Size : 137 x 218 mm

VioTUBE™ HIV

Rapid Immunochromatography Test for HIV-1 & HIV-2

DIPSTICK

INTENDED USE

VioTUBE™ HIV, is a rapid, 3rd generation, qualitative, sandwich immunoassay for simultaneous and differential detection of total antibodies such as IgG, IgM and IgA to HIV-1 and HIV-2 virus in human serum / plasma. For Professional use.

SUMMARY

Acquired immuno deficiency syndrome (AIDS) is caused by at least two retroviruses, the HIV 1 and the HIV 2, collectively referred to as HIV 1 /2. Antibodies to HIV 1 core protein p24, transmembrane protein (gp 41) and/or antibodies to HIV 2 transmembrane protein (gp 36) are prevalent in the sera of individuals with AIDS, ARC or at high risk of contracting AIDS. Detection of these antibodies indicates exposure to the HIV 1/2 virus.

PRINCIPLE

VioTUBE™ HIV utilizes the principle of agglutination of antibodies/ antisera with respective antigen in immuno-chromatography format along with use of nano gold particles as agglutination revealing agent. Highly purified antigens - gp41, gp120 and p24-O fusion polypeptide, representing HIV-1 and HIV-1 group "O" and synthetic peptide gp36 representing HIV-2 are stripped on the membrane as two separate test bands. An assay control forms the third band. Similar antigens are also coated on colloidal gold. A unique combination of synthetic peptides and recombinant antigens reduces cross-reactivity and enable better discrimination between HIV-1 & HIV-2 samples. As the test specimen flows through the membrane test assembly, the highly specific HIV-1/2 antigens-colloidal gold conjugate complexes with the HIV-1/2 specific antibodies in the specimen and travels on the membrane due to capillary action alongwith the rabbit globulin-colloidal gold conjugate. This complex moves further on the membrane to the test region where it is immobilized by the HIV-1/2 antigens coated on the membrane at two separate test zones for HIV-1 & HIV-2. This leads to the formation of colored band(s). The presence of colored band(s) in the test regions indicates the presence of antibodies to HIV-1/2 in the specimen.

The unreacted conjugate and unbound complex, if any, along with the rabbit globulin - gold conjugate move further on the membrane and are subsequently immobilized by the Agglutinating sera for rabbit globulin coated on the membrane at the control region (C), forming a colored band. This control band acts as a procedural control and serves to validate the results.

REAGENTS AND MATERIALS SUPPLIED

VioTUBE™ HIV kit contains:

A. Individual sealed pouches containing:
   1. DIPSTICK : Membrane test assembly stripped with HIV-1 and HIV-2 specific antigens and Agglutinating sera for rabbit globulin along with HIV specific antigen and rabbit globulin- gold conjugate. Each dipstick is individually pouched along with desiccant.
   2. PIPETTE : Sample Applicator.
   3. Desiccant pouch.

B. BUF : Sample Running Buffer: Buffer containing surfactant and preservatives: Sodium Azide 0.1%.

C. TUBE : Test tube with result reading zones.

D. CAP : Test tube caps.

E. Package insert.

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OPTIONAL MATERIAL REQUIRED BUT NOT PROVIDED

Calibrated micropipette capable of delivering 25 µl sample, Disinfectant, Disposable gloves, Biohazard waste container.

STORAGE AND STABILITY

VioTUBE™ HIV is stable up to the expiry date mentioned on the pouch/carton when stored at 4°C to 30°C. Once the pouch is opened, the dipstick must be used immediately. After first opening of the sample running buffer bottle, it can be stored at 4°C to 30°C for the entire duration of its shelf-life.

NOTES

1. Read the instructions carefully before performing the test. For in vitro diagnostic use only. NOT FOR MEDICINAL USE.
2. Do not use beyond expiry date. Do not intermix the reagents from different lots.
3. The dipstick, sample applicator and test tube are for single use only.
4. Contact with the contents of desiccant pouch containing, among other substances, cobalt chloride (CAS# 7646-79-9) should be kept to a minimum. Inhalation / swallowing may cause harm.

Colour	C	M	Y	K
Mauve	30	100	0	0
Black	0	0	0	100

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5. Handle all specimens as potentially infectious. Follow standard biosafety guidelines for handling and disposal of potentially infective material.

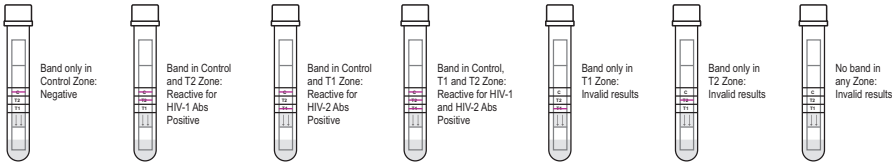
SPECIMEN COLLECTION AND PREPARATION

1. **VioTUBE™ HIV** uses human serum / plasma as specimen.
2. No special preparation of the patient is necessary prior to specimen collection by approved techniques.
3. Preferably use fresh sample. However, specimen may be stored refrigerated (2°C to 8°C) for short duration. For long storage, freeze at -20°C or below.
4. If serum is to be used as specimen, allow blood to clot completely. Centrifuge to obtain clear serum.
5. Repeated freezing and thawing of the specimen should be avoided.
6. Do not heat inactivate before use.
7. Do not use turbid, lipaemic and hemolysed serum/plasma.
8. Do not use hemolysed, clotted or contaminated specimens.
9. Specimen containing precipitates or particulate matter must be centrifuged and the clear supernatant only used for testing.
10. Refrigerated specimens must be brought to room temperature prior to testing.

TESTING PROCEDURE AND INTERPRETATION OF RESULTS

1. Bring the sealed aluminium foil pouch of **VioTUBE™ HIV** dipstick to room temperature.
2. Open the pouch and retrieve the dipstick (taking care not to touch the membrane area), sample applicator and desiccant pouch. Check the color of the desiccant. It should be blue, if it has turned colorless or pink, discard the dipstick and use another dipstick. ***Once opened, the dipstick must be used immediately.***
3. Take the result reading zone marked test tube provided with the kit and label it with patient's identity and number.
4. Tighten the cap of the sample running buffer bottle provided with the kit in the clockwise direction to pierce the buffer bottle nozzle.
5. Put 4 drops of sample running buffer in the tube marked with result reading zones.
6. Place the dipstick on a flat horizontal surface.
7. Carefully dispense **one drop (25 µl)** of serum / plasma on the sample pad using the sample applicator provided.
   NOTE : Ensure that the serum/plasma from the sample applicator or micropipette has been completely taken up by the sample pad.
8. Place the dipstick with the sample into the tube, with the arrows on the dipstick pointing downwards and ensuring that the buffer level is below the sample for the entire duration of the test and close the test tube with cap.
9. Put the test tube vertically straight in the test tube stand.
10. Read the results at the end of **30 minutes** as follows based on the marking of T1/T2/C on the test tube:

RESULT INTERPRETATION



11. The test should be considered invalid if the control band "C" does not appear. The test is also invalid if neither the control nor the test bands appear. Repeat the test with a new **VioTUBE™ HIV** dipstick.

PERFORMANCE CHARACTERISTICS

Internal Evaluation

Six hundred and twenty four samples-out of which one hundred and fourteen HIV-1 Positive, HIV-2 Positive and HIV 1+2 dually positive specimen and five hundred and ten HIV negative samples were tested with **VioTUBE™ HIV** and compared with commercially available ELISA. The results are as shown below.

Specimen Data	Total	VioTUBE™ HIV	Commercial ELISA
Total Number	624	624	624
HIV Positive	114	114	114
HIV Negative	510	509	510

Based on this evaluation:
Sensitivity of **VioTUBE™ HIV** : 100%, Specificity of **VioTUBE™ HIV** : 99.8%

External Evaluation-I (Diagnostic specificity):
A total of One Thousand HIV-negative samples were tested with the **VioTUBE™ HIV** at a European blood Transfusion Centre. No false positive result was recorded. Therefore, the diagnostic specificity as per this evaluation is determined as **100%.**

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Number of samples tested	VioTUBE™ HIV	
	Negative	Positive
1000	1000	0

External Evaluation-II (Diagnostic sensitivity):
Four Hundred and Sixty One HIV-positive samples were tested with the **VioTUBE™ HIV** in a reputed Laboratory in Europe. The samples included HIV-1, HIV-2 and HIV-1 non-B subtype (HIV-1 subtype C prevalent in India) positive samples. All of them were found positive. Therefore, the diagnostic sensitivity as per this evaluation is determined as **100%.**

HIV Type	Number of samples tested	VioTUBE™ HIV	
		Negative	Positive
HIV-1	320	0	320
HIV-2	101	0	101
HIV-1 subtype non-B	40	0	40

External Evaluation-III (Possible Interferences):
To check possible interferences with potentially cross-reactive sera, an independent evaluation was performed with five hundred samples in a reputed Laboratory in Europe. The sera sample includes clinical samples, pregnant women and related infections like HBV, HCV, HAV etc. The table below shows the results of **VioTUBE™ HIV** tested on a variety of samples containing possibly interfering substances:

Sample Type	Number of samples tested	VioTUBE™ HIV	
		Negative	Positive
Clinical specimens	200	200	0
Pregnant women	200	200	0
Related infections*	100	100	0

**Related infections: These are samples (total 100 nos.) from other infectious disease that potentially interfere with anti-HIV immunoassays. The following table depicts the details:*

Sample type	No. of samples tested
HBsAg-positive	20
Anti-HCV positive	20
Anti-HTLV positive	15
Anti-HAV IgM positive	3
Anti-parvovirus B19 positive	15
Anti-Rubella positive	10
Anti-HBsAg	17
TOTAL	**100**

External Evaluation-IV (Seroconversion panel sera evaluations)
Thirty commercially available seroconversion panels from Boston Biomedica Inc., USA, that contains a total of one hundred and seventy four samples was compared with commercially available ELISA's registered in Europe in reputed European laboratories. The results of **VioTUBE™ HIV** were found to be comparable with the said ELISA's.

Precision
Repeatability and reproducibility (inter-assay and inter-lot) were evaluated on a number of negative and positive HIV samples. No variations were found in the outcome of the different tests.

LIMITATIONS OF THE TEST

1. **VioTUBE™ HIV** alone cannot be used to diagnose HIV infection even if the sample is repeatedly reactive or has high intensity of bands.
2. A negative result with **VioTUBE™ HIV** does not preclude the possibility of exposure to or infection with HIV.
3. Presence of a band at the test region(s) even if low in intensity or formation is a positive result.
4. The deliberate slow reaction kinetics of **VioTUBE™ HIV** is designed to maximize and enhance reaction time between sample capture and tracer elements to improve test sensitivity.
5. Most positive results develop within 15 minutes. However, certain sera sample may take a longer time to flow. Therefore, negatives should be confirmed only at 30 minutes. Do not read results after 30 minutes.

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6. Since HIV-1 and HIV-2 viruses are similar in genomic structure and morphology, antibodies to them may cross react. Reactive test bands for both HIV-1 and HIV-2 do not necessarily imply mixed infection. However, to reduce cross-reactivity & better discrimination, **VioTUBE™ HIV** uses a synthetic peptide gp36 with highly conserved epitopes for HIV-2 detection instead of recombinant gp36 antigen. Despite this some HIV-2 sera may show both the bands with **VioTUBE™ HIV.**
7. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
8. **VioTUBE™ HIV** should only be used as a screening test and its results should be confirmed by other supplemental methods before taking clinical decisions.

WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

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11. Data on file: Zephyr Biomedicals.

SYMBOL KEYS

Temperature Limitation	Manufacturer	This side up	Contains sufficient for <n> tests
Use by	Consult Instructions for use	DIPSTICK Dipstick	Do not reuse
Date of Manufacture	REF Catalogue Number	TUBE Test tubes	CAP Test tube caps
LOT Batch Number / Lot Number	BUF Sample Running Buffer	IVD *In vitro* Diagnostic Medical Device	PIPETTE Disposable Plastic Sample Applicator

Manufactured by:

Zephyr Biomedicals

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