

4th Generation

# HIV TRI-DOT + Ag

Rapid Visual Test for Detection of HIV-1 p24 Antigen and  
Differential detection of Antibodies to HIV-1 & HIV-2 in human serum/ plasma

First Company  
in India to be granted  
Drug Manufacturing  
Licence for HIV  
Antigen Rapid Test

P24 Antigen Detection

100%\* Sensitivity

100%\* Specificity

Unique Washing Step

Approved by CDSCO\*\*

Shelf Life: 15 Months at 2-8°C



**Convenient Packsize:**  
**10 Tests & 50 Tests**

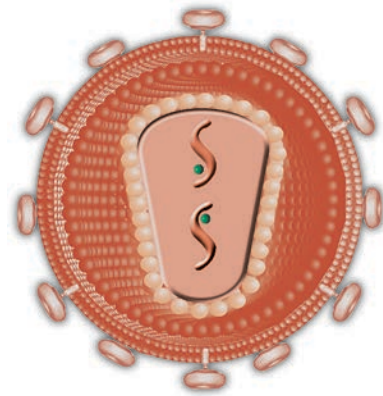
\*Evaluated By: National Institute of Biologicals

\*\* Source: [http://cdsco.nic.in/Medical\\_div/List\\_of\\_critical\\_Diagnostic\\_Kits\\_Approved\\_For\\_Blood\\_Bank\\_Use\\_Till\\_Feb,200.pdf](http://cdsco.nic.in/Medical_div/List_of_critical_Diagnostic_Kits_Approved_For_Blood_Bank_Use_Till_Feb,200.pdf)

# Closing the “Window Period” in HIV Diagnosis

## HIV : A Brief History

The human immunodeficiency virus (HIV) is a lentivirus (a member of retrovirus family) that infect cells of the immune system, destroying or impairing their function. As the infection progresses, the immune system becomes weaker, and the person becomes more susceptible to infections. The most advanced stage of HIV infection is acquired immunodeficiency syndrome (AIDS). It can take 10-15 years for an HIV-infected person to develop AIDS.



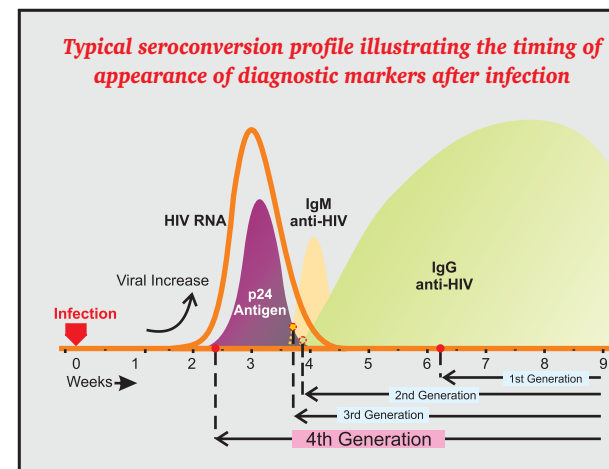
## Immunoassays for HIV Diagnosis

There have been four generations of HIV Immunoassays. Each has delivered a reduction in the window period. The first three generations of HIV immunoassays are based on detection of antibodies to HIV only, but fourth generation immunoassay detects both antibodies to HIV and p24 antigen.

## The Window Period in HIV Detection

**Window Period:** For some time period after contact with the infectious agent the presence of microorganism or antibodies directed against the same cannot be detected. This is known as the “incubation period” and/or “window period”.

**Significance of Window Period:** The window period in HIV detection is an important factor to consider as antibodies are detectable only after 4-5 weeks. Therefore, to shorten the window period in HIV diagnosis p24 antigen detection can be a valuable alternative.



## Need for Early Detection of HIV infection?

- Risk of viral transmission is very high during the primary phase of infection, when viremia & consequently infectivity are highest.
- Early detection of HIV infection increases the efficacy of multi-drug therapy & thus prolongs the asymptomatic phase & reduces the risk of onward transmission.
- Early detection of infection promotes the prompt referral for initiation of treatment, counselling & prevention interventions to reduce the risk of transmission.

## What is p24?

p24 is the product of the gag gene and resides in the viral core. p24 appears early stage (2-4 weeks) after infection due to the initial burst of the virus replication and is associated with high level of viremia during which the individual is highly infectious. The p24 proteins then become undetectable again after sufficient antibodies to HIV have been produced.

Once antibodies are produced, the p24 test will be negative even in people who are infected with HIV. At that point, the standard HIV antibody test will be positive. Later in the course of HIV, p24 protein again becomes detectable.

## Advantage of differential detection of Ag and Ab in HIV:

- The benefits of testing for antigen & antibody are justifiable due to the need to identify individuals with both early & established HIV infections not only within the blood donor population but also in the clinical application.
- Detection of p24 in Babies born to HIV infected mothers. They retain their mother's antibodies for up to 18 months, which means they may test positive on an HIV antibody test, even if they are actually HIV negative.
- Some people who have taken part in HIV vaccine trials may have HIV antibodies even if they are not infected with the virus.
- Screening of donors to detect early infection when individual is seronegative of HIV antibodies i.e. “Window period”.
- Simultaneous detection of p24 antigen and antibodies will help in monitoring the response to therapy and can be used to effectively predict disease outcome.
- Detection of Acute infection and helping in early treatment.

## HIV TRI-DOT + Ag: A Revolution in HIV Rapid Testing



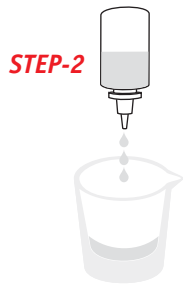
4<sup>th</sup> Generation Assay test detects HIV-1 p24 antigen and antibodies to HIV-1 & HIV-2. The inclusion of p24 antigen assay helps in detecting the HIV infection even before seroconversion takes place. This results in excellent sensitivity & specificity as compared to the 2<sup>nd</sup> and 3<sup>rd</sup> Generation tests. This along with the unique **Flowthrough Technology** ensures reliable and reproducible results.

**HIV TRI-DOT+Ag** has been developed and designed using anti-p24, gp41, C terminus of gp120 & gp36 representing the immunodominant regions of HIV-1 & HIV-2 envelope gene structure respectively. The device (an immunofiltration membrane) includes a “Built-in Quality Control DOT” which will develop colour during the test, thereby, confirming proper functioning of the device, reagents and correct sequential addition of reagent.

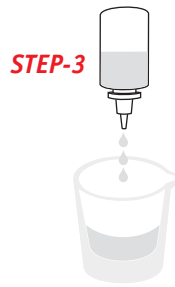
# Test Procedure



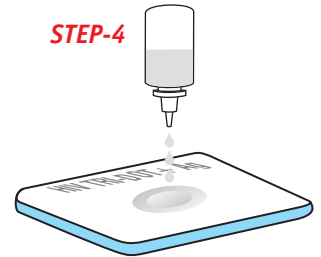
**STEP-1**  
Add 3 drops of sample to Sample cup using sample dropper provided.



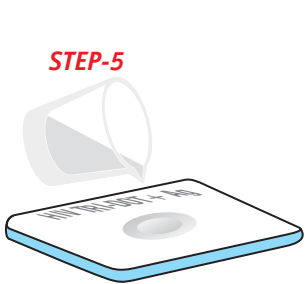
**STEP-2**  
Add 3 drops of sample diluent to Sample cup containing sample.



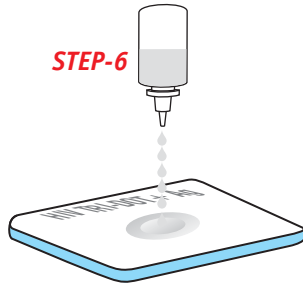
**STEP-3**  
Add 3 drops of Enzyme Conjugate to Sample cup containing sample & sample diluent and mix properly.



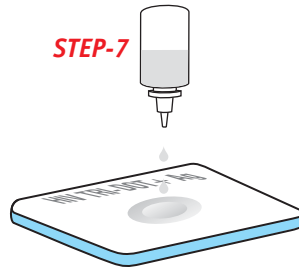
**STEP-4**  
Add 3 drops of Wash Buffer to the centre of the Device.



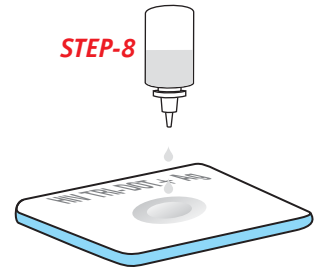
**STEP-5**  
Transfer the complete volume from Sample cup directly to Device or using the transfer dropper.



**STEP-6**  
Add 6 drops of Wash Buffer to device.

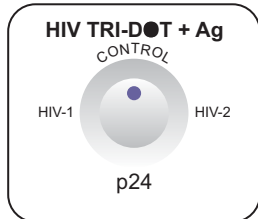


**STEP-7**  
Add 2 drops of TMB Substrate to device.

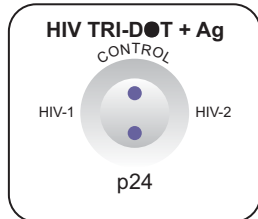


**STEP-8**  
Add 2 drops of Stop Solution to device and **Read Results**.

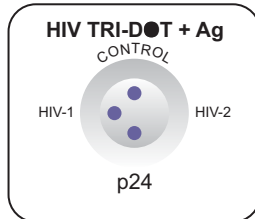
# Result Interpretation



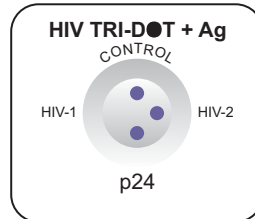
Non reactive for p24 antigen and antibodies to HIV-1 and HIV-2



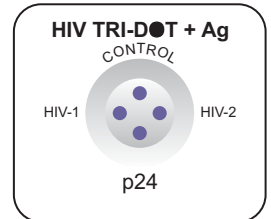
Reactive for p24 antigen



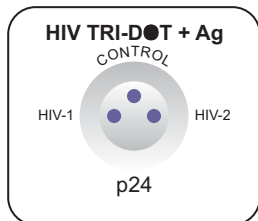
Reactive for p24 antigen and antibodies to HIV-1



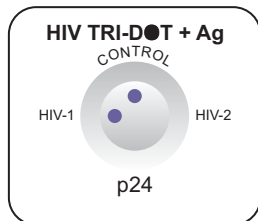
Reactive for p24 antigen and antibodies to HIV-2



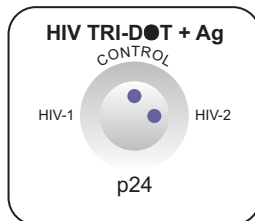
Reactive for p24 antigen and antibodies to HIV-1 & HIV-2



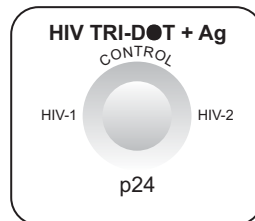
Reactive for antibodies to HIV-1 & HIV-2



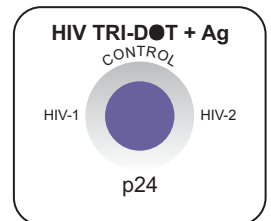
Reactive for antibodies to HIV-1



Reactive for antibodies to HIV-2



Invalid Test and Re-run the test



Invalid Test and Re-run the test

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