



**For professional in vitro diagnostic use only  
Not for sale in USA**

**INTENDED USE**

The American Bionostica Rapid HCV Test is a rapid qualitative test for the detection of antibody specific to Hepatitis C virus in human serum .

**SUMMARY AND EXPLANATION OF THE TEST**

Hepatitis C virus (HCV) is a small, enveloped, single-stranded RNA virus. It is the major cause of parentally transmitted non-A, non-B hepatitis. Antibodies to HCV are reported in 80% of the non-A, non-B hepatitis patients.

The recombinant HCV proteins consist of the critical regions of HCV viruses including core, NS-3, NS-4 and NS-5, <sup>1,2</sup> that are used in this device to detect the HCV specific antibodies.<sup>3,4</sup>

**PRINCIPLE**

This assay is an one-step lateral flow chromatographic immunoassay. The test strip in the device consists of a conjugate pad containing protein A-colloidal gold conjugate and a nitrocellulose membrane strip striped with a test line (T line) and a control line (C line).

The T line is striped with the recombinant HCV proteins, and the C line is striped with rabbit anti-protein A antibody. When a proper amount of specimen applied into the sample pad of the device, the specimen migrates by capillary action through the test strip. If the specimen contains anti-HCV antibodies at the level detectable, a complex will be formed with the protein A from the conjugate pad. The complex will continue to migrate through the membrane strip and is bound by the HCV recombinant antigens striped on the T line, forming a purple colored band. If the specimen does not contain HCV antibodies or the level of the HCV specific antibodies in the specimen is below the detectable level, the T line will not be visible. The C line is striped with rabbit anti-protein A antibody, which should be bound to the protein A conjugate regardless of the presence of the anti-HCV antibody.

**STORAGE AND STABILITY**

Store kit at room temperature 59-86°F (15-30°C). Kit contents are stable for at least 2 years or until the date printed on the label, which ever comes first.

Do not freeze the kit as this may cause malfunction of the kit. Exposing the kit to the temperatures over 30°C will reduce the shelf life of the kit. For example, one week at 45°C will reduce the shelf life of the kit by 10 weeks.

**MATERIALS REQUIRED BUT NOT SUPPLIED:**

1. Test Device
2. Wash Buffer
3. Instructions

**WARNINGS AND PRECAUTIONS**

1. This test is for *in-vitro* diagnostic use by professionals only.
2. Do not use after the expiration date.
3. Do not pipette any material by mouth. Do not smoke, eat or drink in areas where specimens or kits are handled.
4. Individuals performing the test should wear protective clothing such as laboratory coats and disposable gloves

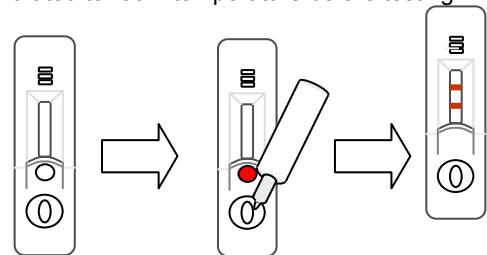
- while collecting and testing samples and thoroughly wash hands afterwards.
5. All spills should be wiped up thoroughly with household bleach or other suitable disinfectant.
6. Treat all materials in the test as if they were infectious. Dispose of all specimens and used assay materials as if they contained infectious agents. Preferred methods are autoclaving for 60 minutes at 121° or incineration.
7. Avoid any contact of hands with eyes and nose during specimen collection and testing.
8. Prior to use, ensure that the product has not expired by verifying that the date of use is prior to the expiration date on the foil pouch.
9. The foil pouch containing the test strip must remain completely sealed before use. Do not use if the foil pouch seal is not intact.
10. Follow proper handling and disposal procedures because blood specimens are potentially infectious.
11. Avoid cross-contamination of specimens by using a new pipette or dropper for each specimen.

**SPECIMEN COLLECTION**

1. This test can be performed on serum samples only.
2. Collect specimen following standard clinical procedure.
3. Testing should be performed as soon as possible after sample collection. Do not leave samples at room temperature for more than 24 hours. Specimens can be refrigerated at 2-8°C for up to 7 days. Otherwise store specimens below 20°C for prolonged periods.
4. Specimens should be shipped in compliance with Federal regulations concerning the transportation of etiologic agents.

**TEST PROCEDURE**

1. Read the entire procedure carefully before performing tests.
2. Refrigerated specimens or other materials must be equilibrated to room temperature before testing.



3. Remove the HCV test device from foil pouch. Place the test device on a flat surface. Dispense 20 ul of serum specimen using a professional micropipettor onto the sample pad of the test device. DO NOT use more than 20 ul specimen for testing. Excess specimen may produce false results.
4. Add three drops of Test Buffer (150 ul) to the sample pad of the test device.

*Note: If migration is not observed in 30 seconds in the results window, add one or two extra drops of wash buffer.*

5. Wait 5 minutes before interpreting results. Discard the device after 10 minutes.

**IMPORTANT: Do not read the test after ten (10) minutes.**

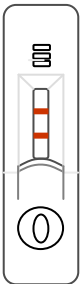
### INTERPRETATION OF RESULTS



1. Positive Result  
Two colored lines appear in the results window, one in the control area and one in the test area. This indicates the presence of antibodies to HCV. The test result can be read as soon as a distinctive pink-purple line appears in the test area. In most strong positive cases, the test line will appear before the control line. When the level of antibodies to HCV is very low, the Test line may be very light purple.



2. Negative Result  
Only one colored line in the results window, in the control area, with no distinctive colored line in the test area. This indicates that no antibody to HCV was detected.



3. Invalid Result  
A distinct colored line should always appear in the control area. The test is invalid if no line forms in the control area.

### LIMITATIONS OF THE PROCEDURE

1. This test is for in vitro diagnostic use only.
2. This test will only indicate the presence of antibodies to HCV in the specimen and should not be used as the sole criteria for the diagnosis of hepatitis C viral infection.
3. The results must be evaluated with other data by a physician before making diagnosis.
4. If the test result is negative and suspension exists, additional follow-up testing using other clinical methods is recommended. A negative result at any time does not preclude the possibility of early infection of Hepatitis C virus.
5. There are 8 different variants of HCV viruses. This HCV test detects antibodies to Type I, II, and III only.

### LITERATURE REFERENCES

- <sup>1</sup> Choo, Q L , G Kuo, A J Weiner, L R Overby, D W Bradley, and M Houghton Isolation of a cDNA clone derived from a blood-borne non- A, non-B viral hepatitis genome. Science 1989; 244:359
- <sup>2</sup> Kuo, G , Q L Choo, H J Alter, and M. Houghton. An assay for circulating antibodies to a major etiologic virus of human non-A, non-B hepatitis. Science 1989; 244:362
- <sup>3</sup> van der Poel, C L , H T M Cuypers, H W Reesink, and P N Lelie. Confirmation of hepatitis C virus infection by new four-antigen recombinant immunoblot assay. Lancet 1991; 337-377
- <sup>4</sup> Wilber, J C Development and use of laboratory tests for hepatitis C infection: a review J Clin Immunoassay 1993; 16:204