
















## SBio HIV Test

Rapid Immunochromatography Test For HIV 1/2 (Device)

REF	90504025
Σ	25 T

 Store at 4 to 30 °C	 Manufacturer	 Batch Number	 Test device	 Do not reuse	 Xn H302, H332 S23-S24/25 S25 Harmful if swallowed. Do not breathe vapour. If swallowed, seek medical advice immediately and show this container or label. Avoid release to the environment. Refer to special instructions.
 Use by (last day of stated month)	 Consult Instructions for use	 In vitro Diagnostic Medical Device	 Sample running buffer	 HIV	
 Date of Manufacture	 Catalogue Number	 Contains sufficient for <n> tests	 This side up	Rapid test for detection of antibodies to HIV-1 and HIV-2 in serum/plasma	

### INTENDED USE

SBio HIV Test, is a rapid, 3rd generation, qualitative, sandwich immunoassay for simultaneous and differential detection of total antibodies i.e. IgG, IgM, IgA etc. 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

SBio HIV Test 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 along with 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 regions 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 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

SBio HIV Test kit has the following components.

- Individual pouched devices each comprising of:
  - Device: Membrane test assembly: Stripped with HIV-1 and HIV-2 antigens and Agglutinating sera for rabbit globulin along with HIV specific antigen and rabbit globulin - gold conjugate.
  - Pipette: Disposable Plastic Sample Applicator.
  - Desiccant Pouch
- Sample Running Buffer: Buffer containing surfactant and preservatives.
- Package insert.

### STORAGE AND STABILITY

SBio HIV Test is stable up to the expiry date mentioned on the label when stored at 4 - 30°C. Once the pouch is opened, the membrane test assembly must be used immediately.

### MATERIAL REQUIRED BUT NOT PROVIDED

- Disinfectant
- Disposable gloves
- Biohazard waste container

### SAMPLE COLLECTION

(1).SBio HIV Test 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 (2–8°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 haemolysed serum/plasma. (8). Do not use haemolysed, 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.

### PRECAUTIONS

(1). For in vitro diagnostic use only. NOT FOR MEDICINAL USE. (2). Bring all reagents and specimen to room temperature before use. (3). Do not use beyond expiry date. (4). Read the instructions carefully before performing the test. (5). Handle all specimens as if potentially infectious. (6). Do not pipette any material by mouth. (7). Do not eat, drink or smoke in the area where testing is done. (8).Use protective clothing and wear gloves when handling samples.(9).Use absorbent sheet to cover the working area. (10). Immediately clean up any spills with sodium hypochlorite. (11). Dispose off all the reagents and material used as if they contain infectious agent. (12). Do not mix components of one lot with another. (13). If desiccant colour at the point of opening the pouch has turned from blue to white, another test assembly must be run. (14). 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.

### TEST PROCEDURE

- Bring the sealed aluminium foil pouch of SBio HIV Test membrane test assembly to room temperature.
- Open a foil pouch by tearing along the "notch".
- Remove the membrane test assembly and the sample applicator. Once opened, the membrane test assembly must be used immediately.
- Label the membrane test assembly with specimen identity.
- Place the membrane test assembly on a flat horizontal surface.
- Carefully dispense one drop (25µl) of serum / plasma into the specimen well 'S' using the sample applicator provided.
- Add three drops of sample running buffer into the same well 'S'.
- Observe the development of visible coloured band at Test regions ('1' for HIV-1 and/or '2' for HIV-2).
- Positive results may be observed within 20 minutes.
- 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 SBio HIV Test membrane test assembly.

## INTERPRETATION OF RESULTS



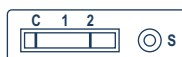
### NEGATIVE

A coloured band appears only in the control area marked 'C'.



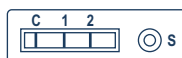
### HIV-1 POSITIVE

A coloured band appears in the control area as well as in the area marked '1'. The sample is reactive for HIV-1.



### HIV-2 POSITIVE

A coloured band appears in the control area as well as in the area marked '2'. The sample is reactive for HIV-2.



### HIV-1 & HIV-2 DUAL POSITIVE

A coloured band appears in the control area as well as in the areas marked '1' & '2'. This indicates a mixed infection.



### INVALID

The test should be considered invalid if the control band 'C' does not appear. The test is also invalid if only the test band and no control band appear. Repeat the test with a new SBio HIV Test membrane test assembly.

## PERFORMANCE CHARACTERISTICS

### Internal Evaluation

Six hundred and twenty four samples-out of which, one hundred and fourteen HIV-1 Positive, HIV-2 positive and HIV1+2 dually positive specimen and five hundred and ten HIV negative samples were tested with SBio HIV Test and compared with commercially available ELISA. The results are as shown below.

Specimen Data	Total	SBio HIV Test	Commercial ELISA
Total Number	624	624	624
HIV Positive	114	114	114
HIV Negative	510	509	510

Based on this evaluation:

Sensitivity of SBio HIV Test: 100%

Specificity of SBio HIV Test: 99.8%

### External Evaluation – I (Diagnostic specificity):

A total of One thousand HIV-negative samples were tested with the SBio HIV Test at a European blood Transfusion Centre. No false positive result was recorded. Therefore, the diagnostic specificity as per this evaluation is determined as 100%.

Number of samples tested	SBio HIV Test	
	Negative	Positive
1000	1000	0

### External Evaluation – II (Diagnostic sensitivity):

Four Hundred and Sixty One HIV- positive samples were tested with the SBio HIV Test 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	SBio HIV Test	
		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 SBio HIV Test tested on a variety of samples containing possibly interfering substances:

Sample Type	Number of samples tested	SBio HIV Test	
		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 Biomedical 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 SBio HIV Test 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

(1).SBio HIV Test 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 SBio HIV Test 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 SBio HIV Test is designed to maximize and enhance reaction time between sample capture and tracer elements to improve test sensitivity. (5). Most positive results develop within 20 minutes. However, certain sera samples may take a longer time to flow. Therefore, negatives should be confirmed only at 30 minutes. Do not read results after 30 minutes. (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, SBio HIV Test 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 SBio HIV Test. (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).SBio HIV Test 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.

### BIBLIOGRAPHY

(1). Kim, C. Y., Tillis, J. G. 1973 J. Clin. Invest, 52, 1176-1186. (2) Magnus, L.O. et. al. 1975, J. Am. Med. Assoc. 231, 356-359. (3).Kee Myung Lee et.al., Emergence of Vaccine- induced escape mutant of Hepatitis B Virus with Multiple surface gene mutations in a Korean child, J. Korean Med. Sci. 2001; 16, pgs 359-362. (4).Koyanagi T et al. Analysis of HBs antigen negative variant of hepatitis B virus: Unique Substitutions, Glu 129 to Asp and Gly 145 to Ala in the surface antigen gene. Med Sci Monit, 2000; 6(6): 1165-1169.

Manufactured by:

**Qualpro Diagnostics**

A Division of Tulip Diagnostics (P) Ltd.

88/89, Phase II C, Verna Industrial Estate,

Verna, Goa - 403 722, INDIA.

**Regd. Office:** Gitanjali, Tulip Block, Dr. Antonio Do Rego Bagh,  
Alto Santacruz, Bambolim Complex P.O., Goa - 403 202, INDIA.

Manufactured for:

**Singapore SB Biosciences PTE Ltd.**

11 Yishun Street 51, #04-23, The Criterion,  
Singapore 767971