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## OneStep HCV Serum RapiFlo InstaTest

<b>Cat. No. 118770-1</b>
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### Description and Intended Use

The HCV Flow Through test is a rapid, qualitative test for the detection of antibodies to Hepatitis C virus in human serum or plasma, principally with fresh samples. This test is intended primarily as an initial screening test and reactive samples should be confirmed by a supplemental assay such as an ELISA test or RIBA blot assays.

### Background

Hepatitis C virus (HCV) is now known to be the major cause of parenterally transmitted non-A, non-B hepatitis. Until the virus was characterized, diagnosis was made by exclusion of all other known causes of hepatitis. Antibody to HCV is found in over 80% of patients with well documented non-A, non-B hepatitis. The worldwide prevalence of HCV is 0.2 to 2% in blood donors and up to 80% in intravenous-drug users. In a large percentage of HCV cases, transmission is by transfusion and other parental means such as sharing of needles, occupational exposure to blood and hemodialysis. However, in close to half of HCV infections, the route of transmission is unknown.

HCV establishes a chronic infection in 50 to 80% of cases. Chronic infection is often asymptomatic even in the presence of liver damage discernible on biopsy. Chronic HCV is characterized by fluctuating alanine aminotransferase levels and recognizable changes in liver histology. Chronic infection can lead to cirrhosis and hepatocellular carcinoma.

Cloning of the viral genome made it possible to develop serologic assays even though the virus had not been visualized by electron microscopy or grown in cell culture. Figure 1 (on page 3) shows the map of the putative functional regions of the HCV genome and derivations of the HCV antigens.

### Principles of the Tests

The test involves capturing of antibodies to HCV by immunodominant proteins of the virus immobilized onto a porous membrane. After washing, the presence of antibodies is revealed by treatment with conjugate which will bind to absorbed HCV antibodies, forming a red spot on the membrane.

An additional reagent control spot has been applied onto the membrane to check for the reactivity of the reagents on the kit. In practice therefore, the test has been designed so that one red spot appears (the control spot) if the sample is non-reactive, and two red spots appear if the sample contains HCV antibodies.

### Kit Content

1. Test devices: 25 pcs.
2. Buffer solution in dropper bottle (blue cap): contains sodium azide as preservative.
3. Wash solution in dropper bottle (red cap): contains sodium azide as preservative.
4. Protein-A Gold conjugate in dropper bottle (white cap): contains sodium azide as preservative.
5. Transfer pipettes.

### Precautions for User and General Safety Instructions

1. For in-vitro use only.
2. Do not use after expiration date.
3. Do not use reagents from different kits.
4. Store reagents 2-8 degrees Centigrade. Do not freeze.
5. Devices should be kept dry in the recloseable foil pouch with dessicant. Allow the devices and pouch to equilibrate to room temperature before opening the pouch to avoid condensation of moisture onto the devices. Always reseal the foil pouch after use.
6. Do not smoke, eat or drink in areas where testing is conducted.
7. Do not mouth pipette. Universal precautions should be practiced. PVC gloves and proper protective eyewear and clothing should be worn. Wash hands thoroughly afterwards.
8. Infectious specimens and nonacid-containing spills should be wiped thoroughly with 5% sodium hypochlorite.
9. All waste materials should be properly disinfected before disposal. Liquid and solid wastes should be autoclaved for at least 1 hour at 121.5 degrees Centigrade.
10. Once the assay has been started, all subsequent steps should be completed without interruption and within the recommended time limits.

### Specimen Collection and Preparation

This test can be performed on either serum or plasma. It is recommended that fresh samples be used if possible. If this is not possible, samples should be stored in a refrigerator (2-8°C) before being analyzed. For long term storage, specimens should be frozen at -20°C.

#### Frozen specimens:

The test works best when used with fresh samples that have never been frozen and thawed. However, most frozen samples will work well if the suggested procedure below is followed:

1. Allow the sample to thaw in a vertical position in a rack. Do not agitate the sample. This allows particles to settle to

the bottom of the tube/vial. Alternatively centrifuge the sample.

2. Insert a pipette just below the surface of the sample to obtain one drop of the sample for the test, being careful not to take any particulate into the pipette.

If this procedure still results in a very slow flow and/or high background, make a dilution of 1 part of sample with 3 parts of the buffer solution (blue cap bottle). Use only 1 drop of this diluted sample for the test.

### Test Procedures

Label one device for each test sample. **DO NOT REUSE DEVICES.** When adding the samples and solutions to the device, be sure to allow them to soak through the membrane before proceeding to the next step. Solutions or sample should only be added to the inner circle of the device.

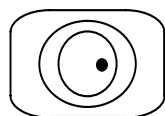
1. Dispense 2 drops of buffer solution from the blue top dropper bottle into the device.
2. Add 1 drop of sample using the pipette provided.
3. Dispense 2 drops of buffer solution into the device.
4. Dispense 2 drops of wash solution from the red top dropper into the device.
5. Dispense 2 drops of Protein-A gold conjugate from the white top dropper bottle into the device.
6. Dispense 3 drops of wash solution into the device.
7. Read results within 10 minutes for easiest interpretation.

### Interpretation of Results

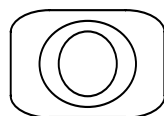
1. Two red spots appearing in the inner circle indicates a positive reaction. Any degree of redness should be considered as positive.
2. Only one red spot appearing indicates a negative reaction.
3. No red spot at all or a totally red membrane indicates an invalid result. If a slight pink color develops on the entire surface of the membrane, this may be the result of a lipemic sample or particulate in the sample, and the sample should be diluted one part sample with two part buffer (blue top bottle) and retested.



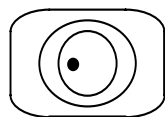
**Positive Result**



**Negative Result**



**Invalid Result**



**Negative Result**

### Limitations of the Procedure

1. Use fresh samples whenever possible. Frozen and thawed samples (especially repeatedly) contain particulates which can block the membrane. This slows the flow of reagents and can lead to high background color, making the interpretation of results difficult. (See remarks on Frozen Specimens)
2. Optimal assay performance requires strict adherence to the assay procedure described in this insert sheet. Deviations may lead to aberrant results.
3. Lipemic, hemolyzed, icteric or heat inactivated sera may cause erroneous results.
4. As with other serological assays, the results of these assays should be used in conjunction with information available from clinical evaluation and other diagnostic procedures.

### Bibliography

1. Alter, H.J., R.H. Purcell, J.W. Shih, J.C. Melpoider, M. Houghton, Q.L. Choo, and G. Kuo. 1989. Detection of antibody to hepatitis C virus in prospectively followed transfusion recipients with acute and chronic non-A, non-B hepatitis. *N. Engl. J. Med.* 321:1494-1500.
2. Houghton, M., A. Wiener, J.Han, G, Kuo, and Q.L. Choo. 1991. Molecular biology of the hepatitis C viruses: implications for diagnosis, development and control of viral disease. *Hepatology* 14:381-388.
3. Wilbur, J.C., 1993. Development and use of laboratory tests for hepatitis C infection: a review. *J. Clin. Immunoassay* 16:204-207

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Figure 1

