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

STANDARD Q

HIV/Syphilis Combo

REF QHSC01B

STANDARD™ Q HIV/Syphilis Combo Test

PLEASE READ BACK PAGE CAREFULLY BEFORE YOU PERFORM THE TEST

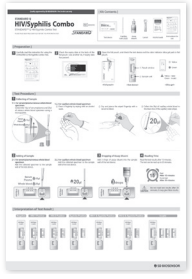
STANDARD™

[Kit Contents]

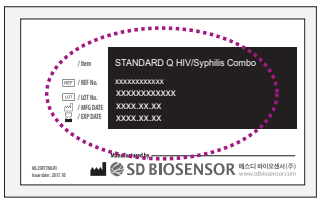
Test device | Capillary tube (20µl) | Assay diluent | Lancet | Alcohol swab | Instructions for use

[Preparation]

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

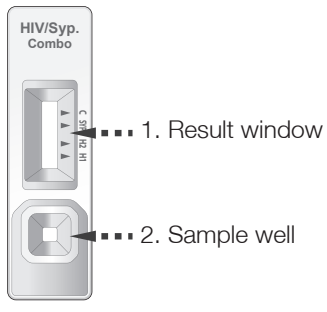


2 Check the expiry date at the back of the foil pouch. Use another lot, if expiry date has passed.



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

<Foil pouch>



<Test device>

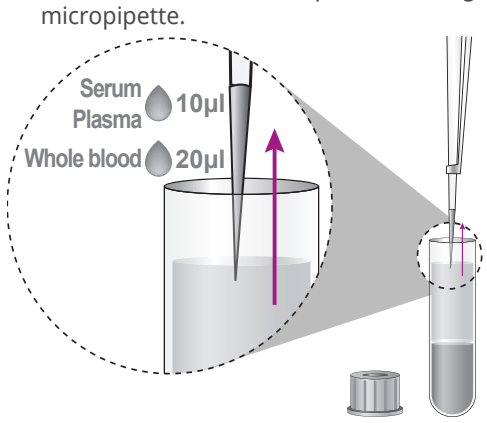
<Silica gel>

[Test Procedure]

1 Collecting of Sample

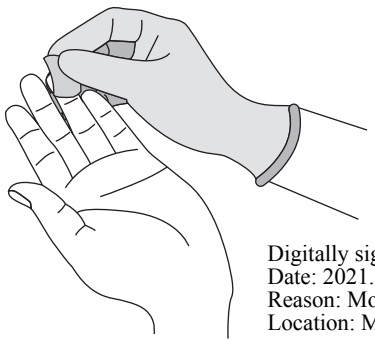
1-1. For serum/plasma/venous whole blood specimen

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



1-2. For capillary whole blood specimen

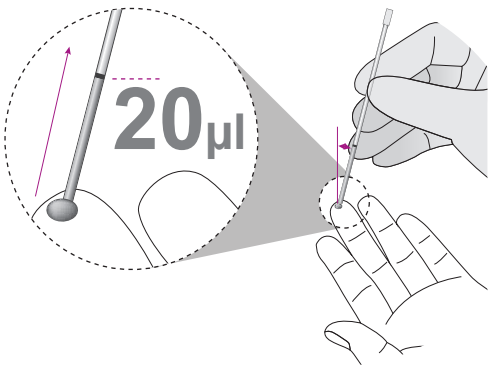
① Clean a fingertip by wiping with an alcohol swab.



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

Digitally signed by Bolea Petru
Date: 2021.09.27 14:26:54 EEST
Reason: MoldSign Signature
Location: Moldova

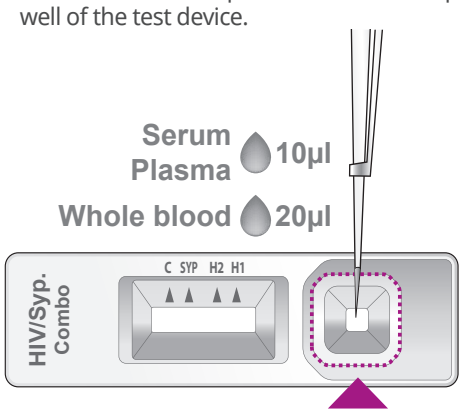
③ Collect the 20µl of capillary whole blood to the black line of the capillary tube (20µl).



2 Adding of Sample

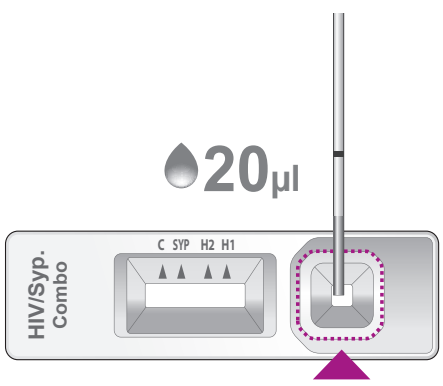
2-1. For serum/plasma/venous whole blood specimen

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



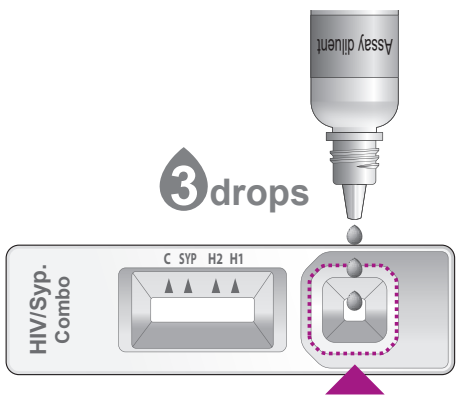
2-2. For capillary whole blood specimen

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



3 Dropping of Assay diluent

Add 3 drops of assay diluent into the sample well of the test device.



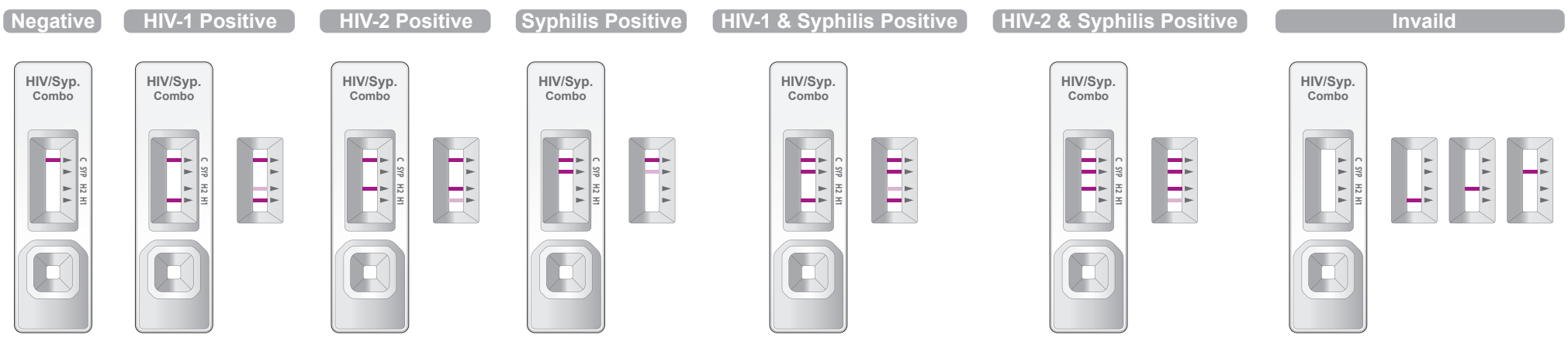
4 Reading Time

Read the test results after 15 minutes.
The test can be read up to 20 minutes.

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 diseases by sex-transmitted infection. Furthermore, they have an influence on each other in many ways. Many studies show that syphilis can increase the transmission of HIV by rising of the expression value of genital ulcers and syphilis not only increase the HIV-1 viral load but decrease the 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. 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 detect antibodies to HIV-1/2 and syphilis in individuals at risk for HIV-1/2 and syphilis infection. This is only for professional, only for an initial screening test.

[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 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.

[Kit contents]

① Test device ② Assay diluent ③ Capillary tube (20μl) ④ Lancet ⑤ Alcohol swab ⑥ Instructions for use

[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

Store the kit 2-40°C /36-104°F, out of direct sunlight. Kit materials are stable until the expiration date printed on the outer box. Do not freeze.

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 assay diluent of another lot.
4. Do not smoke, drink or eat while handling specimen.
5. Wear personal protective equipment, such as gloves and lab coats when handling kit reagents. Wash hands thoroughly when afterwards.
6. Clean up spills thoroughly using an appropriate disinfectant.
7. Handle all specimens as if they contain infectious agents.
8. Observe established precautions against microbiological hazards throughout testing procedures.
9. 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.
10. Silica gel in foil pouch is to absorb moisture and keep humidity from affecting products. If the moisture indicating silica gel beads change from yellow to green, the test device in the pouch should be discarded.
11. Allow Kit components to reach room temperature (15-30°C) before performing a test.

SPECIMEN COLLECTION AND PREPARATION

[Serum]

1. Collect the whole blood into the commercially available plain tube, NOT containing anti-coagulants such as heparin, EDTA or sodium citrate, by venipuncture 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 1 week after collection. Using the specimen in the long-term keeping more than 1 week can cause non-specific reaction. 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 1 week after collection. Using the specimen in the long-term keeping more than 1 week can cause non-specific reaction. 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. Clean the area to be lanced with an alcohol swab.
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 samples.

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. Allow test device and collected sample to room temperature prior to testing.
2. Carefully read instructions for using the STANDARD Q HIV/Syphilis Combo Test.
3. Check the expiry date at the back of the foil pouch. Use another lot, if expiry date has passed.
4. Open the foil pouch, and check the test device and the silica gel pack in the foil pouch.
5. Methods for following steps can be changed depending on the specimen applicator.

[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 sample well of the test device.
3. Add 3 drops of assay diluent into the sample well of the test device.
4. Read the test results after 15 minutes. Test can be read up to 20 minutes.

- **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 sample well of the test device.
5. Add 3 drops of assay diluent into the sample well of the test device.
6. Read the test results after 15 minutes. Test can be read up to 20 minutes.

CAUTION

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

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.

Syphilis Positive Result

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

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Product Disclaimer

Whilst every precaution has been taken to ensure the diagnostic ability and accuracy of this product, the product is used outside of the control of the SD BIOSENSOR and distributor and the result may accordingly be affected by environmental factors and/or user error. A person who is the subject of the diagnosis should consult a doctor for further confirmation of the result.

Warning

The SD BIOSENSOR and distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect of consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.

IVD

Manufactured by SD Biosensor, Inc.
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Any inquiries regarding instructions provided should be addressed to: sales@sdbiosensor.com
or you can also contact us through www.sdbiosensor.com

L23HIV2ENR3
Issue date: 2018.08

REF Reference number

IVD *In vitro* Diagnostics

Consult Instructions for Use

Contains Sufficient for <n> Tests

Caution

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