HIV TRI-DOT *

Your First Step in HIV Rapid Diagnosis

Diagnostic Enterprises

Accurate Results in Less than 3 minutes

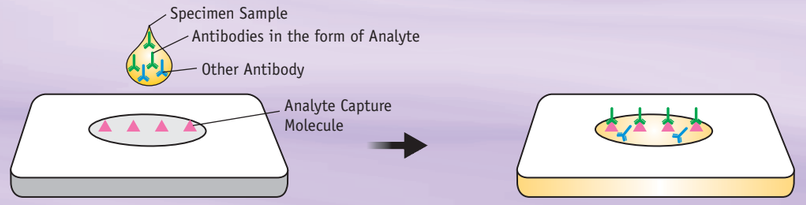
Maximise Accuracy

Minimise Discrepancies

* *Patent No.: 188977 & Design No.: 171800*

How Flow Through Technology Works

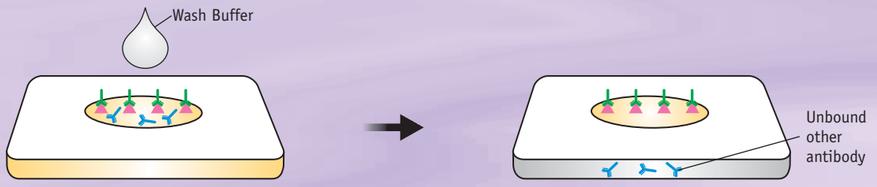
Step-1



Specimen dropped on the membrane

Analyte is captured on analyte capture molecule

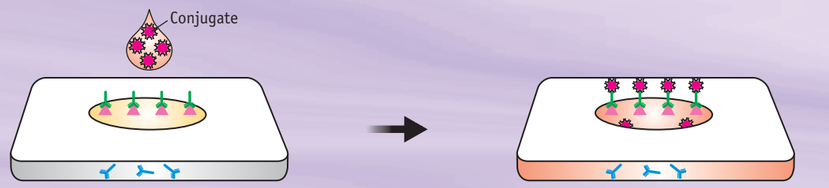
Step-2



Membrane is washed to get rid of cross-reacting antibodies

Wash Buffer washes cross reacting antibodies not bound to analyte capture molecule

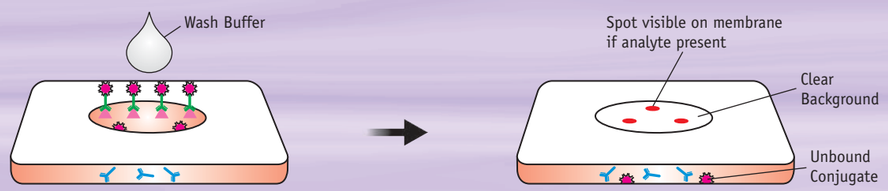
Step-3



Solution containing detection molecule, having two components one that binds analyte specifically & second component gives visual effects poured on to the membrane

As liquid flow through, detection molecule binds to the captured analyte

Step-4



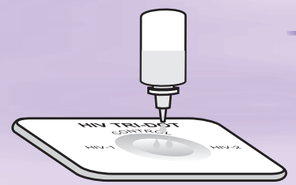
Membrane is washed second time to get rid of unbound detection molecule

FINAL RESULT - Highest Sensitivity & Highest Specificity

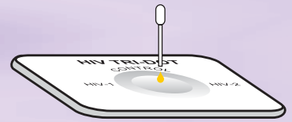
HIV TRI-DOT is based on flow through technology, which is considered as a Gold Standard in HIV Testing as this technology imparts an edge over other existing technology on the basis of its higher accuracy & precision in the test results.

This is the only technology, which includes washing steps in between the assay procedure similar to ELISA procedure, which brings out highest performance both in terms of Sensitivity & Specificity. The importance of washing steps lies on the fact that most of the non-specific antibodies - more prone to produce discrepant (false positive) result gets washed away, thus giving 100% accurate result.

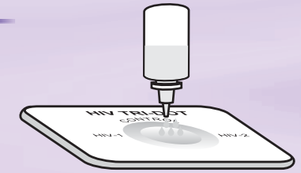
Test Procedure



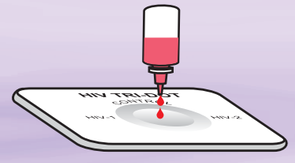
Add **3** drops of Buffer Solution to the centre of the Device



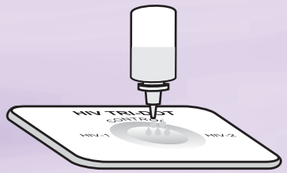
Add **1** drop of patient's sample (serum or plasma) using the sample dropper provided



Add **5** drops of Buffer Solution



Add **2** drops of Conjugate Solution directly from the vial



Add **5** drops of Buffer Solution

Interpretation of Results

Non-Reactive

Reactive for HIV-1 Antibodies

Reactive for HIV-2 Antibodies

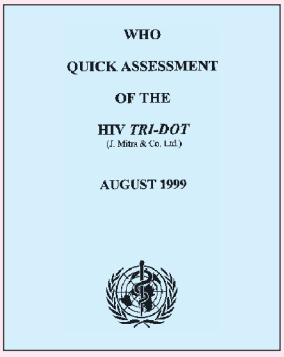
Reactive for HIV-1 & HIV-2 Antibodies

INVALID

Salient Features:

- Use of envelop antigen gp41, C-terminus of gp120 for HIV-1 & gp36 for HIV-2
- Differential detection of HIV-1 & HIV-2
- Detection of Group 'O' & Subtype 'C', suitable for Asian subcontinents
- Shelf life : **15** Months at **2-8°C**
- Available in Convenient Pack Size : 50 Tests, 100 Tests & 200 Tests

HIV TRI-DOT is based on Patented Flow Through Technology



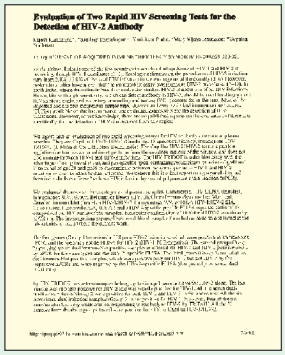
WHO Geneva, evaluation of the HIV TRI-DOT

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.

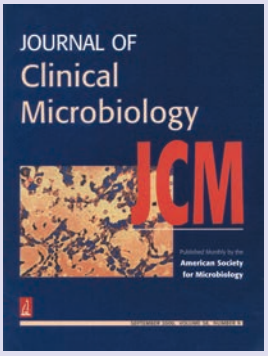
--WHO Quick Assessment of the HIV TRI-DOT; August 1999
WORLD HEALTH ORGANIZATION; CH-1211, Geneva, 27-Switzerland

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 nPCR/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.



--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

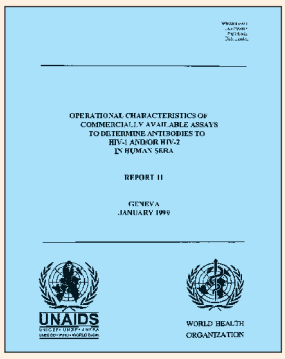
Human Immunodeficiency Virus (HIV) rapid screening assay, HIV TRI-DOT was compared with standard enzyme linked immunosorbent assay according to testing algorithm. The total number of serum sample subjected to test were 9312. With overall 99.5% sensitivity and 99.9% specificity. The test has been found 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



--UNAIDS, WORLD HEALTH ORGANIZATION
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