the original unopened foil pouches. Each Test Unit contains a desiccant. The test should be used without delay once the pouch has been opened. In case the temperature of the Test Unit is considerably below room temperature and the humidity of the air is high, it is advisable to let the Test Unit reach room temperature before opening the pouch. The shelf-life of Test Unit may be 18 months from the date of manufacture. The expiration date is printed on the pouch.

SAMPLE COLLECTION AND STORAGE

1. The test prefers using the fresh samples.
2. If specimens are not immediately tested they should be refrigerated at 2-8°C for up to 2 days or storage periods greater than 2 days, serum or plasma can be stored at –20°C.
3. Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.

WARNINGS AND PRECAUTIONS

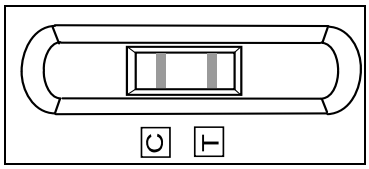
1. Wear disposable gloves while handling Specimens. Wash hands thoroughly afterwards.
2. Wipe up spills thoroughly using an appropriate intermediate to high level disinfectant.
3. Decontaminate and autoclave all specimens, reaction Kits and any potentially contaminated materials.
4. Avoid splashing or aerosol formation.
5. Do not use the Kit after the expiration date.
6. For in vitro diagnostic use only. In the United States, this kit is intended for Research Use Only.
7. The lysis samples might cause the false positive.

TEST PROCEDURE

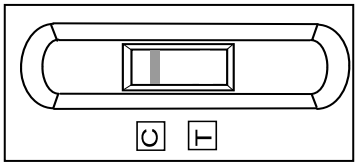
1. Remove the "Test Device" from its foil wrapper by tearing along the "splice" and place it on a clean level surface.
2. Fill the disposable dropper with the sample.
3. Hold the disposable dropper in a vertical position and apply 2 drops of sample (one by one) into the sample well of the test device. Allow each drop to soak in before adding the next one.
4. Read the results in 20 minutes.

INTERPRETATION

Positive Result: If there is one rose-pink color band in the control region (marked with a "C"), ***and*** one or two rose-pink color band in the test region (marked with a "T"), *HCV antibody is* present and the specimen is positive.



Negative Result: The absence of a color band in the test region next to the letter "T" indicates the absence of any detectable HCV antibody.



Invalid Result: If a color band **does not** appear in the control region "C", the test results are invalid. The sample may have been added to the wrong window, or the Test Device may have deteriorated. This specimen should be re-tested using a new Test Device.

LIMITATIONS OF THE TEST

1. This HCV kit is limited to the detection of HCV antibody only.
2. Although the kit is very accurate in detecting HCV antibody, a very low incidence of false results might occur.
3. If negative or questionable results are obtained, and the infection is suspected, the test should be repeated on a fresh serum specimen.
4. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after evaluation of all clinical and laboratory findings.

External Controls:

Like any *in vitro* device, performance of HCV antibody should be checked for accuracy and batch to batch variation by using known serum pools. These sera should be used in the same way as described in the assay procedure for serum samples. It is recommended that these control sera be used at least once with every batch or new shipment.

Internal Controls:

In addition to the external controls the test device has built-in controls. With each testing there should always be a rose-pink color band in the control region ("C"). If the color band does not appear in the control region, the result should be considered invalid. Also, after performing the test, the result window ("T") should look clear white or uniform light pink. If the result window shows large red or purple streaks at the end of 10 minutes, the test should be considered invalid. Repeat the test using a fresh test device.

Correlation with ELISA

Total patient samples of 182 included 74 positive and 103 negative had been assayed by ELISA and One-step kit. The correlation is 97.25%.

ELISA	One-step		
		+	-
	+	74	0
	-	5	103

REFERENCES

1. Alter, H.J. et al.N.Engl.J.Med.321:1494-1500, 1989.
2. Choo Q-L.,et al. Science 244:359-361, 1989
3. Choo Q-L.;et al. Br. Med Bull 46:423-441, 1990
4. Esteban J.I.,et al. N.Engl.J.Med.323:1107-1112, 1990
5. Kuo G.; et al. Science 244:362-364, 1989
6. Houghton, M., et al. Hepatology 14:381-388, 1991.

7. McHutchison J.G., et al. Hepatology 15:19-25, 1992
8. van der Poel C.L.,et.al. Lancet 337:317-319, 1991
9. Wilbur.J.C. J.Clin.Immunoassay 16:204-207, 1993.

~sd
Vers. 060807
~rm 12-18-08