WHO Prequalification of In Vitro Diagnostics
PUBLIC REPORT

Product: STANDARD Q HIV/Syphilis Combo Test
WHO reference number: PQDx 0382-117-00

STANDARD Q HIV/Syphilis Combo Test with product code **09HIV20D**, manufactured by **SD Biosensor, Inc, Rest-of-World regulatory version**, was accepted for the WHO list of prequalified in vitro diagnostics and was listed on 26 May 2020.

Summary of WHO prequalification assessment for STANDARD Q HIV/Syphilis Combo Test

	Date	Outcome
Prequalification listing	26-May-2020	listed
Dossier assessment	1-May-2020	MR
Site inspection(s) of quality management system	17-19 -Apr-2019	MR
Product performance evaluation	Quarter 4-2019	MR

MR: Meets Requirements

Intended use

According to the claim of intended use from SD Biosensor Inc, "*STANDARD Q HIV/Syphilis Combo Test is a rapid chromatographic immunoassay for the qualitative detection of antibodies specific to HIV-1 including subtype O, HIV 2 and Syphilis (Treponema pallidum) in human serum, plasma or whole blood. The test is for in vitro diagnostic use and intended as an aid to early diagnosis of HIV and Syphilis infection for HIV or Syphilis infected patients, patients with signs and symptoms for HIV and Syphilis and persons at risk. It provides only an initial screening test result. More specific alternative diagnosis methods should be performed in order to obtain the confirmation of HIV Virus and Syphilis infection*."

Assay description

According to the claim of assay description from SD Biosensor Inc, "*STANDARD Q HIV/Syphilis Combo Test has "H1", "H2", "SYP" and "C" line region pre-coated with recombinant HIV-1 GP41 protein / recombinant HIV-1 subtype O GP41, recombinant HIV-2 GP36 protein, recombinant p17 Treponema pallidum protein (recombinant TPP 17 protein) and monoclonal anti-HIV-1 / monoclonal anti-syphilis respectively. The anti-HIV-1/anti-HIV-1 subtype O in patient sample interacts with the recombinant HIV-1 GP41-gold / recombinant HIV-1 subtype O GP41-gold and the anti-HIV-2 in patient sample interacts with the recombinant HIV-2 GP36-gold in the conjugation pad. The anti-syphilis in patient*

sample interacts with the recombinant TPP 17 protein-gold. The complex moves along the membrane chromatographically with assay diluent and is captured by the recombinant HIV-1 and HIV-2 antigens and/or recombinant TPP 17 antigen on the each test line (H1, H2, SYP). If the antibodies against HIV 1/ 2 and/or syphilis are in the patient sample, visible lines are formed in the each test line. The control line should always appear if the test procedure is performed properly."

Test kit contents

Component	**25 tests (product code 09HIV20D)**
Test device (individually in a foil pouch with desiccant)	25
Buffer Bottle	1 x 4 mL
Capillary tube (20µl)	Pack of 25
Instructions for use	1
Sterile lancet	25
Alcohol swabs	25

Items required but not provided

- Micropipette and tip
- Blood collection tube
- PPE (Personal Protective Equipment)
- Biohazard container
- Timing device

Storage

The test kit should be stored at 2-40°C.

Shelf-life upon manufacture

24 months.

Warnings/limitations

Please refer to the instructions for use attached to this public report.

Prioritization for prequalification
Based on the established eligibility criteria, STANDARD Q HIV/Syphilis Combo Test was given priority for WHO prequalification assessment.

Dossier assessment

SD Biosensor Inc submitted a product dossier for STANDARD Q HIV/Syphilis Combo Test as per the "Instructions for compilation of a product dossier" (PQDx_018 version 3). The information (data and documentation) submitted in the product dossier was reviewed by WHO staff and external technical experts (assessors) appointed by WHO.

The manufacturer's responses to the nonconformities found during dossier review were accepted on 1 May 2020.

Commitment for prequalification

SD Biosensor, Inc committed to provide the interim study report and raw data for device stability studies on 24 November 2020 and the final report and raw data on the 23 March 2022.

Based on the product dossier screening and assessment findings, the product dossier for STANDARD Q HIV/Syphilis Combo Test meets WHO prequalification requirements.

Manufacturing site inspection

An inspection of SD Biosensor Inc. located at 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea was conducted from the 17th to the 19th of April 2019. At the time of considering the product application for Prequalification, the Manufacturer of the product had a well-established quality management system and manufacturing practices in place that would support the manufacture of a product of consistent quality. Routine inspections of the Manufacturing site will be conducted with copies of the WHO Public Inspection Report (WHOPIR) published on the WHO Prequalification web page as per Resolution WHA57.14 of the World Health Assembly. Note that a WHOPIR reflects the information on the most current inspection performed at a manufacturing site for *in vitro* diagnostic products and gives a summary of the inspection findings.

Information on the most current inspection can be found at:
https://www.who.int/diagnostics_laboratory/evaluations/PQDxSiteInspection/en/

All published WHOPIRs are with the agreement of the manufacturer.
The manufacturer's responses to the nonconformities found at the time of the inspection were accepted on 16th of December 2019.

Based on the site inspection and corrective action plan review, the quality management system for STANDARD Q HIV/Syphilis Combo Test meets WHO prequalification requirements.

Product performance evaluation

STANDARD Q HIV/Syphilis Combo Test was evaluated at the Institute of Tropical Medicine, Belgium on behalf of WHO in the 4th quarter of 2019, according to protocol PQDx_150, version 4.1.

Clinical performance evaluation

In this limited laboratory-based evaluation of clinical performance characteristics, a panel of 400 serum/plasma specimens was used. The specimens were characterized using the following reference algorithms. For HIV: Vironostika HIV Ag/Ab (bioMérieux) and Enzygnost Anti-HIV 1/2 Plus (Siemens Healthcare Diagnostics) or Genscreen HIV-1/2 Version 2 (Bio-Rad) in parallel; followed by INNO-LIA HIV I/II Score (Fujirebio Inc.) on initially reactive specimens. For Treponema pallidum: Vitros Syphilis TPA Assay (Ortho Clinical Diagnostics), followed by SERODIA-TP.PA (Fujirebio Inc.).

Clinical performance characteristics in comparison with an agreed reference standard				
	HIV-1/2		**Syphilis**	
	Initial (95% CI)	**Final (95% CI)**	**Initial (95% CI)**	**Final (95% CI)**
Sensitivity % (N=200)	100 (98.2-100)	100 (98.2-100)	95.0 (91.0-97.6)	95.5 (91.6-97.9)
Specificity % (N= 200)	99.0 (96.4-99.9)	99.5 (97.2-100)	99.5 (97.2-100)	99.5 (97.2-100)
Invalid rate % (N= 400)	0%			
Inter-reader variability % (N= 400)	3.25%*		1.0%	

** All 13 disagreements on HIV-1/2 results were on the HIV-2 line in HIV-1 positive specimens.*

Out of 200 HIV-1 positive specimens, STANDARD Q HIV/Syphilis Combo Test showed the presence of the HIV-2 line in 30 (15 %) specimens, although in most cases (n=28), the HIV-2

line was weaker than the HIV-1 line, which is interpreted as HIV-1 positive result according to the IFU of the assay.

Analytical performance evaluation

Analytical performance characteristics		
	HIV-1/2	**Syphilis**
Sensitivity during seroconversion in comparison with a benchmark assay (Enzygnost Anti-HIV 1/2 Plus)	Of a total of 52 specimens in 8 panel, 23 were detected by the assay under evaluation; versus 21 specimens detected by the benchmark assay (Enzygnost Anti-HIV 1/2 Plus). Seroconversion sensitivity index of -0.25, therefore detection is 0.25 specimens earlier than the benchmark assay.	Of a total of 9 specimens in 1 panel, 5 were detected by the assay under evaluation; versus 2 specimens detected by the benchmark assay (Vitro Syphilis TPA Assay).
Analytical sensitivity on a mixed titer panels	All 25 specimens of panel PRB-205 (SeraCare) were correctly classified.	All 17 specimens of panel PSS-202 (SeraCare) were correctly classified.
Analytical sensitivity on WHO reference preparation panels	All 6 HIV subtypes/groups in the 1st International Reference Panel for anti-HIV (NIBSC code 02/210) were detected.	The 1st International Standard for human syphilitic plasma IgG (NIBSC code 05/122) was detected.
Lot to lot variation on a dilution panel	Lot to lot variation was within +/- 1 two-fold dilutions for all 10 dilution series.	Lot to lot variation was within +/- 1 two-fold dilutions for all 10 dilution series.

Operational characteristics and ease of use

This assay does not require laboratory equipment and can be performed in laboratories with limited facilities or in non-laboratory settings.

The assay was found easy to use by the operators performing the evaluation.

Key operational characteristics	
Number of steps*	2 steps in total 1 step with precision pipetting (only for serum/plasma)
Time to result	15 minutes
Endpoint stability (interval)	5 minutes (the test can be read between 15 and 20 minutes after addition of diluent)
Internal QC	Yes, reagent addition control

** Definition: each action required to obtain a result (excluding specimen collection, device preparation – opening the pouch), e.g. for RDTs: add specimen, add buffer (2 steps).*

Based on these results, the performance evaluation for STANDARD Q HIV/Syphilis Combo Test meets the WHO prequalification requirements.

Labelling

1. **Labels**
2. **Instructions for use**

1. Labels

1.1 Device Package

STANDARD Q

HIV/Syphilis Combo 25T

Unit : mm

자재명	Package	도수	2도 (먹, Pantone 2415C)
문안번호	B25HIV2MLR0-WHO	후가공	유광코팅 / 3면접착
크기	W165 * H71 * D124	작업일자	2020.05.19
용지/질량	로얄아이보리/300g	담당부서	디자인팀, 마케팅팀

STANDARD Q

HIV/Syphilis Combo

25

ES
CONTENIDO
1) Dispositivo de ensayo x 25
2) Tubo capilar (20µl) x 25
3) Botella de buffer x 1
4) Lanceta estéril x 25
5) Hisopo con alcohol x 25
6) Instrucciones de uso x 1

FR
CONTENU
1) Dispositif de test x 25
2) Tube capillaire (20µl) x 25
3) Flacon de solution de tampon x 1
4) Lancette stérile x 25
5) Tampon alcoolisé x 25
6) Mode d'emploi x 1

PT
CONTEÚDO
1) Dispositivo de teste x 25
2) Tubo capilar (20µl) x 25
3) Frasco de buffer x 1
4) Lanceta estéril x 25
5) Gaze com álcool x 25
6) Instruções de uso x 1

IT
CONTENUTO
1) Dispositivo di test x 25
2) Tubo capillare (20µl) x 25
3) Fiala della soluzione tampone x 1
4) Lancetta sterile x 25
5) Tampone imbevuto di alcool x 25
6) Istruzioni per l'uso x 1

DE
INHALT
1) Testgerät x 25
2) Kapillaren (20µl) x 25
3) Puffer flasche x 1
4) Sterile Lanzette x 25
5) Alkoholtupfer x 25
6) Gebrauchsanweisung x 1

STANDARD Q

HIV/Syphilis Combo Test

STANDARD™ Q HIV/Syphilis Combo Test

CONTENTS
1) Test device x 25
2) Capillary tube (20µl) x 25
3) Buffer bottle x 1
4) Sterile Lancet x 25
5) Alcohol swab x 25
6) Instructions for use x 1

B25HIV2MLR0-WHO
Issue date: 2020.05

IVD

2°C-40°C (36°F-104°F)

25

LOT : LOT NO. :
: MFG DATE :
: EXP DATE :

Cat. No.: 09HIV20D

8 809319 394051

STANDARD Q

HIV/Syphilis Combo

25

www.sdbiosensor.com

SD BIOSENSOR

STANDARD Q

HIV/Syphilis Combo Test

STANDARD™

Manufactured by
SD Biosensor, Inc.
Head office
C-4th,6th, 16, Deogyeong-daero 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, REPUBLIC OF KOREA
+82-31-300-0400 www.sdbiosensor.com
Manufacturing site
74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, REPUBLIC OF KOREA

1.2 Foil pouch

Σ 1

1Test

STANDARD Q

Rapid Test

STANDARD™

/ Item

STANDARD Q HIV/Syphilis Combo

REF / REF No.

QHSC01B / CAT No.: 09HIV20D

LOT / LOT No.

XXXXXXXXXX

/ MFG DATE

YYYY.MM.DD.

/ EXP DATE

YYYY.MM.DD.

#Buffer Lot: XXXXXXXXXX

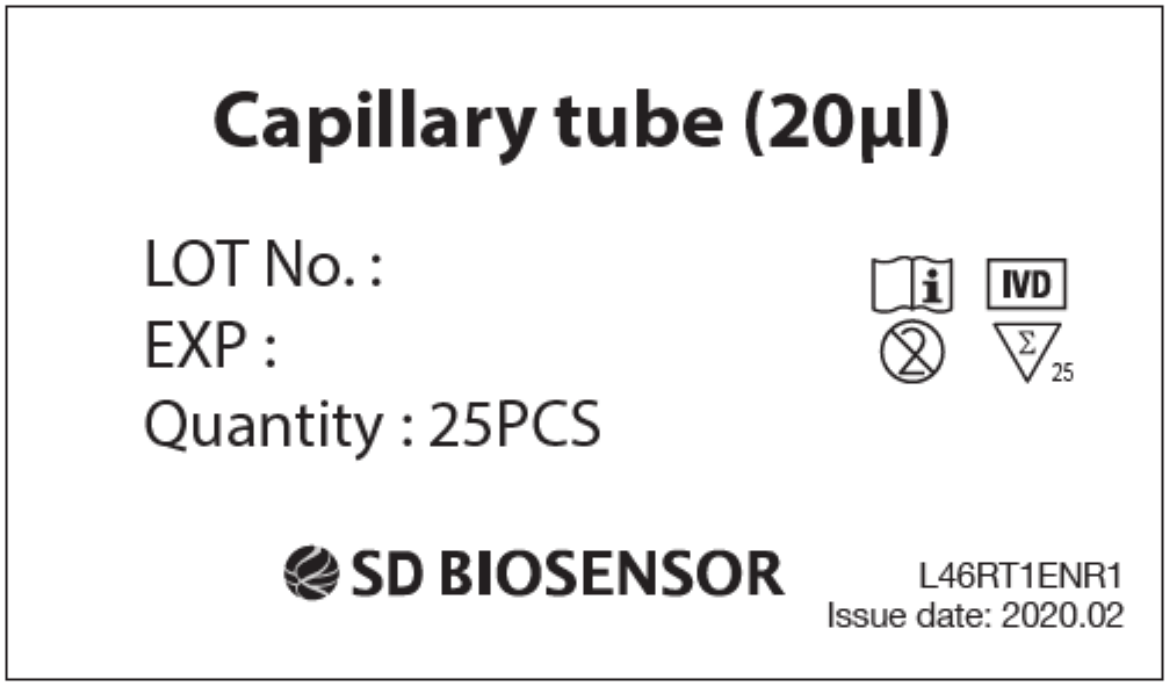
Manufactured by

SD BIOSENSOR 에스디 바이오센서(주)

www.sdbiosensor.com

1.3 Buffer label

1.4 Inverted cup(5 $\mu\ell$) label



1.5 Sterile Lancet label

1.6 Alcohol swab label

Front

Back

2. Instructions for use[1]

[1] English version of the IFU was the one that was assessed by WHO. It is the responsibility of the manufacturer to ensure correct translation into other languages.

Quality approved by SD BIOSENSOR / For *In vitro* diagnostic use only

STANDARD Q

HIV/Syphilis Combo

STANDARD™ Q HIV/Syphilis Combo Test

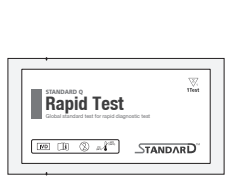
PLEASE READ BACK PAGE CAREFULLY BEFORE YOU PERFORM THE TEST

REF QHSC01B

Cat. No.: 09HIV20D

SD BIOSENSOR

[Kit Contents]



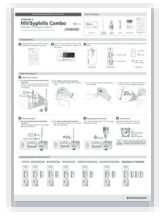
Test device (individually in a foil pouch with desiccant)

Capillary tube (20μl)

Buffer bottle

Sterile Lancet

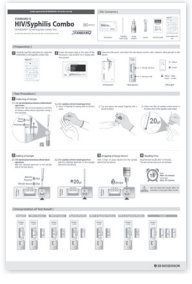
Alcohol swab



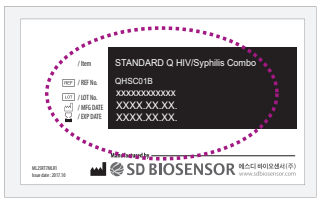
Instructions for use

[Preparation]

1 Carefully read the instruction for using the STANDARD Q HIV/Syphilis Combo Test.

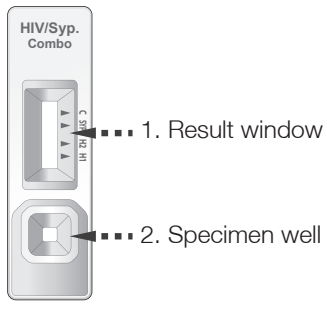


2 Check the expiry date at the back of the foil pouch. Use another lot, if expiry date has passed.

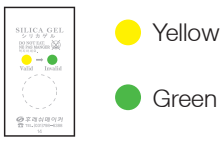


3 Open the foil pouch, and check the test device and the color indicator desiccant pack in foil pouch.

<Foil pouch>



<Test device>



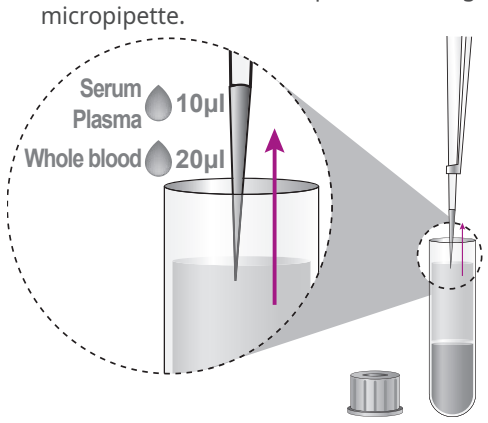
<Desiccant>

[Test Procedure]

1 Collecting of Sample

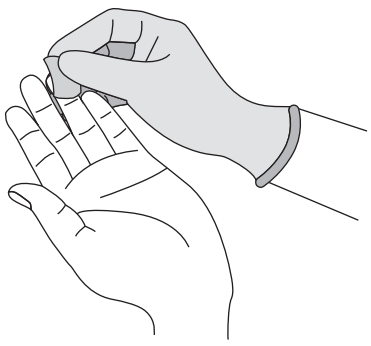
1-1. For serum/plasma/venous whole blood specimen

Collect the 10μl of serum/plasma or 20ul of venous whole blood specimen using a micropipette.

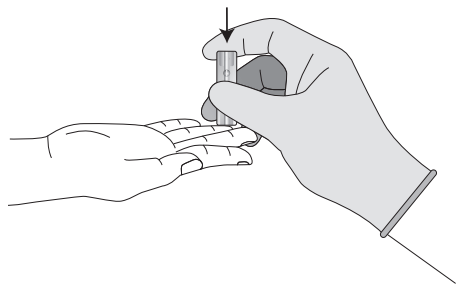


1-2. For capillary whole blood specimen

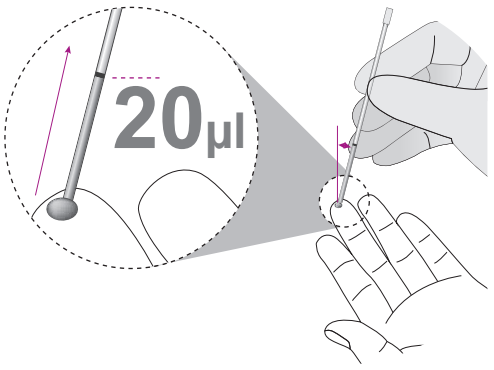
① Clean a fingertip by wiping with an alcohol swab.



② Dry and pierce the wiped fingertip with a sterile lancet to bleed.



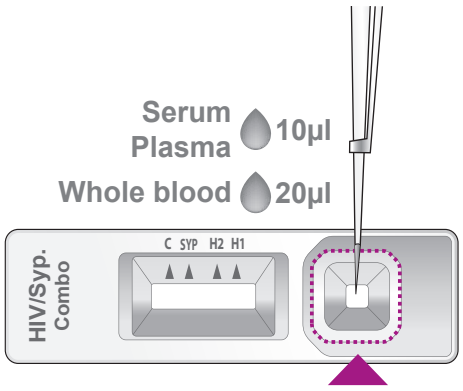
③ Collect the 20μl of capillary whole blood to the black line of the capillary tube (20μl).



2 Adding of Sample

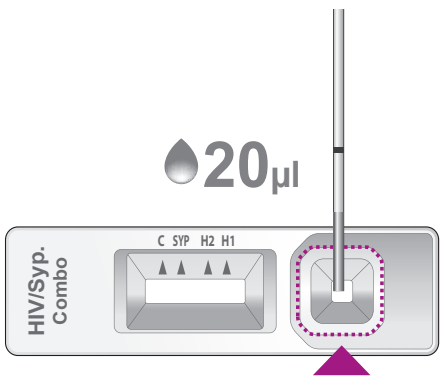
2-1. For serum/plasma/venous whole blood specimen

Add the collected specimen to the sample well of the test device.



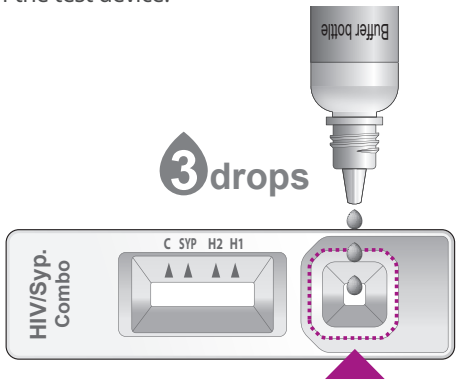
2-2. For capillary whole blood specimen

Add the collected specimen to the sample well of the test device.



3 Dropping of Buffer

Hold the buffer bottle at 90˚ angle to the test device without touching the specimen well to avoid contamination of the buffer.
Add 3 drops of the buffer into the specimen well of the test device.



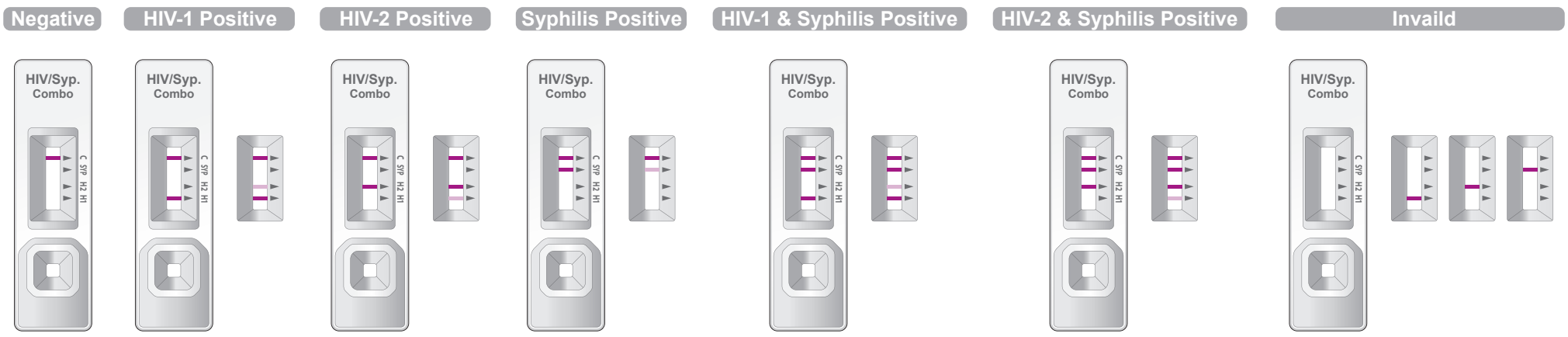
4 Reading Time

Read the test results between 15 to 20 minutes after adding Buffer.

Read
After 15 minutes
Do not read
After 20 minutes

CAUTION Do not read test results after 20 minutes. It may give false results.

[Interpretation of Test Result]



SD BIOSENSOR

EXPLANATION AND SUMMARY

[Introduction]

It is common that co-infection of HIV and syphilis occur in similar patient group since they are both are sexually transmitted infections. Furthermore, they have an influence on each other in many ways. Many studies show that syphilis can increase the transmission of HIV: the presence of genital ulcers can increase shedding of HIV; syphilis also increases HIV-1 viral load and decreases CD4 T-cell count. It is known that the manifestation and symptoms of syphilis are different in HIV-infected patient group, so therapeutics of syphilis should be changed in HIV co-infected patients. For these reasons, there are no doubts about the usefulness of management of HIV and syphilis in tandem. Especially, it is essential to check whether pregnant women have the HIV/syphilis infection due to the risk of mother-to-child transmission (MTCT) of HIV and syphilis infection. STANDARD Q HIV/Syphilis Combo Test is able to quick screen the HIV/syphilis infection and gives the advantage of managing these two diseases at the same time.

[Intended use]

STANDARD™ Q HIV/Syphilis Combo Test is a rapid chromatographic immunoassay for the qualitative detection of antibodies specific to HIV-1 including subtype O, HIV 2 and Syphilis (*Treponema pallidum*) in human serum, plasma or whole blood. The test is for in vitro diagnostic use and intended as an aid to diagnosis of HIV and Syphilis infection for HIV or Syphilis infected patients, patients with signs and symptoms for HIV and Syphilis and persons at risk including pregnant women. The test is intended to be used by trained healthcare or laboratory professionals or other health care workers who have received appropriate training. This product can be used by trained lay providers operating in point-of-care settings in resource-limited countries. It provides only an initial screening test result. More specific alternative diagnosis methods should be performed in order to obtain the confirmation of HIV Virus and Syphilis infection.

[Test principle]

STANDARD Q HIV/Syphilis Combo Test has "H1", "H2", "SYP" and "C" line region pre-coated with recombinant HIV-1 GP41 protein / recombinant HIV-1 subtype O GP41, recombinant HIV-2 GP36 protein, recombinant p17 *Treponema pallidum* protein (recombinant TPP 17 protein) and monoclonal anti-HIV-1 / monoclonal anti-syphilis respectively. The anti-HIV-1/anti-HIV-1 subtype O in patient specimen interacts with the recombinant HIV-1 GP41-gold / recombinant HIV-1 subtype O GP41-gold and the anti-HIV-2 in patient specimen interacts with the recombinant HIV-2 GP36-gold in the conjugation pad. The anti-syphilis in patient specimen interacts with the recombinant TPP 17 protein-gold. The complex moves along the membrane chromatographically with buffer and is captured by the recombinant HIV-1 and HIV-2 antigens and/or recombinant TPP 17 antigen on the each test line (H1, H2, SYP). If the antibodies against HIV 1/ 2 and/or syphilis are in the patient specimen, visible lines are formed in the each test line. The control line should always appear if the test procedure is performed properly.

[Kit contents]

① Test device (individually in a foil pouch with desiccant) x 25 ② Buffer bottle x 1 ③ Capillary tube (20µl) x 25
④ Sterile lancet x 25 ⑤ Alcohol swab x 25 ⑥Instructions for use x 1

[Materials required but not provided]

① Micropipette and tip ② Blood collection tube ③ PPE (Personal Protective Equipment) ④ Biohazard container

KIT STORAGE AND STABILITY

1. Store the kit unopened at 2-40°C/36-104°F, out of direct sunlight.
2. Do not open the aluminum pouch until you are ready to perform a test.
3. The buffer bottle provided in the kit is stable until the expiry date of the kit after opening its cap, if it is tightly closed.

WARNINGS AND PRECAUTIONS

1. Do not reuse the test kit.
2. Do not use the test kit if the pouch is damaged or the seal is broken.
3. Do not use after the expiration date.
4. Do not use buffer bottle of another lot.
5. Do not smoke, drink or eat while handling specimen.
6. Wear personal protective equipment, such as gloves and lab coats when handling kit reagents. Wash hands thoroughly when afterwards.
7. Clean up spills thoroughly using an appropriate disinfectant.
8. Handle all specimens as if they contain infectious agents.
9. Observe established precautions against microbiological hazards throughout testing procedures.
10. Dispose of all specimens and materials used to perform the test as bio-hazard waste. Laboratory chemical and bio-hazard wastes must be handled and discarded in accordance with all local, state, and national regulations.
11. Desiccant in foil pouch is to absorb moisture and keep humidity from affecting products. If the moisture indicating desiccant beads change from yellow to green, the test device in the pouch should be discarded.
12. Allow Kit components to reach room temperature (15-30°C) before performing a test.
13. Follow necessary precautions when handling specimens with this test. Use personal protective equipment (PPE) consistent with guideline[11].
14. The buffer contains 0.01% sodium azide as a preservative which may be toxic if ingested. When disposed of through a sink, flush with large quantities of water.

SPECIMEN COLLECTION AND PREPARATION

[Serum]

1. Collect whole blood by venipuncture into commercially available tubes WITHOUT anti-coagulant, and leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant.
2. If serum in the plain tube is stored in a refrigerator at 2-8°C / 36-46°F, the specimen can be used for testing within 4 days after collection. For prolonged storage, it should be at below -40°C / -40°F.
3. It should be brought to room temperature prior to use.

[Plasma]

1. Collect the venous whole blood into the commercially available anti-coagulant tube such as heparin, 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 2-8°C / 36-46°F, the specimen can be used for testing within 4 days after collection. For prolonged storage, it should be at below -40°C / -40°F.
3. It should be brought to room temperature prior to use.

[Whole blood]

- **Capillary whole blood**

1. Capillary whole blood should be collected aseptically 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.
4. Collect the capillary whole blood to the black line of the capillary tube for the testing.
5. The capillary whole blood must be tested immediately after collection.

- **Venous whole blood**

1. Collect the venous whole blood into the commercially available anti-coagulant tube such as heparin, EDTA or sodium citrate by venipuncture.
2. If venous whole blood in an anti-coagulant tube is stored in a refrigerator at 2-8°C / 36-46°F, the specimen can be used for testing within 1-2 days after collection.
3. Do not use hemolyzed blood specimen.

CAUTION

- Anticoagulants such as heparin, EDTA or sodium citrate do not affect the test result.
- As known relevant interference, haemolytic samples, rheumatoid factors-contained samples and lipaemic, icteric samples can lead to impair the test results.

TEST PROCEDURE

[Preparation]

1. Carefully read the instructions for using the STANDARD™ Q HIV/Syphilis Combo Test.
2. Look at the expiry date at the back of the foil pouch. Use another lot, if expiry date has passed.
3. Allow the STANDARD™ Q HIV/Syphilis Combo Test components and specimen to come to room temperature(15-25°C/59-77°F) for 30min prior to testing.
4. Check that the test device packaging is not damaged. If damaged, discard the test and use another test. If a humidity indicator inside shows saturation (color changed from orange to green), throw away the test device and take another test device packaging. If the color of the buffer bottle does not show a change, you can use the test. Throw away the buffer bottle in the non-sharps (non-infectious) disposal container.
5. Procedure method should be followed for the specific specimen type being tested.

[Test Procedure]

- **For serum/plasma/venous whole blood specimen**

1. Collect the 10µl of serum/plasma or 20ul of venous whole blood specimen using a micropipette.
2. Add the collected specimen to the specimen well of the test device.
3. Add 3 drops of buffer into the sample well of the test device.
4. Read the test results between 15 to 20 minutes after adding buffer.

- **For capillary whole blood specimen**

1. Clean a fingertip by wiping with an alcohol swab.
2. Dry and pierce the wiped fingertip with a lancet to bleed.
3. Collect the 20µl of capillary whole blood to the black line of the capillary tube (20µl).
4. Add the collected whole blood to the specimen well of the test device.
5. Add 3 drops of buffer into the sample well of the test device.
6. Read the test results between 15 to 20 minutes after adding buffer.

CAUTION

- Do not read test results after 20 minutes. It may give false results.
- Place the test device on the flat surface after applying the specimen.
- Use correct amount of specimen and buffer.

INTERPRETATION OF TEST RESULTS

Negative Result

- The presence of only "C" line indicates a negative result.

HIV-1 Positive Result

- The presence of two lines as "C" and "H1" line indicates a positive result for HIV-1.
- In case of the presence of three lines as "C", "H1" and "H2", if the intensity of the "H1" line is stronger than "H2" line, its should be interpreted as HIV-1 positive.

HIV-2 Positive Result

- The presence of two lines as "C" and "H2" line indicates a positive result for HIV-2.
- In case of the presence of three lines as "C", "H2" and "H1", if the intensity of the "H2" line is stronger than "H1" line, it should be interpreted as HIV-2 positive.

NOTE Interprete faint lines of "H1" and/or "H2" as the positive for HIV-1 and/or HIV-2.

Syphilis Positive Result

- The presence of two lines as "C" and "SYP" line indicates a positive result for Syphilis.

NOTE Interprete faint lines of "SYP" as the positive for Syphilis.

HIV-1 & Syphilis Positive Result

- The presence of three lines as "C", "H1" and "SYP" line indicates a positive result for HIV-1 and Syphilis.

HIV-2 & Syphilis Positive Result

- The presence of three lines as "C", "H2" and "SYP" line indicates a positive result for HIV-2 and Syphilis.

Invalid Result

- No presence of "C" line indicates an invalid result even in the presence of other lines. It is recommended that the specimen be retested using a new device.

CAUTION

- In case the intensity of 'H1' and 'H2' line is similar, confirmatory testing is recommended to confirm the virus type or a co-infection.
- Positive results should be considered in conjunction with the clinical history and other data available to the physician.

LIMITATION OF TEST

1. All three test lines ("H1", "H2" and "C") may develop when tested with specimen containing high titers of HIV-1 antibodies. Hence, reactive test bands for both HIV-1 and HIV-2 may not indicate mixed infection but may result from the cross reactivity of HIV-1 and HIV-2 because of the similarity of their genomic structure.
2. A positive result indicates presence of antibodies to HIV-1/2 and/or Syphilis. However, a positive result does not indicate a conclusive HIV and Syphilis infection diagnosis. A positive result should be confirmed by a supplemental test.
3. A negative result does not eliminate the possibility of infection with HIV-1/2 and Syphilis. The STANDARD Q HIV/Syphilis combo Test may not detect extremely low concentration of the antibody to HIV-1/2 and Syphilis. For negative result with this kit additional test using other clinical method is necessary.
4. The test results alone should not be used in diagnosis of infection with HIV-1/2 and Syphilis. For overall clinical diagnosis, results must be used in conjunction with the patient's clinical symptoms, and clinical history.

QUALITY CONTROL

1. A colored line appearing in the control line is an internal reagent and procedural control. It will appear if the test has been performed correctly and the reagent are reactive.
2. Control materials are not supplied with this test kit. However, it is recommended that the positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

PERFORMANCE CHARACTERISTICS

1. Diagnostic sensitivity:

- HIV Ab detection: The Diagnostic Sensitivity for anti-HIV antibody detection, calculated on 637 positive samples, is 100% (637/637) with a Wilson 95% confidence interval of [99.4% - 100.0%].

	STANDARD Q HIV/Syphilis Combo Test	
	HIV negative	HIV positive
Anti-HIV-1 positive/Anti-Tp negative	0	247
Anti-HIV-1/Anti-Tp positive	0	250
Anti-HIV-1 positive non-B subtype	0	40
Anti-HIV-2 positive	0	100
Sensitivity	637/637 = 100%	

- Syphilis Ab detection: The Diagnostic Sensitivity for anti-Treponema pallidum antibody detection, calculated on 400 positive samples, is 98.8% (395/400) with a Wilson 95% confidence interval of [97.1% - 99.5%].

	STANDARD Q HIV/Syphilis Combo Test	
	Syphilis negative	Syphilis positive
Anti-Tp/Anti-HIV positive	4	246
Anti-Tp positive/anti-HIV negative	1	149
Sensitivity	395/400 = 98.8%	

2. Diagnostic specificity:

The Diagnostic Specificity for anti-HIV Ab detection, calculated on 1500 negative samples, is 99.9% (1499/1500) with a Wilson 95% confidence interval of [99.6% - 100.0%].
The Diagnostic Specificity for anti-Tp Ab detection, calculated on 1500 negative samples, is 100% (1500/1500) with a Wilson 95% confidence interval of [99.7% - 100.0%].

	STANDARD Q HIV/Syphilis Combo Test			
	HIV		Syphilis	
	Negative	Positive	Negative	Positive
Blood donors EDTA-K3 plasma	1000	0	1000	0
Blood donors EDTA-K3 whole blood	499	1	500	0
Specificity	1499/1500 = 99.9%		1500/1500 = 100%	

BIBLIOGRAPHY

1. Owen SM et al. Alternative Algorithms for Human Immunodeficiency Virus Infection Diagnosis Using Tests That Are Licensed in the United States. J Clin Microbiol 46:1588-1595, 2008.
2. Barre-Sinoussi F, Chermann JC, Rey F, et al: Isolation of a T-lymphotropic retrovirus from a patient at risk for acquired immune deficiency syndrome (AIDS). Science 220:868-871, 1983.
3. Centers for Disease Control: Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus, and other bloodborne pathogens in health-care settings. Morbidity and Mortality Weekly Rep 37:377-388, 1988.
4. Hoff R, Weiblen BJ, Schwerzler M, et al: Specific antibodies to HIV-2 detected in an anonymous newborn blood specimen from Massachusetts. Fourth Consensus Conference on Testing for Human Retroviruses, March 1989.
5. Charneau P, Borman AM, Quillant C, et al: Isolation and envelope sequence of a highly divergent.
6. Farhi, D; Dupin, N (September–October 2010). "Origins of syphilis and management in the immunocompetent patient: facts and controversies". Clinics in Dermatology 28 (5): 533–8.
7. Miller JN : value and limitation of nontreponemal and treponemal tests in the laboratory diagnosis of syphilis. Clin. Obstet Gynecol 18: 191-203, 1975.
8. Syphilis - CDC Fact Sheet (Detailed)". CDC. November 2, 2015. Retrieved 3 February 2016.
9. Alexander, JM; Sheffield, JS; Sanchez, PJ; Mayfield, J; Wendel GD, Jr (January 1999). "Efficacy of treatment for syphilis in pregnancy.". Obstetrics and gynecology 93 (1): 5-8.
10. A Gerber et al., Recombinant Treponema pallidum antigens in syphilis serology. Immunobiology. 196(5):535-49, 1996-1997.
11. Perspectives in Disease Prevention and Health Promotion Update: Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Bloodborne Pathogens in Health-Care Settings. MMWR, June 24,1988/37(24):377-388.

IVD

Manufactured by SD Biosensor, Inc.
Head office : C-4th&5th, 16, Deogyeong-daero 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, REPUBLIC OF KOREA
Manufacturing site : 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, REPUBLIC OF KOREA

Please contact us for any complaints/inquiries/suggestions via email (sales@sdbiosensor.com), phone (+82-31-300-0400) or website (www.sdbiosensor.com).

R-L23HIV2ENR4-W
Issue date: 2020.05

REF Reference number | IVD *In vitro* Diagnostics | Consult Instructions for Use | Σ Contains Sufficient for <n> Tests | Caution | Note | Do not re-use. | To indicate the temperature limitations in which the transport package has to be kept and handled. | Use by | LOT Batch code | Manufacturer | Date of manufacture | Indicate that you should keep the product dry | Keep away from sunlight | Do not use if packaging is damaged

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 075369 0056 Rev. 01

Holder of Certificate: **SD Biosensor, Inc.**
C-4th&5th, 16, Deogyeong-daero
1556beon-gil, Yeongtong-gu
Suwon-si, Gyeonggi-do 16690
REPUBLIC OF KOREA

Certification Mark:

Scope of Certificate: **Design, Development, Production and Distribution of Blood Glucose Monitoring System, Lipid Test System, G6PD Test System, Hemoglobin A1c Test System, In Vitro Diagnostic Medical Device for Immunochromatography, In Vitro Diagnostic Kits for ELISA, Molecular Diagnostic reagent kit used in the detection of infectious diseases, DNA/ RNA extraction kit and service of respective instruments**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 075369 0056 Rev. 01

Report No.: 74961292_CN

Valid from: 2022-03-26
Valid until: 2025-03-25

Date, 2022-03-25

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 075369 0056 Rev. 01

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

SD Biosensor, Inc.
C-4th&5th, 16, Deogyeong-daero, 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do 16690, REPUBLIC OF KOREA

Design, Development, Production and Distribution of Blood Glucose Monitoring System, Lipid Test System, G6PD Test System, Hemoglobin A1c Test System, In Vitro Diagnostic Medical Device for Immunochromatography, In Vitro Diagnostic Kits for ELISA, Molecular Diagnostic reagent kit used in the detection of infectious diseases, DNA/ RNA extraction kit and service of respective instruments

SD Biosensor, Inc.
74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do 28161, REPUBLIC OF KOREA

Production and Distribution of Blood Glucose Monitoring System, Lipid Test System, G6PD Test System, Hemoglobin A1c Test System, In Vitro Diagnostic Medical Device for Immunochromatography, In Vitro Diagnostic Kits for ELISA, Molecular Diagnostic reagent kit used in the detection of infectious diseases, DNA/ RNA extraction kit and service of respective instruments

SD Biosensor, Inc.
4-18, Dongbu-daero, Jinwi-myeon, Pyeongtaek-si, Gyeonggi-do 17712, REPUBLIC OF KOREA

Quality control and service of instrument

SD Biosensor, Inc.
688, Dureungyuri-ro, Ochang-eup, Cheongwon-gu, Cheongju-si, Chungcheongbuk-do 28107, REPUBLIC OF KOREA

Warehouse and Distribution of Blood Glucose Monitoring System, Lipid Test System, G6PD Test System, Hemoglobin A1c Test System, In-Vitro Diagnostic Medical Device for Immunochromatography, In Vitro Diagnostic Kits for ELISA, Molecular Diagnostic reagent kit used in the detection of infectious diseases and DNA/RNA extraction kit

SD Biosensor, Inc.
A-402, 16, Deogyeong-daero, 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do 16690, REPUBLIC OF KOREA

Production and Quality control of Molecular Diagnostic reagent kit used in the detection of infectious diseases and DNA/RNA extraction kit

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 075369 0056 Rev. 01

SD Biosensor, Inc.
C-1st&3rd, D-1st&2nd&3rd,745-46, Yeoncheong-ro, Bugang-myeon, Sejong-si 30071, REPUBLIC OF KOREA

Warehouse and Quality control of raw materials of Blood Glucose Monitoring System, Lipid Test System, G6PD Test System, Hemoglobin A1c Test System, In Vitro Diagnostic Medical Device for Immunochromatography, In Vitro Diagnostic Kits for ELISA, Molecular Diagnostic reagent kit used in the detection of infectious diseases and DNA/RNA extraction kit.

SD Biosensor, Inc.
221, Simogoecheon-ro, Hyeondo-myeon, Seowon-gu, Cheongju-si, Chungcheongbuk-do 28211, REPUBLIC OF KOREA

Warehouse of raw materials and product of Blood Glucose Monitoring System, Lipid Test System, G6PD Test System, Hemoglobin A1c Test System, In Vitro Diagnostic Medical Device for Immunochromatography, In Vitro Diagnostic Kits for ELISA, Molecular Diagnostic reagent kit used in the detection of infectious diseases and DNA/RNA extraction kit.

SD Biosensor, Inc.
18-29, Cheomdangieop 2-ro, Sandong-eup, Gumi-si, Gyeongsangbuk-do 39174, REPUBLIC OF KOREA

Production and Quality control of Molecular Diagnostic reagent kit used in the detection of infectious diseases and DNA/RNA extraction kit

./.

Quality approved by SD BIOSENSOR / For *In vitro* diagnostic use only

STANDARD Q

HIV/Syphilis Combo

STANDARD™ Q HIV/Syphilis Combo Test

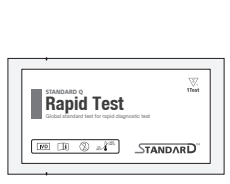
PLEASE READ BACK PAGE CAREFULLY BEFORE YOU PERFORM THE TEST

REF QHSC01B

Cat. No.: 09HIV20D

SD BIOSENSOR

[Kit Contents]



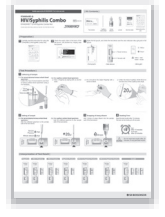
Test device (individually in a foil pouch with desiccant)

Capillary tube (20μl)

Buffer bottle

Sterile Lancet

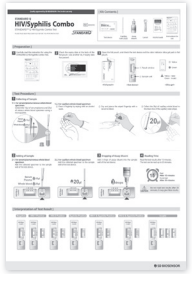
Alcohol swab



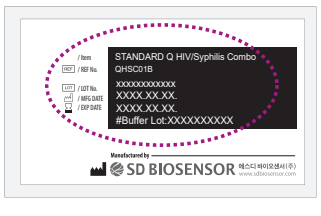
Instructions for use

[Preparation]

1 Carefully read the instruction for using the STANDARD Q HIV/Syphilis Combo Test.

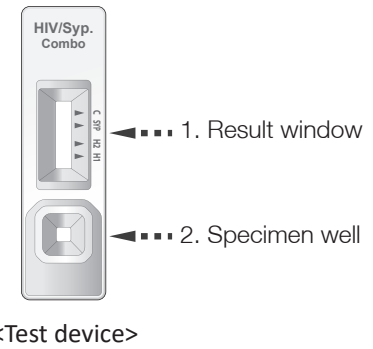


2 Check the expiry date at the back of the foil pouch. Use another lot, if expiry date has passed.

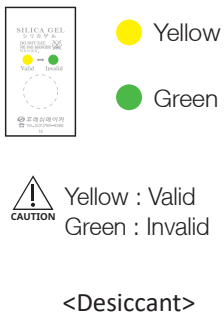


3 Open the foil pouch, and check the test device and the color indicator desiccant pack in foil pouch.

<Foil pouch>



<Test device>



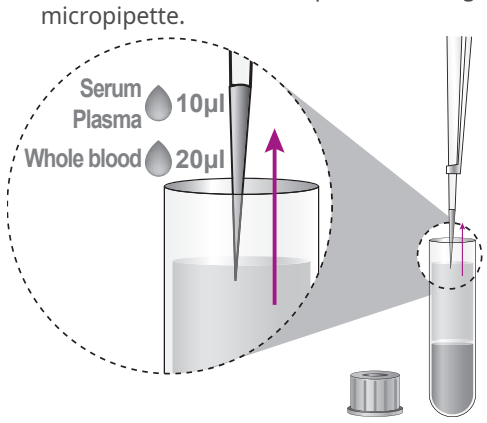
<Desiccant>

[Test Procedure]

1 Collecting of Specimen

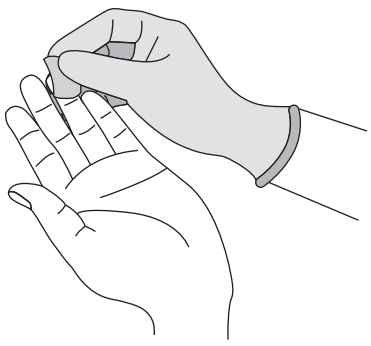
1-1. For serum/plasma/venous whole blood specimen

Collect the 10μl of serum/plasma or 20ul of venous whole blood specimen using a micropipette.

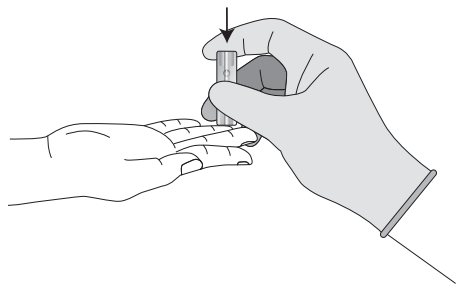


1-2. For capillary whole blood specimen

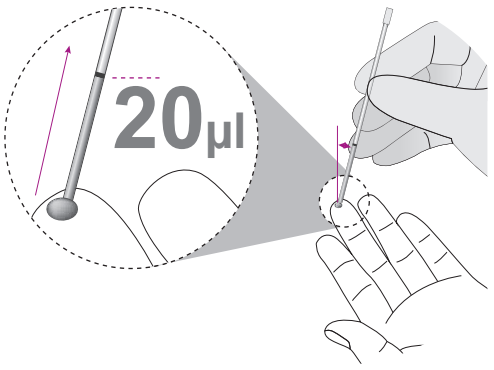
① Clean a fingertip by wiping with an alcohol swab.



② Dry and pierce the wiped fingertip with a sterile lancet to bleed.



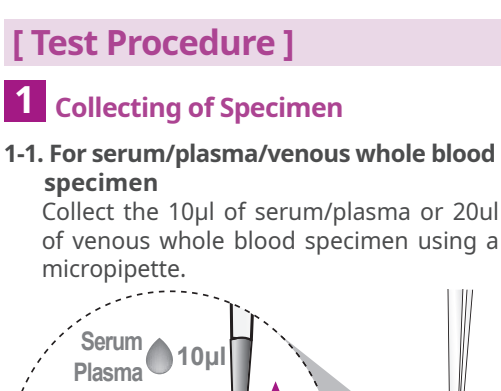
③ Collect the 20μl of capillary whole blood to the black line of the capillary tube (20μl).



2 Adding of Specimen

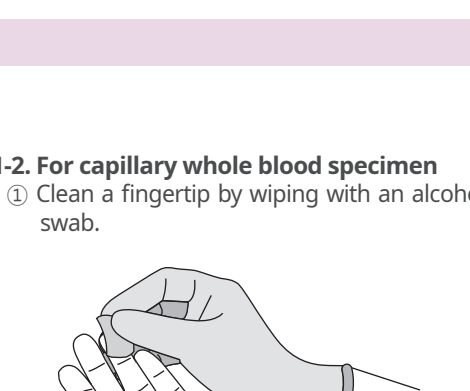
2-1. For serum/plasma/venous whole blood specimen

Add the collected specimen to the specimen well of the test device.



2-2. For capillary whole blood specimen

Add the collected specimen to the specimen well of the test device.



3 Dropping of Buffer

Hold the buffer bottle at 90˚ angle to the test device without touching the specimen well to avoid contamination of the buffer.
Add 3 drops of the buffer into the specimen well of the test device.

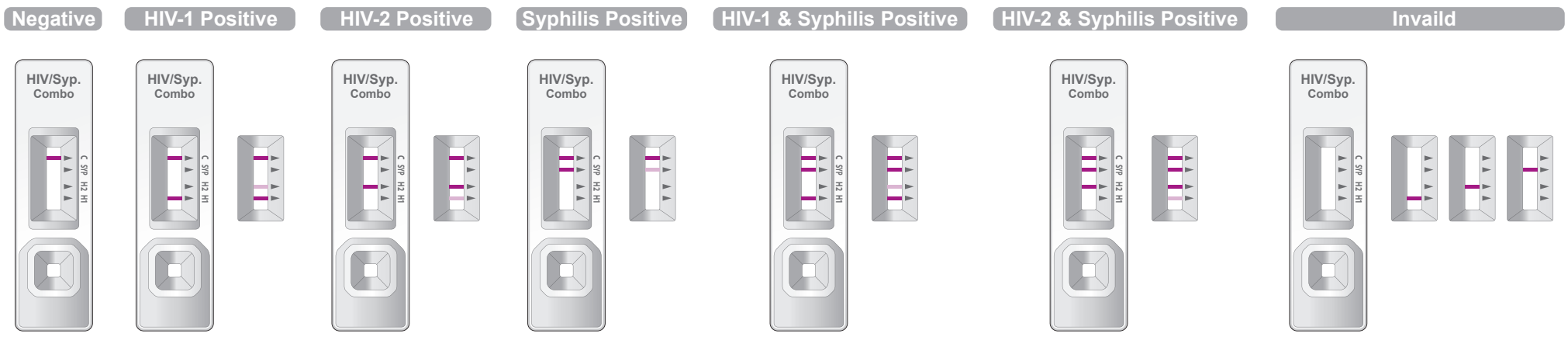
4 Reading Time

Read the test results between 15 to 20 minutes after adding Buffer.

Read
After 15 minutes
Do not read
After 20 minutes

CAUTION Do not read test results after 20 minutes. It may give false results.

[Interpretation of Test Result]



SD BIOSENSOR

EXPLANATION AND SUMMARY

[Introduction]

It is common that co-infection of HIV and syphilis occur in similar patient group since they are both are sexually transmitted infections. Furthermore, they have an influence on each other in many ways. Many studies show that syphilis can increase the transmission of HIV: the presence of genital ulcers can increase shedding of HIV; syphilis also increases HIV-1 viral load and decreases CD4 T-cell count. It is known that the manifestation and symptoms of syphilis are different in HIV-infected patient group, so therapeutics of syphilis should be changed in HIV co-infected patients. For these reasons, there are no doubts about the usefulness of management of HIV and syphilis in tandem. Especially, it is essential to check whether pregnant women have the HIV/syphilis infection due to the risk of mother-to-child transmission (MTCT) of HIV and syphilis infection. STANDARD Q HIV/Syphilis Combo Test is able to quick screen the HIV/syphilis infection and gives the advantage of managing these two diseases at the same time.

[Intended use]

STANDARD™ Q HIV/Syphilis Combo Test is a rapid chromatographic immunoassay for the qualitative detection of antibodies specific to HIV-1 including subtype O, HIV 2 and Syphilis (*Treponema pallidum*) in human serum, plasma or whole blood. The test is for in vitro diagnostic use and intended as an aid to diagnosis of HIV and Syphilis infection for HIV or Syphilis infected patients, patients with signs and symptoms for HIV and Syphilis and persons at risk including pregnant women. The test is intended to be used by trained healthcare or laboratory professionals or other health care workers who have received appropriate training. This product can be used by trained lay providers operating in point-of-care settings in resource-limited countries. It provides only an initial screening test result. More specific alternative diagnosis methods should be performed in order to obtain the confirmation of HIV Virus and Syphilis infection.

[Test principle]

STANDARD Q HIV/Syphilis Combo Test has “H1”, “H2”, “SYP” and “C” line region pre-coated with recombinant HIV-1 GP41 protein / recombinant HIV-1 subtype O GP41, recombinant HIV-2 GP36 protein, recombinant p17 *Treponema pallidum* protein (recombinant TPP 17 protein) and monoclonal anti-HIV-1 / monoclonal anti-syphilis respectively. The anti-HIV-1/anti-HIV-1 subtype O in patient specimen interacts with the recombinant HIV-1 GP41-gold / recombinant HIV-1 subtype O GP41-gold and the anti-HIV-2 in patient specimen interacts with the recombinant HIV-2 GP36-gold in the conjugation pad. The anti-syphilis in patient specimen interacts with the recombinant TPP 17 protein-gold. The complex moves along the membrane chromatographically with buffer and is captured by the recombinant HIV-1 and HIV-2 antigens and/or recombinant TPP 17 antigen on the each test line (H1, H2, SYP). If the antibodies against HIV 1/ 2 and/or syphilis are in the patient specimen, visible lines are formed in the each test line. The control line should always appear if the test procedure is performed properly.

[Kit contents]

① Test device (individually in a foil pouch with desiccant) x 25 ② Capillary tube (20μl) x 25 ③ Buffer bottle x 1
④ Sterile lancet x 25 ⑤ Alcohol swab x 25 ⑥Instructions for use x 1

[Materials required but not provided]

① Micropipette and tip ② Blood collection tube ③ PPE (Personal Protective Equipment) ④ Biohazard container

KIT STORAGE AND STABILITY

1. Store the kit unopened at 2-40°C/36-104°F, out of direct sunlight.
2. Do not open the aluminum pouch until you are ready to perform a test.
3. The buffer bottle provided in the kit is stable until the expiry date of the kit after opening its cap, if it is tightly closed.

WARNINGS AND PRECAUTIONS

1. Do not reuse the test kit.
2. Do not use the test kit if the pouch is damaged or the seal is broken.
3. Do not use after the expiration date.
4. Do not use buffer bottle of another lot.
5. Do not smoke, drink or eat while handling specimen.
6. Wear personal protective equipment, such as gloves and lab coats when handling kit reagents. Wash hands thoroughly when afterwards.
7. Clean up spills thoroughly using an appropriate disinfectant.
8. Handle all specimens as if they contain infectious agents.
9. Observe established precautions against microbiological hazards throughout testing procedures.
10. Dispose of all specimens and materials used to perform the test as bio-hazard waste. Laboratory chemical and bio-hazard wastes must be handled and discarded in accordance with all local, state, and national regulations.
11. Desiccant in foil pouch is to absorb moisture and keep humidity from affecting products. If the moisture indicating desiccant beads change from yellow to green, the test device in the pouch should be discarded.
12. Allow Kit components to reach room temperature (15-30°C) before performing a test.
13. Follow necessary precautions when handling specimens with this test. Use personal protective equipment (PPE) consistent with guideline[11].
14. The buffer contains 0.01% sodium azide as a preservative which may be toxic if ingested. When disposed of through a sink, flush with large quantities of water.

SPECIMEN COLLECTION AND PREPARATION

[Serum]

1. Collect whole blood by venipuncture into commercially available tubes WITHOUT anti-coagulant, and leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant.
2. If serum in the plain tube is stored in a refrigerator at 2-8°C / 36-46°F, the specimen can be used for testing within 4 days after collection. For prolonged storage, it should be at below -40°C / -40°F.
3. It should be brought to room temperature prior to use.

[Plasma]

1. Collect the venous whole blood into the commercially available anti-coagulant tube such as heparin, 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 2-8°C / 36-46°F, the specimen can be used for testing within 4 days after collection. For prolonged storage, it should be at below -40°C / -40°F.
3. It should be brought to room temperature prior to use.

[Whole blood]

- **Capillary whole blood**

1. Capillary whole blood should be collected aseptically 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.
4. Collect the capillary whole blood to the black line of the capillary tube for the testing.
5. The capillary whole blood must be tested immediately after collection.

- **Venous whole blood**

1. Collect the venous whole blood into the commercially available anti-coagulant tube such as heparin, EDTA or sodium citrate by venipuncture.
2. If venous whole blood in an anti-coagulant tube is stored in a refrigerator at 2-8°C / 36-46°F, the specimen can be used for testing within 1-2 days after collection.
3. Do not use hemolyzed blood specimen.

CAUTION

- Anticoagulants such as heparin, EDTA or sodium citrate do not affect the test result.
- As known relevant interference, haemolytic specimens, rheumatoid factors-contained specimens and lipaemic, icteric specimens can lead to impair the test results.

TEST PROCEDURE

[Preparation]

1. Carefully read the instructions for using the STANDARD™ Q HIV/Syphilis Combo Test.
2. Look at the expiry date at the back of the foil pouch. Use another lot, if expiry date has passed.
3. Allow the STANDARD™ Q HIV/Syphilis Combo Test components and specimen to come to room temperature(15-25°C/59-77°F) for 30min prior to testing.
4. Check that the test device packaging is not damaged. If damaged, discard the test and use another test. If a humidity indicator inside shows saturation (color changed from orange to green), throw away the test device and take another test device packaging. If the color of the buffer bottle does not show a change, you can use the test. Throw away the buffer bottle in the non-sharps (non-infectious) disposal container.
5. Procedure method should be followed for the specific specimen type being tested.

[Test Procedure]

- **For serum/plasma/venous whole blood specimen**

1. Collect the 10μl of serum/plasma or 20ul of venous whole blood specimen using a micropipette.
2. Add the collected specimen to the specimen well of the test device.
3. Add 3 drops of buffer into the specimen well of the test device.
4. Read the test results between 15 to 20 minutes after adding buffer.

- **For capillary whole blood specimen**

1. Clean a fingertip by wiping with an alcohol swab.
2. Dry and pierce the wiped fingertip with a lancet to bleed.
3. Collect the 20μl of capillary whole blood to the black line of the capillary tube (20μl).
4. Add the collected whole blood to the specimen well of the test device.
5. Add 3 drops of buffer into the specimen well of the test device.
6. Read the test results between 15 to 20 minutes after adding buffer.

CAUTION

- Do not read test results after 20 minutes. It may give false results.
- Place the test device on the flat surface after applying the specimen.
- Use correct amount of specimen and buffer.

INTERPRETATION OF TEST RESULTS

Negative Result

- The presence of only “C” line indicates a negative result.

HIV-1 Positive Result

- The presence of two lines as “C” and “H1” line indicates a positive result for HIV-1.
- In case of the presence of three lines as “C”, “H1” and “H2”, if the intensity of the “H1” line is stronger than “H2” line, its should be interpreted as HIV-1 positive.

HIV-2 Positive Result

- The presence of two lines as “C” and “H2” line indicates a positive result for HIV-2.
- In case of the presence of three lines as “C”, “H2” and “H1”, if the intensity of the “H2” line is stronger than “H1” line, it should be interpreted as HIV-2 positive.

NOTE

Interprete faint lines of “H1” and/or “H2” as the positive for HIV-1 and/or HIV-2.

Syphilis Positive Result

- The presence of two lines as “C” and “SYP” line indicates a positive result for Syphilis.

NOTE

Interprete faint lines of “SYP” as the positive for Syphilis.

HIV-1 & Syphilis Positive Result

- The presence of three lines as “C”, “H1” and “SYP” line indicates a positive result for HIV-1 and Syphilis.

HIV-2 & Syphilis Positive Result

- The presence of three lines as “C”, “H2” and “SYP” line indicates a positive result for HIV-2 and Syphilis.

Invalid Result

- No presence of “C” line indicates an invalid result even in the presence of other lines. It is recommended that the specimen be retested using a new device.

CAUTION

- In case the intensity of ‘H1’ and ‘H2’ line is similar, confirmatory testing is recommended to confirm the virus type or a co-infection.
- Positive results should be considered in conjunction with the clinical history and other data available to the physician.

LIMITATION OF TEST

1. All three test lines (“H1”, “H2” and “C”) may develop when tested with specimen containing high titers of HIV-1 antibodies. Hence, reactive test bands for both HIV-1 and HIV-2 may not indicate mixed infection but may result from the cross reactivity of HIV-1 and HIV-2 because of the similarity of their genomic structure.
2. A positive result indicates presence of antibodies to HIV-1/2 and/or Syphilis. However, a positive result does not indicate a conclusive HIV and Syphilis infection diagnosis. A positive result should be confirmed by a supplemental test.
3. A negative result does not eliminate the possibility of infection with HIV-1/2 and Syphilis. The STANDARD Q HIV/Syphilis combo Test may not detect extremely low concentration of the antibody to HIV-1/2 and Syphilis. For negative result with this kit additional test using other clinical method is necessary.
4. The test results alone should not be used in diagnosis of infection with HIV-1/2 and Syphilis. For overall clinical diagnosis, results must be used in conjunction with the patient’s clinical symptoms, and clinical history.

QUALITY CONTROL

1. A colored line appearing in the control line is an internal reagent and procedural control. It will appear if the test has been performed correctly and the reagent are reactive.
2. Control materials are not supplied with this test kit. However, it is recommended that the positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

PERFORMANCE CHARACTERISTICS

1. Diagnostic sensitivity:

- HIV Ab detection: The Diagnostic Sensitivity for anti-HIV antibody detection, calculated on 637 positive specimens, is 100% (637/637) with a Wilson 95% confidence interval of [99.4% - 100.0%].

	STANDARD Q HIV/Syphilis Combo Test	
	HIV negative	HIV positive
Anti-HIV-1 positive/Anti-Tp negative	0	247
Anti-HIV-1/Anti-Tp positive	0	250
Anti-HIV-1 positive non-B subtype	0	40
Anti-HIV-2 positive	0	100
Sensitivity	637/637 = 100%	

- Syphilis Ab detection: The Diagnostic Sensitivity for anti-Treponema pallidum antibody detection, calculated on 400 positive specimens, is 98.8% (395/400) with a Wilson 95% confidence interval of [97.1% - 99.5%].

	STANDARD Q HIV/Syphilis Combo Test	
	Syphilis negative	Syphilis positive
Anti-Tp/Anti-HIV positive	4	246
Anti-Tp positive/anti-HIV negative	1	149
Sensitivity	395/400 = 98.8%	

2. Diagnostic specificity:

The Diagnostic Specificity for anti-HIV Ab detection, calculated on 1500 negative specimens, is 99.9% (1499/1500) with a Wilson 95% confidence interval of [99.6% - 100.0%].
The Diagnostic Specificity for anti-Tp Ab detection, calculated on 1500 negative specimens, is 100% (1500/1500) with a Wilson 95% confidence interval of [99.7% - 100.0%].

	STANDARD Q HIV/Syphilis Combo Test			
	HIV		Syphilis	
	Negative	Positive	Negative	Positive
Blood donors EDTA-K3 plasma	1000	0	1000	0
Blood donors EDTA-K3 whole blood	499	1	500	0
Specificity	1499/1500 = 99.9%		1500/1500 = 100%	

BIBLIOGRAPHY

1. Owen SM et al. Alternative Algorithms for Human Immunodeficiency Virus Infection Diagnosis Using Tests That Are Licensed in the United States. J Clin Microbiol 46:1588-1595, 2008.
2. Barre-Sinoussi F, Chermann JC, Rey F, et al: Isolation of a T-lymphotropic retrovirus from a patient at risk for acquired immune deficiency syndrome (AIDS). Science 220:868-871, 1983.
3. Centers for Disease Control: Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus, and other bloodborne pathogens in health-care settings. Morbidity and Mortality Weekly Rep 37:377-388, 1988.
4. Hoff R, Weiblen BJ, Schwerzler M, et al: Specific antibodies to HIV-2 detected in an anonymous newborn blood specimen from Massachusetts. Fourth Consensus Conference on Testing for Human Retroviruses, March 1989.
5. Charneau P, Borman AM, Quillant C, et al: Isolation and envelope sequence of a highly divergent.
6. Farhi, D; Dupin, N (September–October 2010). “Origins of syphilis and management in the immunocompetent patient: facts and controversies”. Clinics in Dermatology 28 (5): 533–8.
7. Miller JN : value and limitation of nontreponemal and treponemal tests in the laboratory diagnosis of syphilis. Clin. Obstet Gynecol 18: 191-203, 1975.
8. Syphilis - CDC Fact Sheet (Detailed)”. CDC. November 2, 2015. Retrieved 3 February 2016.
9. Alexander, JM; Sheffield, JS; Sanchez, PJ; Mayfield, J; Wendel GD, Jr (January 1999). “Efficacy of treatment for syphilis in pregnancy.”. Obstetrics and gynecology 93 (1): 5-8.
10. A Gerber et al., Recombinant Treponema pallidum antigens in syphilis serology. Immunobiology. 196(5):535-49, 1996-1997.
11. Perspectives in Disease Prevention and Health Promotion Update: Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Bloodborne Pathogens in Health-Care Settings. MMWR, June 24,1988/37(24):377-388.

IVD

Manufactured by SD Biosensor, Inc.
Head office : C-4th&5th, 16, Deogyeong-daero 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, REPUBLIC OF KOREA
Manufacturing site : 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, REPUBLIC OF KOREA

Please contact us for any complaints/inquiries/suggestions via email (sales@sdbiosensor.com), phone (+82-31-300-0400) or website (www.sdbiosensor.com).

L23HIV2ENR4-WHO
Issue date: 2020.06

REF Reference number
IVD *In vitro* Diagnostics
Consult Instructions for Use
Contains Sufficient for <n> Tests
CAUTION
Note
Do not re-use.
To indicate the temperature limitations in which the transport package has to be kept and handled.
Use by
LOT Batch code
Manufacturer
Date of manufacture
Indicate that you should keep the product dry
Keep away from sunlight
Do not use if packaging is damaged