Diagnostic Enterprises

4th Generation

HCV TRI-DOT

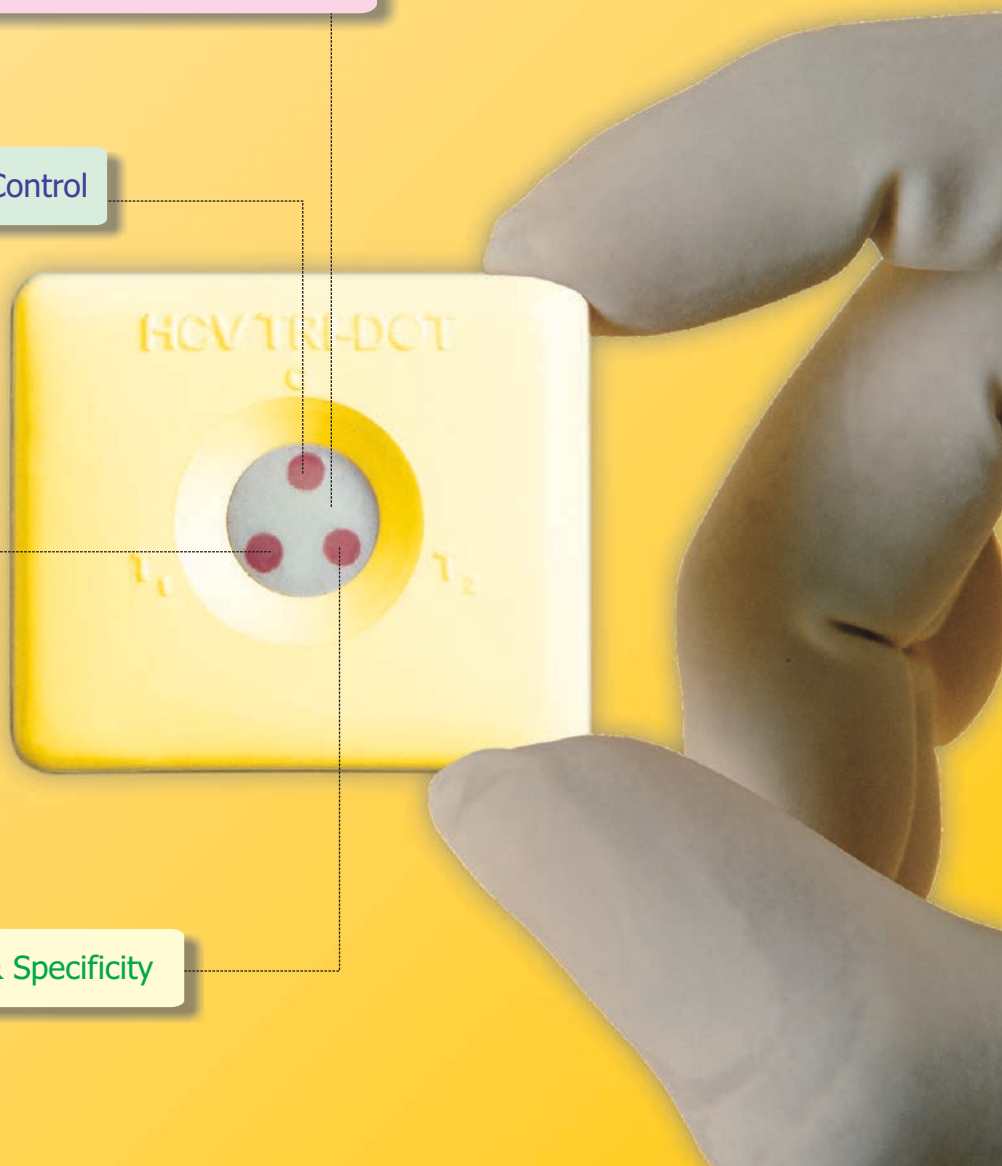
Rapid Visual Test for the Detection of Antibodies to Hepatitis C in Human Serum or Plasma

Unique Combination of HCV Antigens Core, NS3, NS4 & NS5

In Built Quality Control

Result in less than 3 min.

High Sensitivity & Specificity



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).

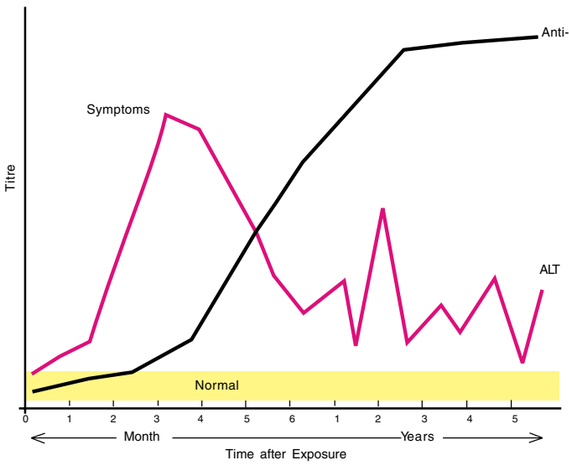


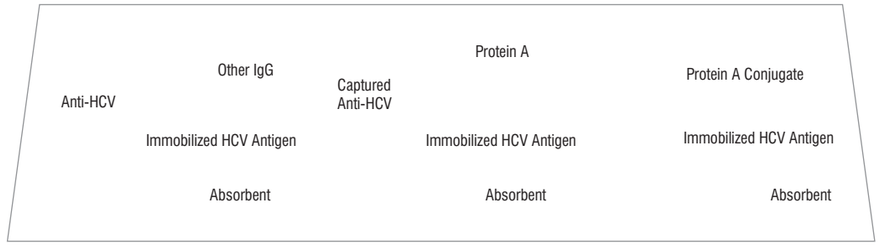
Fig. 1 Hepatitis C Virus Infection
Typical Serological Course

HCV TRI-DOT

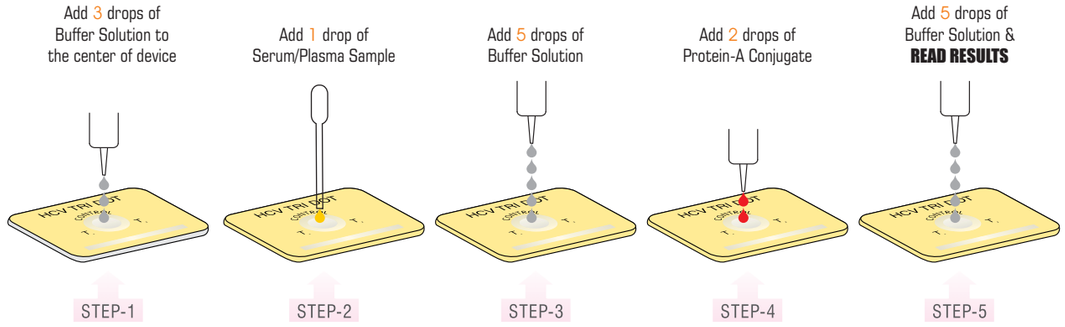
The HCV TRI-DOT is a rapid, visual, sensitive, specific and qualitative in-vitro diagnostic test for the detection of antibodies to Hepatitis C Virus in human serum or plasma.

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.

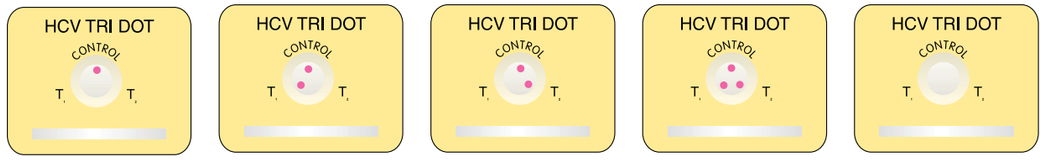
PRINCIPLE



SIMPLE TO PERFORM



TEST INTERPRETATION



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 control dot which validates the test
- Excellent Sensitivity and Specificity
- Highly purified HCV antigens for Core, NS3, NS4, NS5 immobilized on the device
- No Instrument required

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.

*EVALUATION OF HCV TRI-DOT

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.

Evaluated by Path (Programe for Appropriate Technology in Health USA) using specimens from USA, India and Indonesia. The Sensitivity is 100% and Specificity is 99.2% in this panel.

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

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 than company's in house evaluation. It is not for commercial or promotional purpose*

KIT PRESENTATION

10 Test Pack

50 Test Pack

100 Test Pack

for further information, please contact:

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