DUOSCREEN HIV/SYP

RAPID COMBO TEST FOR SIMULTANEOUS DETECTION OF HIV 1/2 ANTIBODY AND ANTI-TREPONEMAL ANTIBODIES IN HUMAN SERUM, PLASMA OR WHOLE BLOOD

DEVICE

INTENDED USE

The Device is intended for the rapid detection of HIV 1/2 Antibody and Treponema pallidum (Syphilis) antibodies in human blood samples (Serum/Plasma/whole blood). This device is designed to provide a quick, accurate, and reliable diagnosis of HIV and *T. pallidum* infection.

SUMMARY

Human immunodeficiency virus (HIV) is caused by at least two types of retrovirus HIV 1 & HIV 2, collectively referred as HIV 1/2. Antibody to HIV 1 transmembrane protein gp 41 and/or antibodies to HIV 2 transmembrane protein gp 36 are present in sera of individual infected with HIV. Syphilis is a sexually transmitted infection caused by the spirochete Treponema Pallidum. The body produces antibodies specific to Treponema pallidum which can be detected by tests like TPHA, FTA-ABS, and rapid treponema antibody assays in addition to non-treponemal antibodies which can be detected by serological tests like VDRL, RPR and TRUST (Toluidine Red Unheated Serum Test).

HIV and syphilis are two systemic, sexually transmitted diseases (STD) that share common risk factors. HIV and syphilis affect similar patient groups and coinfection is common. The presence of syphilis infection increases the chances of transmission of HIV. Untreated syphilis in co-infected individuals can lead to substantial neurologic and cardiovascular consequences as well as significant morbidity and mortality. The HIV and syphilis co-infection specific treponemal test could contribute to reducing errors due to false positive by non-specific tests like RPR. HIV and Syphilis co-infection is considered to be a dangerous combination since HIV makes failure of syphilis treatment more likely and co-infection leads to more profound neurocognitive impairment. HIV/Syphilis co-infected individuals also have poorer immune recovery during ART.

All patients presenting with syphilis should be offered HIV testing and all HIV-positive patients should be regularly screened for syphilis. Timely diagnosis and treatment reduce the risk of HIV and syphilis transmission, protecting both the general population and pregnant women, and preventing severe health complications such as congenital syphilis or perinatal HIV.

Duoscreen HIV/SYP can be used for detecting individual or coinfection of HIV and/or syphilis and preferable as the first antenatal care (ANC) test for pregnant women, detecting both infections at once, saving time and resources, and enabling timely treatment.

TEST PRINCIPLE

Duoscreen HIV/SYP is based on the principle of agglutination of antibodies or antisera with their corresponding antigens in an immunochromatographic format. The test detects antibodies specific to HIV and T. pallidum, using nano-gold particles as the agglutination revealing agent. The nitrocellulose membrane is coated with a recombinant antigen for HIV 1 and HIV 2 at test line 'H' and recombinant antigens specific to *T. pallidum* at the test line 'S' and control reagent coated at the control line 'C'. When serum or plasma or whole blood specimen is applied to the specimen well of the device, the recombinant HIV 1/2 antigen - colloidal gold conjugate & the recombinant *T. pallidum* antigen colloidal gold conjugate will react with HIV specific antibodies and/or *T. pallidum* specific antibodies, if present in the specimen. The antibody-CGC antigen complex with the help of assay buffer move along the membrane because of capillary action to the test regions and form a visible purple colored line at the test region(s). If the specimen contains antibodies specific to *T. pallidum*, the purple-colored line will appear in the test area at test line 'S', corresponding to the *T. Pallidum* line. If the specimen contains antibodies to HIV 1 and/or 2, the purple-colored line will appear in the test area at test line 'H', corresponding to HIV 1/2 line.

The presence of both test lines indicates that the specimen contains antibodies to HIV and *T. pallidum*. The absence of the purple-colored line at both test line regions indicates that the specimen is non-reactive for HIV antigen and *T. pallidum* antigen a negative result. The purple-colored Control line will appear irrespective of the status of the specimen. The control line is a procedural control, serves to demonstrate functional reagents and correct migration of fluid.

INTENDED USER

The test is intended to be performed by a trained user. For professional use only.

SPECIMEN REQUIRED

For serum/plasma/venous whole blood specimen:

Collect 10µl of serum/plasma or 20µl of venous whole blood specimen with the help of micropipette.

Capillary whole blood specimen:

Clean a fingertip by wiping with an alcohol swab. Dry and pierce the wiped fingertip with sterile lancet to bleed. Collect 20µl of sample.

WARNINGS AND PRECAUTIONS

1. Read the instructions carefully before preforming the test.
2. For in vitro diagnostic use only. NOT FOR MEDICINAL USE.
3. Do not use the kit beyond expiry date and do not re-use the test device.
4. Do not intermix components from different lots.
5. Contact with the contents of desiccant pouch containing, among other substances, cobalt chloride (CAS# 7646-79-9) should be kept to minimum. Inhalation / swallowing may cause harm.
6. Handle all specimens as if potentially infectious. Follow standard biosafety guidelines for handling and disposal of potentially infectious material.
7. Assay buffer contains sodium azide 0.09%, avoid skin contact with this reagent. Azide may react with lead & copper in the plumbing system & form highly explosive metal oxides. Flash with large volume of water to prevent azide build up in the plumbing.

REAGENTS AND MATERIALS SUPPLIED

Duoscreen HIV/SYP kit contains:

A. Individual pouches, each containing:
   1. DEVICE Membrane assembly pre-dispensed with HIV-Syphilis Antigen (indicator) colloidal gold conjugate, Rabbit IgG-colloidal gold conjugate, HIV-Syphilis Antigen (capture) and goat anti rabbit IgG coated at the respective regions.
   2. Desiccant pouch.

B. BUF Assay buffer bottle.

C. Package Insert.

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Σ	25T

Materials required but not provided:

Alcohol swab, Sterile blood lancet, Blood collection set, stopwatch.
Calibrated micropipettes, micropipette tips.

TEST KIT STORAGE AND STABILITY

1. Store the sealed pouches at 4°C to 30°C.
2. Do not use beyond the expiration date.
3. **Duoscreen HIV/SYP** has a shelf life of 24 months from the date of manufacturing as indicated on the pouch.
4. **Duoscreen HIV/SYP** is stable up to the expiry date mentioned on the label when stored at 4°C to 30°C. Once the pouch is opened, the membrane test assembly must be used immediately.
5. After first opening of the Assay buffer, the buffer is stable until the expiry date mentioned on the buffer label, if kept at 4°C to 30°C for the duration of its shelf life.
6. DO NOT FREEZE.

SPECIMEN COLLECTION AND PREPARATION

A. Serum

1. Collect the whole blood by venipuncture into plain tubes without anti-coagulant and leave to settle for 30 minutes for blood coagulation and then centrifuge to get serum specimen of supernant.
2. Serum in a plain tube can be used for testing within 3 days if stored at 2°C to 8°C; for longer storage, keep below –40°C.
3. Serum should be brought to room temperature prior to use.

B. Plasma

1. Collect the venous whole blood by venipuncture into anti-coagulant tube such as EDTA or sodium citrate by venipuncture and centrifuge blood to get plasma specimen.
2. If plasma in an anti-coagulant tube is stored in a refrigerator at 2°C to 8°C the specimen can be used for testing within 3 days after collection, for prolonged storage, it should be at below -40°C.
3. Plasma should be brought to room temperature prior to use.

C. Whole Blood

Capillary whole blood

1. Capillary whole blood should be collected by fingertip.
2. Select the finger that is free from callus. Gently rub the finger to warm it to stimulate blood circulation.
3. Squeeze the end of the fingertip and pierce with a sterile lancet. Wipe away the first blood drop. Immediately dispose of the lancet safely. Immerse the open end of a capillary pipette in the next blood drop and release the pressure to draw the blood.
4. The capillary whole blood must be tested immediately after collection.

Venous Whole Blood

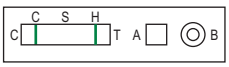
1. Collect the venous whole blood into anti-coagulant tube such as heparin, EDTA, or sodium citrate by venipuncture.
2. Venous whole blood in an anti-coagulant tube is stored in a refrigerator at 2°C to 8°C. The specimen can be used for testing within 1-2 days after collection.

TESTING PROCEDURE

1. Bring **Duoscreen HIV/SYP** kit components, specimen to room temperature prior to testing.
2. Open the pouch, remove the device and place it on a flat surface. Check the colour of the desiccant. It should be blue, if it has turned colourless or pink, discard the device and use another device.
3. Once opened, the device must be used immediately.
4. Tighten the cap of the Assay buffer bottle provided with the kit in the clockwise direction to pierce the dropper bottle nozzle.
5. Label the device with patient's identity.
6. Place the testing device on a flat horizontal surface.
7. Carefully dispense 10 µl of serum / plasma or 20 µl Whole blood into the sample port "A" using the micropipette.
8. Add five drops of Assay buffer into the buffer port "B".

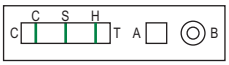
INTERPRETATION OF RESULTS

1. Read results at the end of 30 minutes.
2. Appearance of coloured bands of any intensity (faint to dark) at 'S' and/or 'H' should be considered as positive result.
3. Record the test result as below:



HIV-1/2 Positive:
The presence of colored bands at 'C' & 'H' region is considered Reactive for HIV1/2.

Syphilis Positive:
The presence of colored bands in the 'C' & 'S' region is considered Reactive for Syphilis.

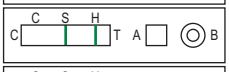


HIV 1/2 & Syphilis Positive:
The presence of colored bands at 'C', 'S' & 'H' region is considered as Reactive for both HIV 1/2 & Syphilis.

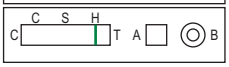
Negative for HIV 1/2 & Syphilis:
The presence of colored band only at 'C' region is considered as non-reactive for HIV 1/2 & Syphilis.

Invalid Result:

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 appears.



Repeat the test with a new **Duoscreen HIV/SYP** device.

PERFORMANCE CHARACTERISTICS

Internal evaluation:
Duoscreen HIV/SYP evaluated with known positive and known negative samples of HIV and Syphilis:

Duoscreen HIV/SYP						
Analyte	Total no. of known positive samples	Total no. of known negative samples	Results		Sensitivity	Specificity
			Positive	Negative		
HIV	28	115	28	115	100%	100%
SYPHILIS	22	115	22	115	100%	100%

External evaluation:
The performance of **Duoscreen HIV/SYP** was evaluated using a panel of 200 samples (9 HIV positive, 16 Syphilis positive and 191 HIV negative and 184 Syphilis negative samples), in comparison with commercially available CE marked HIV (CLIA) and Syphilis (ELISA) kits. The results of the evaluation are as follows:

Specimen Data	Duoscreen HIV/SYP		Commercially available CE-marked kit		Duoscreen HIV/SYP	
	HIV 1/2	Syphilis	HIV 1/2 (CLIA)	Syphilis (ELISA)	Sensitivity	Specificity
No. of Positive Samples	9	16	9	16	100%	100%
No. of Negative Samples	191	184	191	184		
Total specimen tested	200	200	200	200		

LIMITATIONS OF THE PRODUCT
(1) The test procedure, precautions and interpretation of results for this test must be followed while testing. (2) The test devices are for in vitro diagnostic use only. Do not reuse the test device. (3) If a test result is nonreactive and clinical symptoms persist, additional testing using other clinical methods is recommended. (4) 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. (5) **Duoscreen HIV/SYP** should only be used as a screening test and its results should be confirmed by other supplemental methods before taking clinical decisions. (6) Do not compare the intensity of the test lines and the control lines to judge the concentration of the antibodies in the test sample. (7) Do not use the test kit beyond its expiration date. The shelf life of the kit is as indicated on the outer package.

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) Ferris Satyaputra Stephanie Hendry et al., The Laboratory Diagnosis of Syphilis. (2) Melody Ren et al., The Intersection of HIV and Syphilis: Update on the Key Considerations in Testing and Management. (3) Lina Fan et al., Consequences of HIV/Syphilis Co-Infection on HIV Viral Load and Immune Response to Antiretroviral Therapy. (4) Galia Karp et al., Syphilis and HIV co-infection. (5) Effect of syphilis infection on HIV acquisition: a systematic review and meta-analysis Meng Yin Wu, Hui Zi Gong , Kui Ru Hu , He-yi Zheng , Xia Wan , Jun Li. (6) Dual HIV/syphilis rapid diagnostic tests can be used as the first test in antenatal care 27 November 2019 Policy brief. (7) WHO Prequalification of In Vitro Diagnostics Programme. public report number PQDx 0179-012-00. Geneva: World Health Organization, 2015. (8) Rodriguez, Patricia J et al. Cost-effectiveness of dual maternal HIV and syphilis testing strategies in high and low HIV prevalence countries: a modelling study. Lancet Glob Health. 2021;9(1):e61 - e71. Accessed. (9) Elimination of mother-to-child transmission of HIV and Syphilis (EMTCT): Process, progress, and program integration Melanie Taylor, Lori Newman, Naoko Ishikawa, Maura Laverty, Chika Hayashi, Massimo Ghidinelli, Razia Pendse, Lali Khotenashvili, Shaffiq Essajee. (10) Seroprevalence of Syphilis, Human Immunodeficiency Virus and its Co-infection in Patients Attending an ICTC at a Tertiary Care Hospital in Villupuram, Tamil Nadu, India. National Journal of Laboratory Medicine. 2023 Jan. (11) Effect of syphilis infection on HIV acquisition: a systematic review and meta-analysis. (12) The Association Between Syphilis Infection and HIV Acquisition and HIV Disease Progression in Sub-Saharan Africa. Trop Med Infect Dis. 2025 Feb. (13) Syphilis and HIV: a dangerous combination. (14) Data on file: Zephyr Biomedicals.

SYMBOL KEYS

Temperature Limitation	Consult Instructions for use	Date of Manufacture	DEVICE Device
Manufacturer	IVD *In vitro* Diagnostic Medical Device	This side up	
Use by	REF Catalogue Number	Do not reuse	Do not use if package is damaged
Σ Contains sufficient for <n> tests	LOT Batch Number / Lot Number	BUF Assay buffer	

Manufactured by:

Zephyr Biomedicals
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