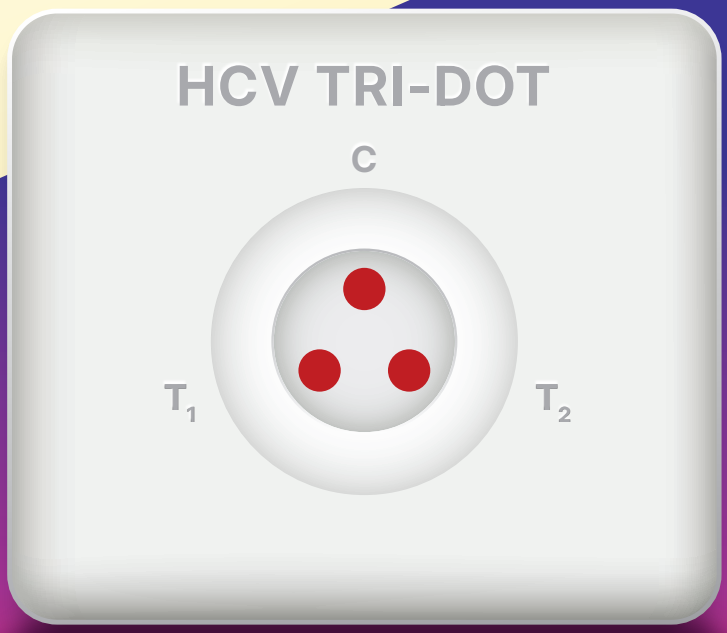
4TH GENERATION

HCV TRI-DOT

Rapid Visual Test for the Detection of Antibodies to Hepatitis C in Human Serum or Plasma

- High Sensitivity & Specificity
- In Built Quality Control
- Result in less than 3 min.
- Unique Combination of HCV Antigens Core, NS3, NS4 & NS5



1ST COMPANY IN INDIA

To be granted
Drug Manufacturing Licence for
HCV RAPID TEST

Licence approved by Drug Controller General of India, Ministry of Health & Family Welfare, Govt. of India.

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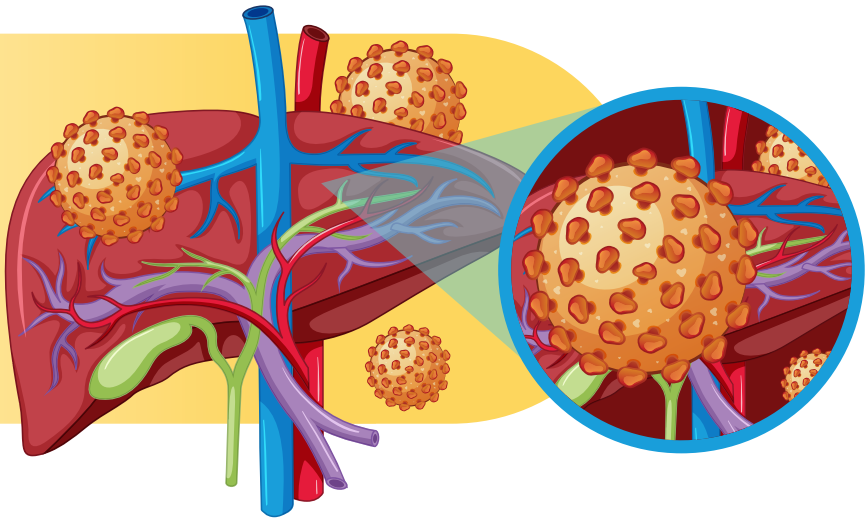


Introduction

Hepatitis C Virus was identified in 1989 as the main aetiological agent of non-A, non-B hepatitis (NANBH) accounting for greater than 90% of post-transfusion hepatitis cases. HCV is a spherical virus of about 30-60 nm in diameter with single positive stranded RNA and is related to the family flaviviridae. It is considered to be the major cause of acute chronic hepatitis, liver cirrhosis and hepatocellular carcinoma throughout the world. It is therefore necessary to correctly diagnose Hepatitis C infection.

The test for antibodies to HCV was proved to be highly valuable in the diagnosis and study of the infection, especially in the early diagnosis of HCV after transfusion. The diagnosis of hepatitis C can be easily made by finding elevated serum ALT levels and presence of anti-HCV in serum/plasma (Fig. 1).

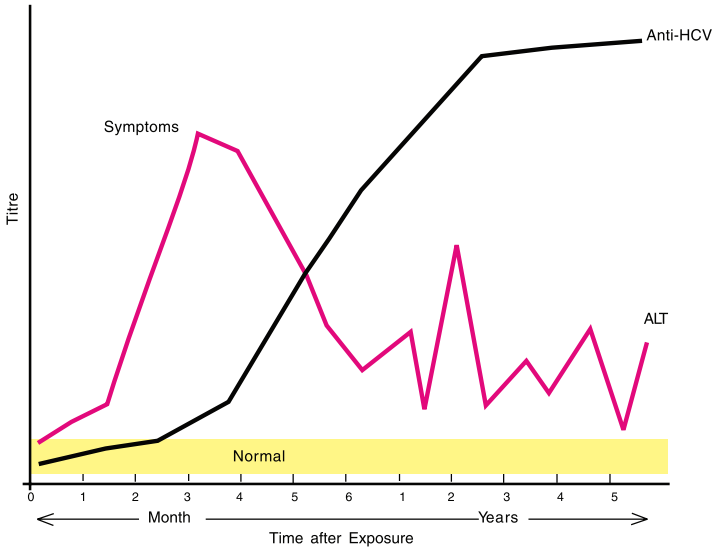


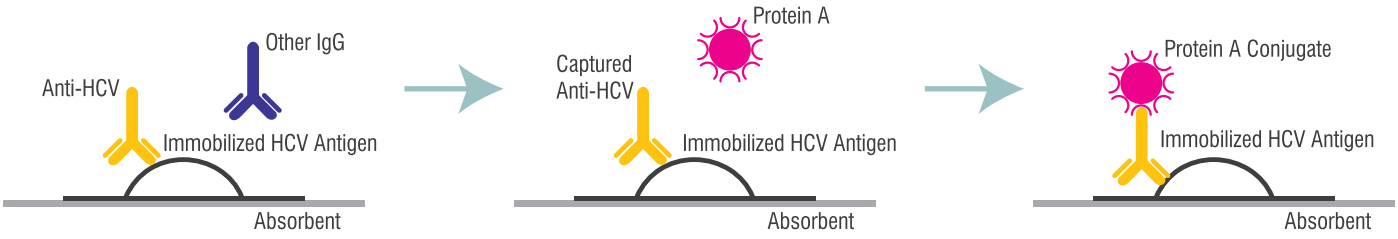
Fig. 1 Hepatitis C Virus Infection
Typical Serological Course

HCV TRI-DOT

The HCV TRI-DOT is a rapid, visual, sensitive, specific and qualitative in-vitro diagnostic test for the detection of antibodies to Hepatitis C Virus in human serum or plasma.

The HCV TRI-DOT has been developed and designed using a unique combination of HCV antigens for the putative core (structural), protease/helicase NS3 (non-structural), NS4 (non-structural) and replicase NS5 (non-structural) regions of the virus in the form of two test dots 'T_1' & 'T_2' to detect all the genotypes of HCV. The antigens used are chemically treated and unfolded in a special way to make the different epitopes of Core & NS3 antigens more reactive and specific to their respective antibodies thereby minimizing the chances of cross reactivity and enhancing the specificity. Also, the superior sensitivity of the test allows for the significantly earlier detection of antibodies during sero-conversion following HCV infection, thereby reducing the incidence of post transfusion hepatitis and providing a safer blood supply.

Principle



Simple to Perform

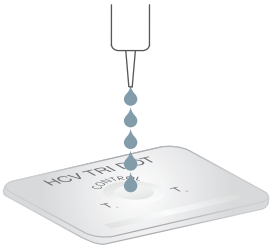
Add 3 drops of Buffer Solution to the center of device

Step 1

Add 1 drop of Serum/Plasma Sample

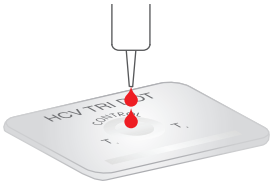
Step 2

Add 5 drops of Buffer Solution



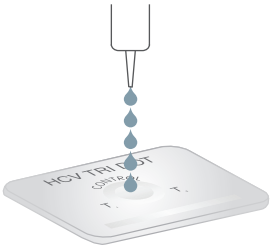
Step 3

Add 2 drops of Protein-A Conjugate



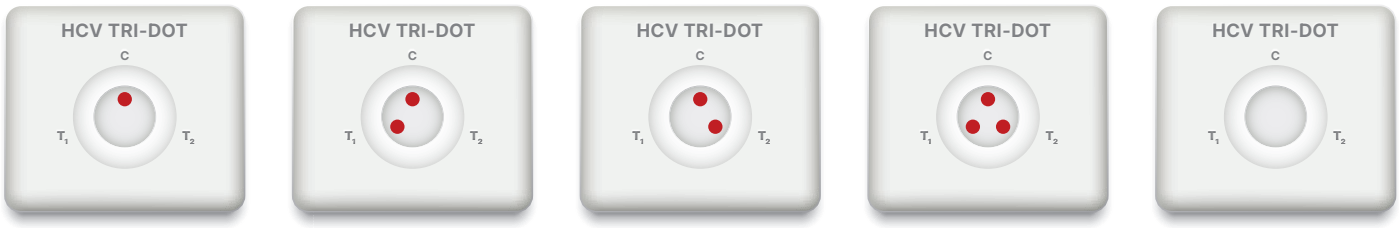
Step 4

Add 5 drops of Buffer Solution & READ RESULTS



Step 4

Test Interpretation



Non-Reactive

Reactive for HCV antibodies

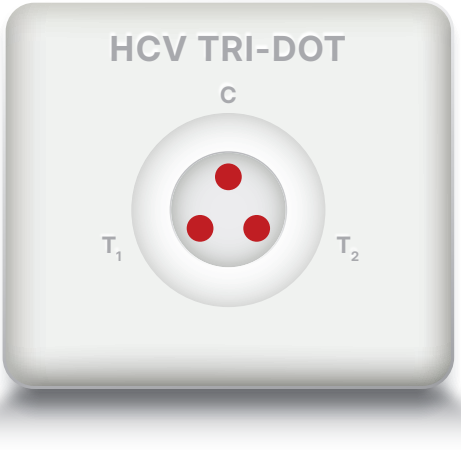
Reactive for HCV antibodies

Reactive for HCV antibodies

Invalid

Use of HCV TRI- DOT

- In Diagnostic Centers.
- In emergency and urgent testing situations.
- In small nursing homes and clinics.
- For Gastroenterologists who want to diagnose their patients.



Salient features of HCV TRI-DOT

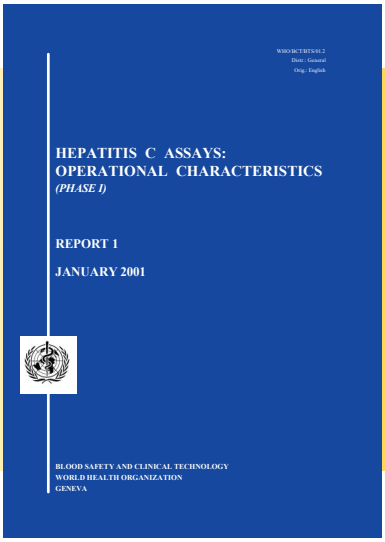
- Based on "Flow Through Technology", which is similar to Elisa Technology beacuse of involvement of washing steps at various levels to enhance the specificity
- Results in less than 3 minutes.
- In built quality contral dot which validates the test
- Excellent Sensitivity and Specificity
- Highly purified HCV antigens for Core, NS3, NS4, NS5 immobilized on the device
- Long Shelf Life: 24 Months at 2-8°C
- No Instrument required

Evaluation of HCV TRI-DOT

WORLD HEALTH ORGANIZATION (WHO), Geneva evaluation

Evaluated by WHO Geneva with **100% Sensitivity & 98.9% Specificity.** The samples included in the panels for evaluation were from Asian, European, Latin American and African origin.

Hepatitis C Assay: Operational Characteristics (Phase 11. Report. 2, July 2001. Blood Safety and Clinical Technology. World Health Organization, Geneva
Page No.: 14



PATH, USA evaluation

Evaluated by PATH, USA (Programe for Appropriate Technology in Health) with **100% Sensitivity & 99.2% Specificity.** The samples included in the panels for evaluation were from USA, India and Indonesia.

Evaluated by CMC Vellore with accuracy indices of 100% Sensitivity & 100% Specificity.

Performance of the test has been also determined by Drug Controller General of India at their reference centre National Institute of Biologicals, New Delhi.

*This information is provided for the Scientific Community Enquiring for an independent evaluation other thon company's in house evaluation. It is not for commercial or promotional purpose

Kit Presentation
10 Test Pack
50 Test Pack
100 Test Pack

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