■ Test Procedure



Read the results within next 10 minutes

■ Interpretation of Results

Note: Results should not be read beyond 10 minutes







One dot at C

Two dots at T & C

Dot only at T

No Dot

Ordering Information

Product	Code No.	Pack size
Signal* HCV ver. 3.0	53FT201-10	10 Tests
	53FT201-50	50 Tests



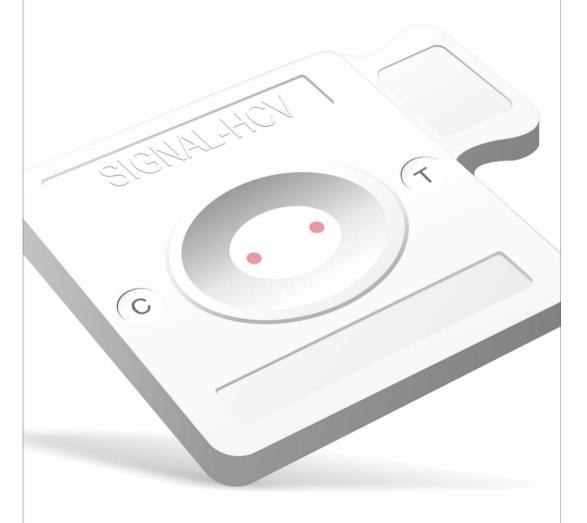
THE MANUFACTURING SITE'S QMS IS CERTIFIED FOR ISO 13485:2003, ISO 9001:2008

(Comprises of former IVD business undertaking of Span Diagnostics Ltd.)
Plot No. 336, 338, 340, Road No. 3, G.I.D.C., Sachin - 394 230, (Surat), INDIA.
Telephone: 0261-239 7712 to 15, Facsimile: 0261-239 7719, Website: www.arkray.co.in
Specifications may change without prior notice









Flow through

immunodot test format for detection of

Antibodies to Hepatitis C in serum or plasma

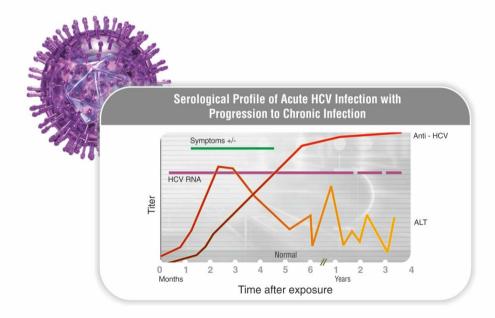
■ Fact File

WHO estimates that up to 3.0% of the world's population has been infected with HCV. HCV is one of the major cause of acute hepatitis & chronic liver disease, including cirrhosis & liver cancer. Worldwide, there may be more than 170 million chronic carriers of HCV.

In India, there are about 12-13 million HCV carriers & modeling data predict that the burden of disease could soon increase substantially. The major causes of HCV infection worldwide are use of unscreened blood in transfusions and re-use of needles & syringes.

Statistically, as many people are infected with HCV as are with HIV. In absence of concentrated efforts to contain the spread of HCV, viz. timely & accurate diagnosis and treatment of the infected populations, the death rate by HCV will undoubtedly surpass that of AIDS in foreseeable future. In absence of effective vaccination against HCV, accurate diagnosis and treatment are the only tool to reduce a risk of HCV transmission.

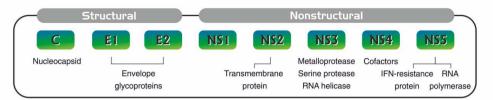
Detection of anti HCV antibodies specific to HCV is the only reliable marker for the accurate and early diagnosis of HCV infection.



■ Nucleus of Signal HCV ver. 3.0

HCV, isolated from different populations, including that from India, shows significant variations in their nucleotide sequences. Each of the major genotypes differs in their biological behavior and aminoacid sequences of various structural and nonstructural proteins that comprises the viral genome. Signal *HCV* Ver 3.0 overcomes these difference by offering mosaic recombinant antigen from both "Structural" and "Non structural" regions, representing about 60% of HCV genome.

Organization of HCV Genome



Signal HCV_{Ver. 3.0} with mosaic recombinant antigens and new cassette color offer better performance. It is an advanced 3rd generation diagnostic test for the qualitative detection of antibodies to HCV in human serum or plasma.

Salient Features



Visual two dot flow through assay with inbuilt control dot to validate successful completion of assay procedure gives results in 10 minutes.



New cassette color with proprietary conjugate containing uniform sized gold particles ensures prominent appearance of dots for unambiguous interpretation of test results.



3rd generation improved test comprising mosaic recombinant antigens from the CORE, NS3, NS4 and NS5 genomic regions. Antigen immobilised on membrane, enables detection of low titer and low affinity antibodies in its early seroconversion stage.



Optimally designed test protocol with proprietary washing buffer ensures highest specificity by removing all non specific interfering proteins.



Unique cassette design with handle for maximum user safety and convenience along with self dropping bottles ensuring maximum ease of use.

■ Performance*



Specificity 100%