

Instructions For Use  
 \* Please carefully read the instructions before use

# Sirin Diagnostics One Step HCV Test

(HCV Test Cassette)

Format: Cassette  
 Specimen: Serum/Plasma

## INTENDED USE

The Sirin Diagnostics One Step HCV Test is a rapid and convenient immuno- chromatographic assay for qualitative detection of antibodies against HCV in human serum/plasma sample. It is intended for professional use as an aid in diagnosis of Hepatitis C Virus (HCV) infection. This assay provides only a preliminary result. Clinical expertise and professional judgement should only be sought to further evaluate the result of the test.

## SUMMARY

Hepatitis C Virus (HCV) is a leading cause of hepatitis. The worldwide prevalence of HCV is 0.2% to 2% in blood donors and up to 80% in intravenous drug users. Hepatitis C virus (HCV) is a single-stranded RNA virus that causes acute chronic hepatitis. The viral particles are transmitted through exposure of infectious body fluids or blood, blood transfusion, and use of contaminated needles or syringes. Chronic hepatitis may progress to severe outcomes without prompt medical intervention including cirrhosis and liver cancer (hepatocellular carcinoma). Diagnosis of HCV infections could be based on serological tests.

## PRINCIPLE

The Sirin Diagnostics® One Step HCV Test is an antibody-capture immunochromatographic assay, detecting HCV antibodies in blood specimens. The membrane is pre-coated with specific HCV antigens on the test line region (T) and goat anti-mouse on the control line region (C). During testing, the specimen is allowed to react with the gold-colored conjugate (specific HCV antigens-colloidal gold conjugate), which has been pre-dried on the test. The mixture then moves upward on the membrane chromatographically by the capillary action. For a positive result, a pink-colored line with the specific HCV antigens-gold conjugate complex will form in the test line region (T) of the membrane. Absence of this pink-colored line in the test line region (T) indicates a negative result. To serve as an internal process control, the control line should always appear in the control region (C) after the test is completed indicating that the test is performed properly and the reagents of the test are working. Absence of the colored line in the control region is an invalid result regardless of the presence or absence of the test line.

## MATERIALS PROVIDED

The Sirin Diagnostics® One Step HCV Test contains the following items to perform the assay:

- One Step HCV Test Device
- Instruction for use
- Pipette

## MATERIALS REQUIRED

- Clock or timer
- Sample container
- Glove
- Sterile lancet

## WARNING AND

- Read instruction for use carefully before performing this test.
- For in vitro diagnostic use only.
- Do not use the test device beyond the expiration date.
- The test device should remain in the sealed pouch until use. Do not use the test device if the pouch is damaged or if the seal is broken.
- Do not reuse the device.
- Treat and properly handle the specimens and used device as if they were potentially infectious. Dispose all specimens and used devices in a proper bio-hazard container. The handling and disposal of the hazardous materials should follow local, national, or regional regulating regulations.
- There should be no eating, drinking or smoking where specimens are being handled.
- Do not mix and interchange different specimens.
- Wear disposable gloves, lab coat and eye protection while handling potentially infectious materials and performing the assay. Wash hands thoroughly afterwards.

- Clean spills thoroughly using an appropriate disinfectant.
- Keep out of children's reach.
- Do not swallow the desiccant

## SPECIMEN PREPARATION

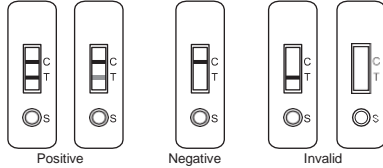
- Centrifuge whole blood to get serum or plasma specimen.
- If specimen is not tested immediately, it should be refrigerated at 2-8°C. For storage period greater than three days, freezing is recommended. Such specimen should be brought and equilibrated to room temperature prior to use.
- Serum containing precipitate may yield inconsistent test result. Such specimens must be clarified prior to assaying.

## TEST PROCEDURE

Review specimen preparation instructions and bring the pouched test device to room temperature (15-30°C) prior to testing. Do not open pouch until ready to perform the assay.

- Remove the test device from its protective pouch.
- Place the test device on a clean and level surface.
- Use the pipette to draw and slowly add 1 drop of serum/plasma to the sample well.
- Hold the dropper vertically and transfer 2 drops of buffer (approx. 40µl) to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S).
- Wait for colored lines to appear within 10-15 minutes. Do not interpret results after 15 min

## INTERPRETATION OF RESULTS



**Positive:** Two distinct, pink-colored lines appear, one in the test region (T) and one in the control region (C).

**NOTE:** The intensity of the pink color in the test region (T) may vary depending on the concentration of HCV present in the specimen. Therefore, any shade of pink color in the test region (T) should be considered positive.

**Negative:** Only one pink-colored line appears in the control region (C). No apparent pink line appears in the test region (T). **INVALID:** Control Line fails to appear.

**NOTE:** Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, please contact your local distributor.

## QUALITY CONTROL

Although the testing device contains an internal quality control (pink colored line in the control region), good laboratory practice recommends the daily use of an outside control to ensure proper testing device performance. Quality control samples should be tested according to the standard quality control requirements established by your laboratory.

## STORAGE AND STABILITY

The test device should be stored at 2-30°C in the sealed pouch. Avoid humidity, heat and direct sunlight. The test device is stable through the expiration date printed on the sealed pouch. **DO NOT FREEZE.**

## LIMITATION OF THE TEST

- This product is an in vitro diagnostic test designed for professional use only.
- Humidity and temperature can adversely affect test results.
- There is always a possibility that false results will occur due to the presence of interfering substances in the specimen or factors beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.
- Although the test demonstrates superior accuracy in detecting HCV infections, a low incidence of false results can occur. Therefore, other clinically available tests are required in case of questionable results. 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 all clinical and laboratory findings have been evaluated.

## PERFORMANCE

- Diagnostic Sensitivity

A multi-center prospective study was conducted to evaluate the diagnostic sensitivity of Sirin Diagnostics One Step HCV Test in serum/plasma specimen. A total of 430 positive samples from patients clinically diagnosed as HCV positive were tested with Sirin Diagnostics One Step HCV Test and the tests were compared with that of a CE marked HCV test. Of the 430 HCV positive samples, 428 were tested positive and 2 were tested negative by the Sirin Diagnostics One Step HCV Test. The three samples that were tested negative were further confirmed positive by a CMIA test. All of the samples with known HCV subtypes were tested positive. The diagnostic sensitivity of the Sirin Diagnostics One Step HCV Test was 99.53% (428/430).

Table 1 Summary of Diagnostic Sensitivity of Sirin Diagnostics One Step HCV Test

Genotype	Results of Sirin Diagnostics One Step HCV Test		Results of CE Marked EIA Test		Subtotal
	Positive	Negative	Positive	Negative	
1	1a	6	0	6	53
	1b	47	0	47	
2	2a	26	0	26	39
	2b	10	0	10	
	2a/2b	3	0	3	
3	3a	19	0	19	31
	3b	12	0	12	
	4	8	0	8	
4	4a	8	0	8	22
	4c/4d	6	0	6	
	5a	9	0	9	
6	6a	25	0	25	34
	6e	9	0	9	
	1b/2a	4	0	4	
Unknown genotype	236	2	238	0	238
Subtotal	428	2	430	0	430

## 2. Diagnostic Specificity

A multi-center prospective study was conducted to evaluate the diagnostic specificity of Sirin Diagnostics One of 1740 negative samples were collected from different populations including blood donors, inpatients, pregnant women, and patients with potentially interfering diseases. These samples were tested with the Sirin Diagnostics One Step HCV Test and the results were compared with that of a CE marked HCV. Of the 1740 negative samples, 8 were tested positive by Sirin Diagnostics One Step HCV Test. The diagnostic specificity of Sirin Diagnostics One Step HCV Test was 99.54% (1732/1740), and the false positive rate was 0.46% (8/1740).

Table 2 Summary of Diagnostic Specificity One Step

	Results of Sirin Diagnostics One Step HCV Test		Results of CE Marked EIA Test		Subtotal
	Positive	Negative	Positive	Negative	
Blood Donors	1096	4	1097	3	1100
inpatient	199	1	200	0	200
Pregnant Women	199	1	199	1	200
Potentially interfering diseases	238	2	239	1	240
Subtotal	1732	8	1735	5	1740

## 3. Analytic Sensitivity

### Reactivity with Low Titer HCV Antibody Performance Panel and Worldwide Panel

A low titer HCV antibody panel consisting of 13 members and a worldwide panel consisting of 20 members derived from a multiple geographics representing six genotypes and 12 subtypes (1a, 1b, 2a, 2b, 3, 3a, 4, 4a, 5a, 6, 6a, and 1), were tested with the Sirin Diagnostics One Step HCV Test and the CE marked HCV Test. Study results demonstrated that the Sirin Diagnostics One Step HCV Test was capable of detecting HCV and its sensitivity was similar to that of the CE licensed HCV Test.

## 4. Analytic Specificity

In order to evaluate the specificity of the Sirin Diagnostics One Step HCV Test, 115 normal negative specimens and 85 negative specimens containing the following seromarkers were tested: hepatitis A virus IgM (anti-HAV), herpes simplex virus IgG (HSV), cytomegalovirus (CMV) IgG/IgM, Epstein-Barr Virus (EBV), IgG/IgM, human T-Lymphotropic virus (HTLV), rubella IgM (RV), anti-E. Coli, Helicobacter pylori IgM, C-reactive protein (CRP), antistreptolysin O titre (ASOT), rheumatoid factor (RF). Results demonstrated that Sirin Diagnostics One Step HCV Test has no significant cross-reactivity with the seromarkers listed above.

## 5. Interference

The following substances and conditions were found not to interfere with the test. List of potentially interfering compounds (chemical analytes and biological analytes) and concentrations tested are as follows:

Chemical analytes	Concentrations	Chemical analytes	Concentrations
Acetaminophen	200 ug/ml	Methaqualone	200 ug/ml
Acetylsalicylic Acid	200 ug/ml	Pendimetrazine	200 ug/ml
Amikacin	200 ug/ml	Penicillin G	200 ug/ml
Ascorbic acid	200 ug/ml	Quinine	200 ug/ml
Aspartame	200 ug/ml	Randitidine	200 ug/ml
Atrophine Sulfate	200 ug/ml	Sodium Salicylate	200 ug/ml
Benzoic Acid	200 ug/ml	Tryptophan	200 ug/ml
Caffeine	200 ug/ml	Tricyclics	200 ug/ml
Decoxyephedrine	200 ug/ml	Tetrahydrozoline	200 ug/ml
Dextromethorphan	200 ug/ml	Ethanol	1%
EDTA	800 ug/ml	Methanol	1%
Genetic acid	200 ug/ml	Heparin	1%
Histamine	200 ug/ml	Citrate	3.2%
Biological Analytes	Concentrations	Biological Analytes	Concentrations
Albumin	2 mg/ml	Bilirubin	2 mg/ml
Glucose	2 mg/ml	Hemoglobin	2 mg/ml

## 6. Reproducibility

Three lots of the Sirin Diagnostics One Step HCV Test were tested with both positive and negative samples to evaluate its precision. The resultant data indicated that all three lots of the test were able to produce accurate and consistent results.

## REFERENCES

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- Colombo M, Rumi MG, Donato MF, et al. Hepatitis C antibody in patients with chronic liver disease and hepatocellular carcinoma. Dig Dis Sci 1991; 36:1130-3
- Simmonds P, Holmes EC, Cha TA, et al. Classification of hepatitis C virus into six major genotypes and a series of subtypes by phylogenetic analysis of the NS-5 region. J Gen Virol 1993; 74:2391-9
- CDC, Updated U.S Public Health Service Guidelines for the Management of occupational Exposures to HBV, HCV, and HIV and Recommendations for Post-Exposure Prophylaxis. MMWR 2001; 50 (RR-11):1-42.
- Choo Q-L, Weiner AJ, Overby, LR, et al. hepatitis C virus: the major causative agent of viral non-A, non-B hepatitis. Br Med Bull 1990; 46:423-41
- S. Osborne, E. et al, Expression in E. coli and purification of a chimeric p22-NS3 recombinant antigen of Hepatitis C Virus (HCV). Federation of European Biochemical Societies, Volume 324, number 3, 253-257

## INDEX OF SYMBOLS

	Do not re-use		Manufacturer
	In vitro diagnostic medical device		Use-by date
	Store at 2-30 °C		Consult instructions for use
	Authorized representative in the European Community		Batch code
	Contains sufficient for <n>tests		CE Mark
	Caution		Catalogue number

## MANUFACTURER



Sirin Diagnostics

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