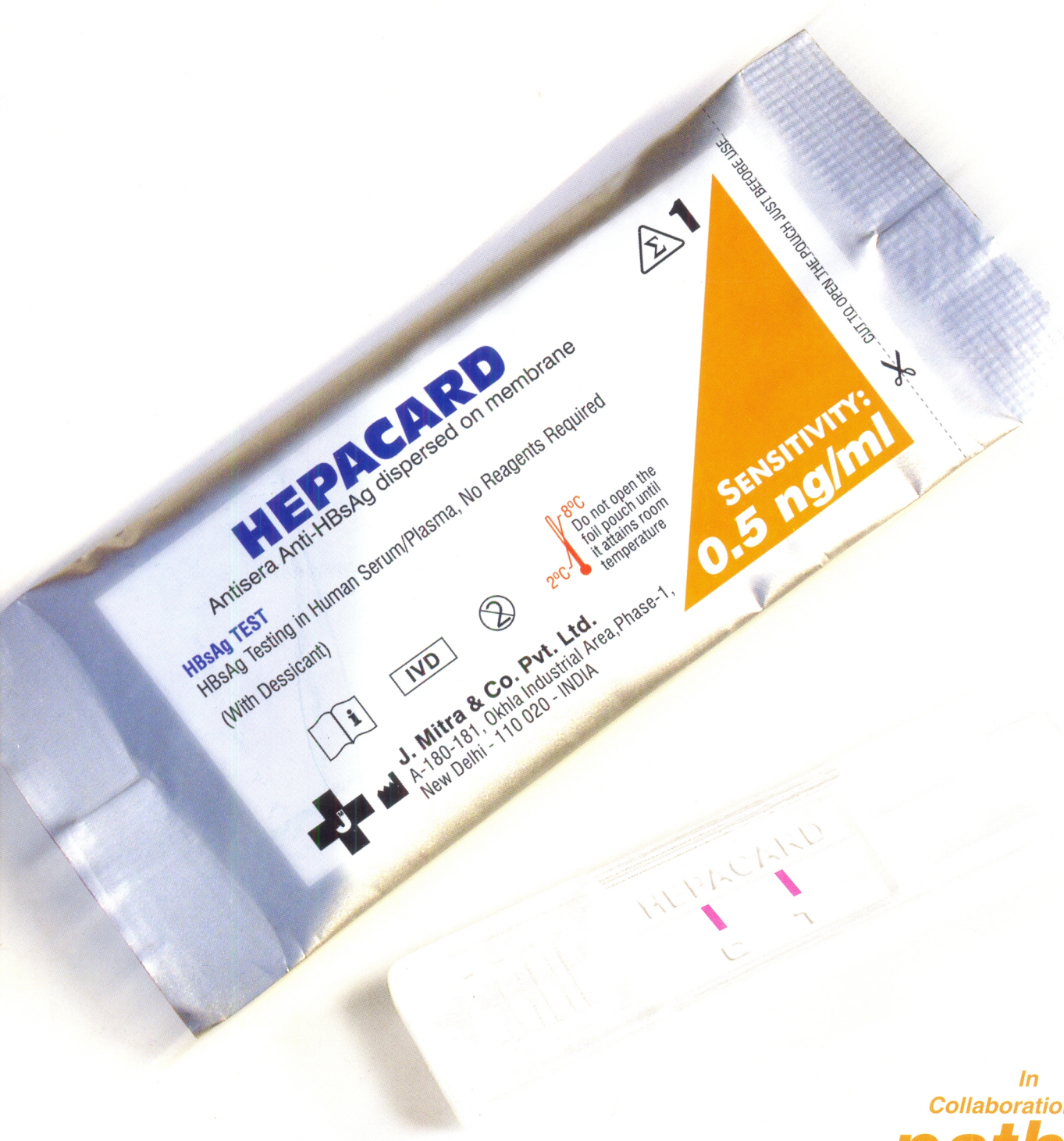
ISO 9001:2008 &
ISO 13485:2012

WHO GMP
CERTIFIED

HEPACARD

One Step, Rapid, Visual & Qualitative Immunoassay for HBsAg detection



In
Collaboration with
path U.S.A.
Program for Appropriate
Technology in Health

Sensitivity: 0.5ng/ml

HEPACARD

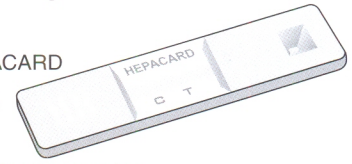
Salient Feature

- One step, rapid, visual and qualitative immunoassay
- See-through device introduced for the first time in India
- No sample preparation required
- Ready to use
- Shelf Life 18 months at 2-8°C
- 100% user safe as there is no direct contact of user with sample & strip. Thus limits the infection risk.

Simple to Perform

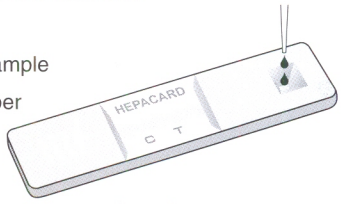
Bring the HEPACARD foil pouch and serum samples to room temperature prior to testing.

Take out the required number of HEPACARD test devices from the foil pouch.



Label the test card with patient's name or identification number.

Add 2 drops (70µl) of serum/plasma sample into the sample well using the dropper provided.



Allow reaction to occur during the next 20 minutes and **READ RESULTS**.

Test Interpretation

Reactive for HBsAg

Non-Reactive for HBsAg

Invalid

Performance Characteristics

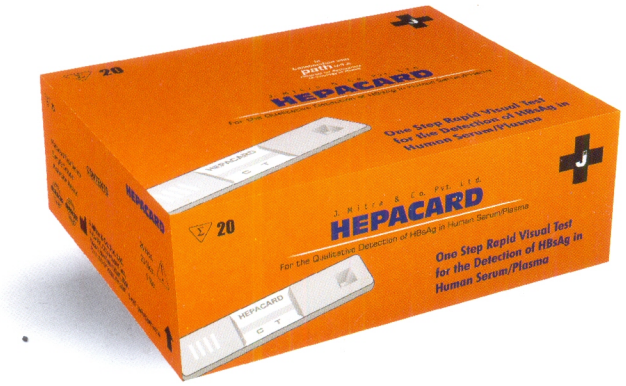
- It can detect all the **eleven** sub-types of HBsAg
- Sensitivity: 0.5 ng/ml
- ***Evaluation Reports:***
  - ***PATH (USA) Evaluation:*** Sensitivity: 100%* Specificity: 100%*
  - ***WHO Evaluation:*** Sensitivity: 100%* Specificity: 99.4%*

**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

20 Test Pack (Single Test Pouch packing)

100 Test Pack (Single Test Pouch packing)



For further information please contact:
J. Mitra & Co. Pvt. Ltd.
A 180-181, Okhla Industrial Area, Phase-1, New Delhi-110 020, INDIA
Ph.: +91-11-47130300, 47130500, 26818971-73
Fax: +91-11-26818970
E-mail: jmitra@jmitra.co.in Internet: www.jmitra.co.in

BR/HPC/009 R-03

ISO 9001:2008 &
ISO 13485:2012

WHO GMP
CERTIFIED

4th Generation

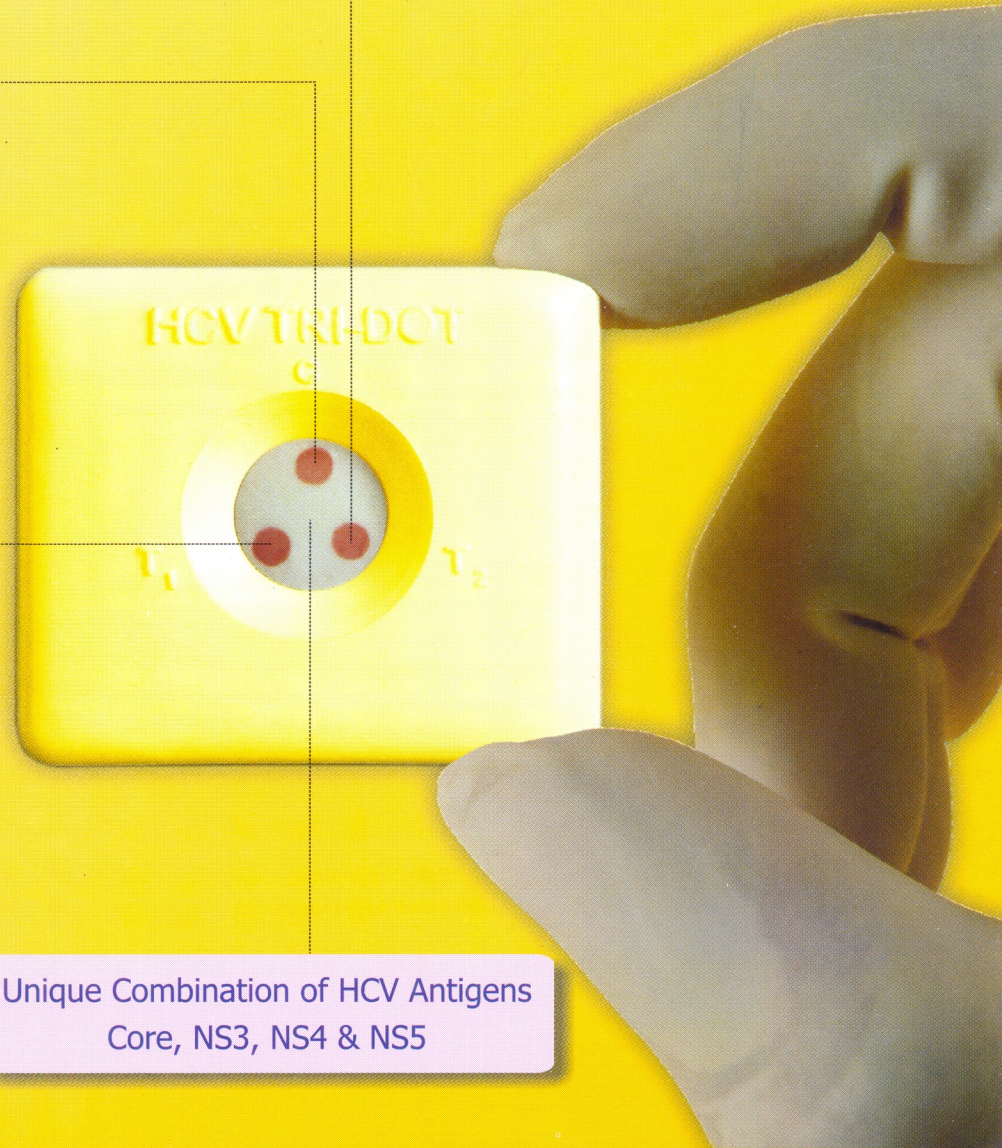
HCV TRI-DOT

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.



First company in India to be granted Drug Manufacturing Licence in HCV Rapid Test

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

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

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).

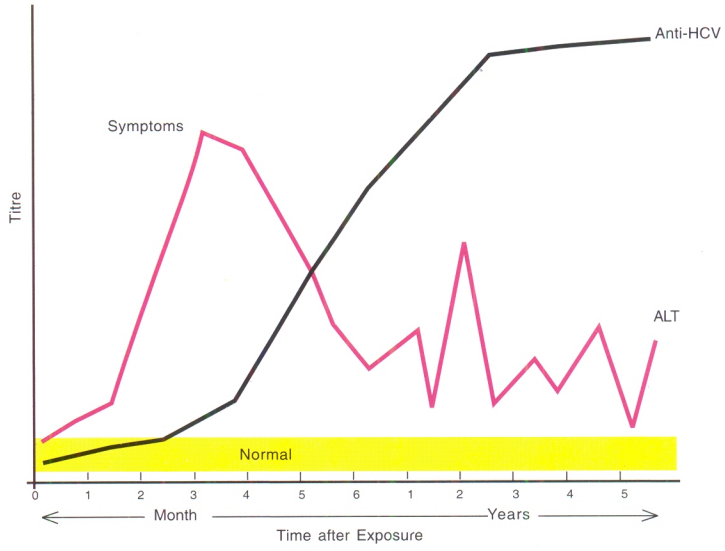


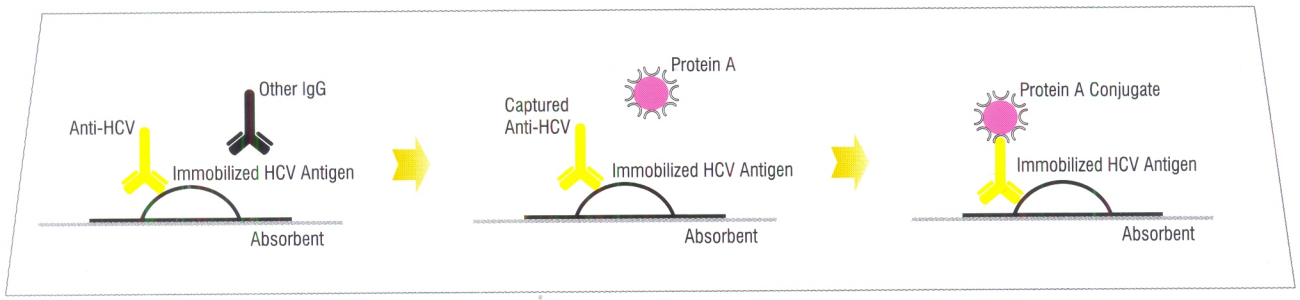
Fig. 1 Hepatitis C Virus Infection
Typical Serological Course

HCV TRI-DOT

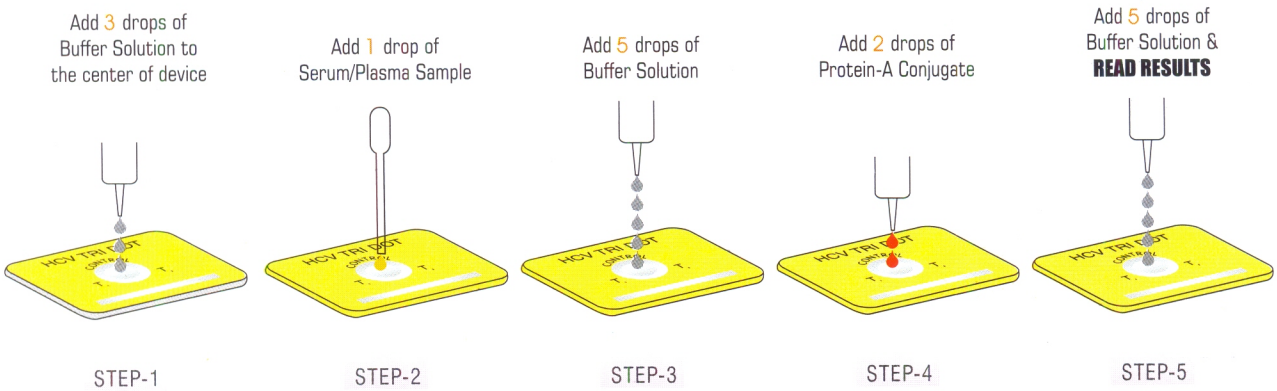
The HCV TRI-DOT is a rapid, visual, sensitive, specific and qualitative in-vitro diagnostic test for the detection of antibodies to Hepatitis C Virus in human serum or plasma.

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.

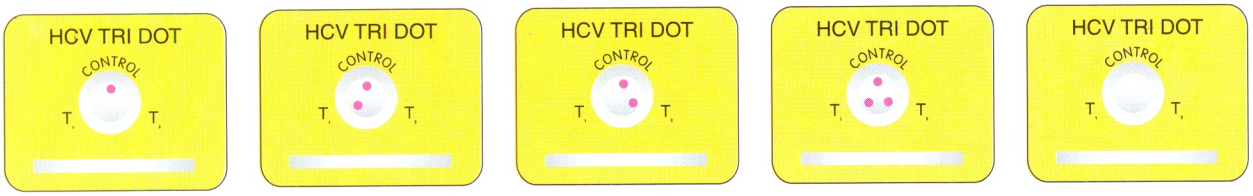
PRINCIPLE



SIMPLE TO PERFORM

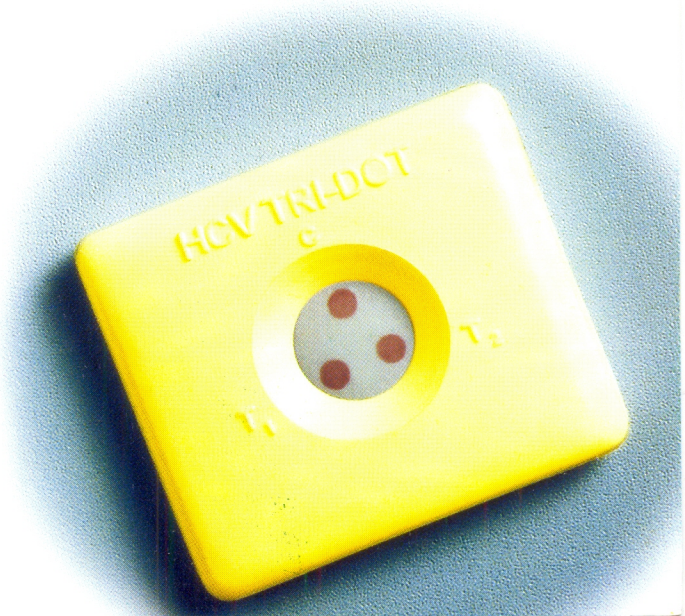


TEST INTERPRETATION



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.



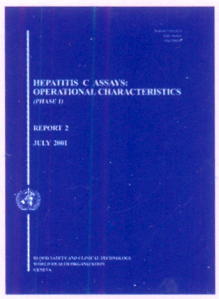
SALIENT FEATURES OF HCV TRI-DOT

- 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 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

*EVALUATION OF HCV TRI-DOT

WORLD HEALTH ORGANIZATION (WHO), Geneva

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 1), Report 2, July 2001, Blood Safety and Clinical Technology, World Health Organization, Geneva
Page No.: 14

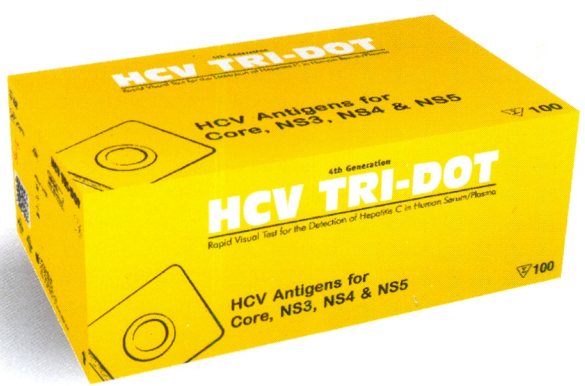
PATH, USA evaluation

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 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:

J. Mitra & Co. Pvt. Ltd.

A 180-181, Okhla Industrial Area, Phase-1, New Delhi-110 020. INDIA
Ph.: +91-11-47130300, 47130500, 26818971-73
Fax: +91-11-26818970
E-mail: jmitra@jmitra.co.in Internet: www.jmitra.co.in

J12403HCD

Accurate Results in Less than 3 minutes

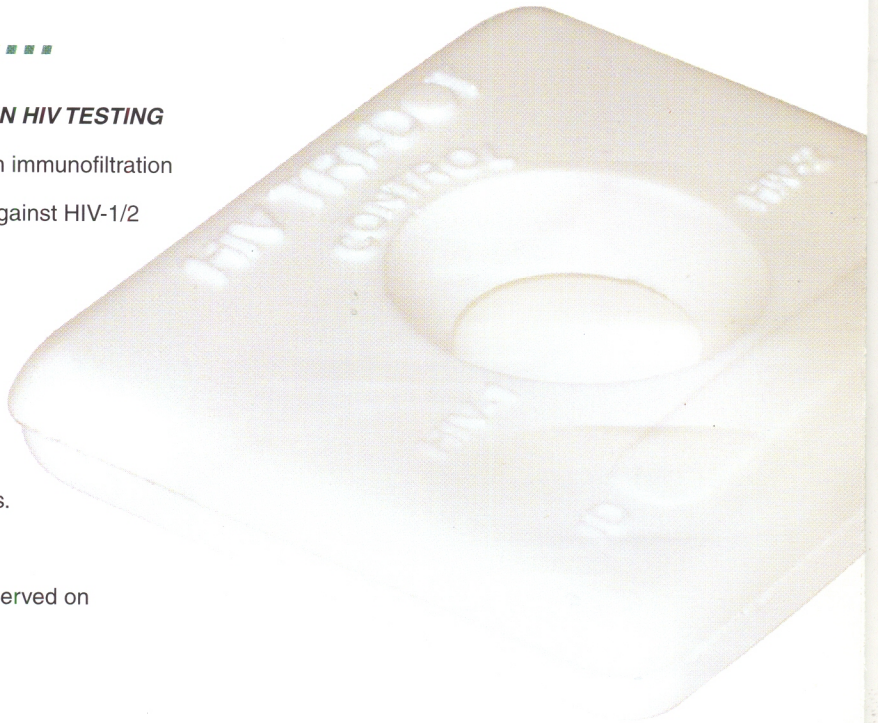
HIV TRI-DOT

Rapid Visual Test for the Differential Detection of antibodies to HIV-1 (including Group O & Subtype C) & HIV-2 in Human Serum or Plasma

ISO 9001:2008 &
ISO 13485:2003

WHO GMP
CERTIFIED

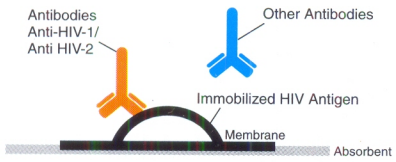
let's talk about technology that's dependable & reliable....



HIV TRI-DOT BASED ON FLOW THROUGH TECHNOLOGY IN HIV TESTING

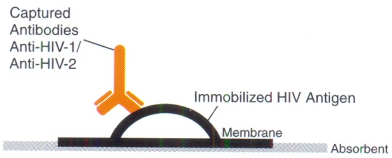
In flow through technology, HIV antigens are immobilized on an immunofiltration membrane. If the serum/ plasma sample contains antibodies against HIV-1/2 antigens, they will bind to the immobilized HIV-1/2 antigens. The sample will also contain other antibodies that are not specific to HIV-1/2 antigens. In this test the non-specific antibodies will be washed away during the washing step. The Protein A Gold conjugate is added as signal reagent, it binds to the Fc portion of anti-HIV-1 and anti HIV-2 antibodies. Unbound conjugate is washed away during the washing step performed after adding the conjugate. Finally the result are observed on the membrane in the form of test dots

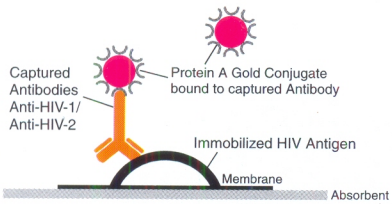
Antibodies bonding with Immobilized Antigen



In flow through technology antibodies to HIV-1/2 bind to the immobilized HIV antigen. Sample also contains other non-specific antibodies.

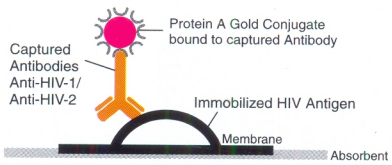
The non-specific antibodies are washed away by washing.





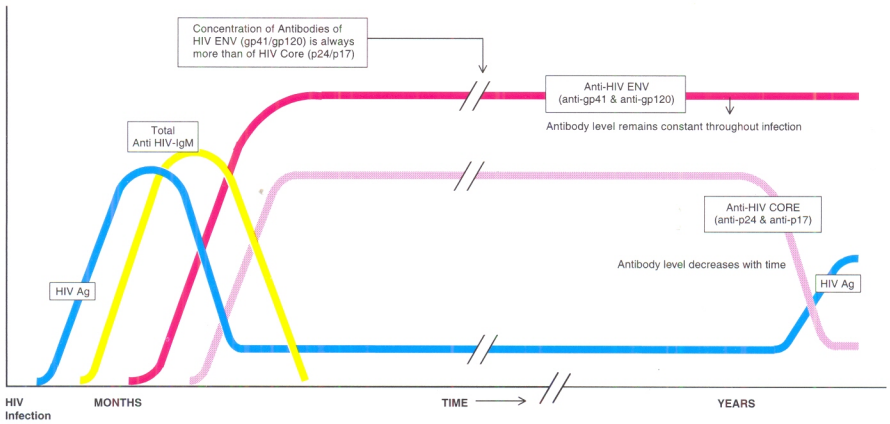
Protein A conjugate binds to the Fc protion of Anti-HIV-1/Anti-HIV-2 antibodies.

After adding the Protein A gold conjugate unbound conjugate is washed away during the washing step.



Envelope Antigens (gp41 and C terminus of gp120) are more suitable than Core Antigens (p24) for HIV-1 Detection

Serological Profile following HIV Infection



1.Antibody formation for HIV ENV (gp41/gp120) is initiated earlier than that of HIV Core (p24 & p17).

2.Antibody level of HIV ENV (gp41/gp120) remains constant throughout the infection, as compared to Antibody level of HIV Core (p24/p17) which falls with time.
At this stage ONLY anti HIV ENV (gp41/gp120) is detectable in the serum.

3.Antibody Concentration of HIV ENV (gp41/gp120) is more than that of HIV Core (p24/p17).

Simple to perform

- Add 3 drops of Buffer Solution
- Add 1 drop of Patient's serum/plasma
- Add 5 drops of Buffer Solution
- Add 2 drops of Conjugate Solution
- Add 5 drops of Buffer Solution

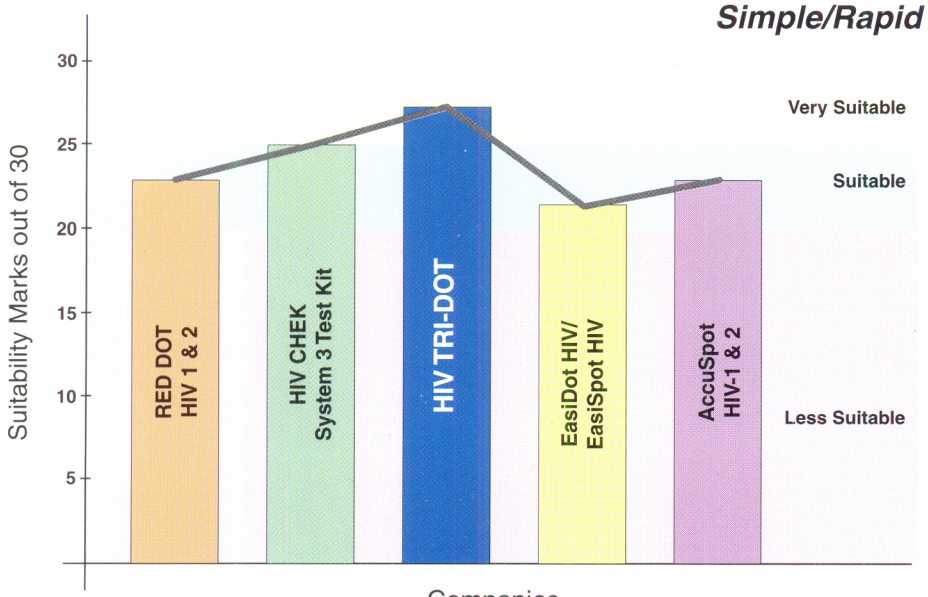
Non-Reactive | Reactive for HIV-1 Antibodies | Reactive for HIV-2 Antibodies | Reactive for HIV-1 & HIV-2 Antibodies

Available in 10, 50 & 100 Test Pack

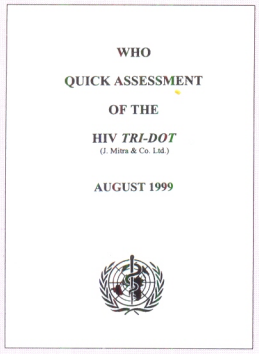
Free Accessories

Highly suitable for use in laboratories

Simple/Rapid assays



** Source available from: Report-11(Operational Characteristics of Commercially available assay to determine antibodies to HIV-1 &/Or HIV-2 in Human Sera) WHO/UNAIDS/Geneva/Jan.1999*



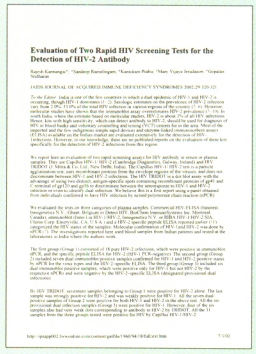
WHO Quick Assessment of the HIV TRI-DOT August 1999

In this study the test HIV TRI-DOT was subjected to early sero-conversion panel in comparison to the reference test. The test was found **100% Sensitive** and **100% Specific**. The average days compared to reference assay on **sero-conversion panel was found 1.7 days** after the reference test.

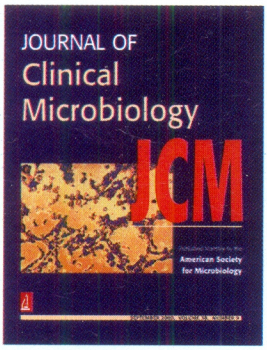
--WHO Quick Assessment of the HIV TRI-DOT; August 1999
WORLD HEALTH ORGANIZATION; CH-1211, Geneva, 27-Switzerland

Evaluation of two HIV screening tests for the detection of HIV-2 antibody

India is one of the few countries in which a dual epidemic of HIV-1 & HIV-2 is occuring, though HIV-1 dominates. Serologic estimates on the **prevalence of HIV-2 infection vary from 2.0%-33.0% of the total HIV infection in various regions of the country. HIV TRI-DOT kit was able to detect all 18 pure HIV-2 samples.** In addtion, the HIV TRI-DOT was able to **discriminate** between HIV-1 and HIV-2 in 17 (94.4%) of the 18 pure HIV-2 infections and correctly identified the seven true dual infections (PCR-positives). Taking n PCR/HIV-2 specific ELISA as the gold standard, HIV TRI-DOT is both sensitive and specific in identifying pure HIV-2 infections and dual infections.


Evaluation of Two Rapid HIV Screening Tests for the Detection of HIV-2 Antibody

--J Acquir Immune Defic Syndr 2002 March 1:29(3):320-321
htpp://ipsapp002.lwwonline.com/content/getfile/1960/94/18/fulltext.htm
Lippincott Williams & Wilkins; 530 Walnut Street; Philadelphia, PA19106, USA



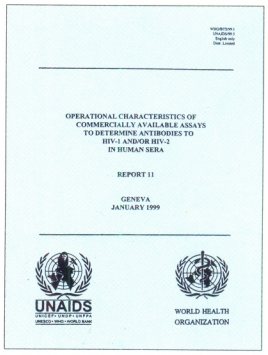
Hospital-Based Evaluation of Two Rapid Human Immunodeficiency Virus Antibody Screening Tests

Human Immunodeficiency Virus (HIV) rapid screening assay, HIV TRI-DOT was compared with standard enzyme linked immunosorbent assay according to testing algorithm. **The total number of serum sample subjected to test were 9312. With overall 99.5% sensitivity and 99.9% specificity.** The test has been found as most suitable for use where facilities and laboratory expertise are limited.

The study adds the valuable perspective of a user, especially in light of the WHO/UNAIDS recommendation (18) for the use of simple, rapid tests to facilitate the expansion of VCT centers towards strengthening strategies for prevention of HIV infection.

--Journal of Clinical Microbiology, Sept. 2000, p. 3445-3447
1752 N Street, N.W.; Washington, DC 20036-2804, USA

Operational Characteristics of Commercially Available Assays to detect Antibodies to HIV-1 & HIV-2 in Human Sera. The results were 99.6% Sensitivity for HIV-1, 100% Sensitivity for HIV-2, and 99.7% Specificity.
Report 11, Geneva January 1999; Refer page 27


OPERATIONAL CHARACTERISTICS OF COMMERCIALLY AVAILABLE ASSAYS TO DETERMINE ANTIBODIES TO HIV-1 AND/OR HIV-2 IN HUMAN SERA

REPORT 11

GENEVA
JANUARY 1999

UNAIDS

WORLD HEALTH ORGANIZATION

--UNAIDS, WORLD HEALTH ORGANIZATION
Blood Transfusion Safety Unit, WHO; 20, Avenue Appia; 1211 Geneva 27, Switzerland

* Note : *This information is provided for the Scientific Community. It is not for commercial or promotional purpose.*

KIT PRESENTATION

10 Test Pack, 50 Test Pack & 100 Test Pack

For further information please contact:
J. Mitra & Co. Pvt. Ltd.
A 180-181, Okhla Industrial Area, Phase-1, New Delhi-110 020 - INDIA
Ph: +91-11-47130300, 47130500, 26818971-73
Fax: +91-11-26818970
E-mail: jmitra@jmitra.co.in Internet: www.jmitra.co.in