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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.
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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

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Quality control and service of instrument

SD Biosensor, Inc.
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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

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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

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SD Biosensor, Inc.
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Production and Quality control of Molecular Diagnostic reagent kit used in the detection of infectious diseases and DNA/RNA extraction kit

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

STANDARD Q

HIV/Syphilis Combo

STANDARD™ Q HIV/Syphilis Combo Test

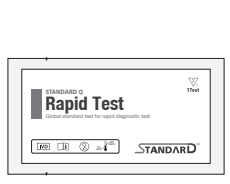
PLEASE READ BACK PAGE CAREFULLY BEFORE YOU PERFORM THE TEST

REF QHSC01B

Cat. No.: 09HIV20D

SD BIOSENSOR

[Kit Contents]



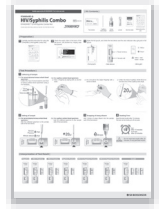
Test device (individually in a foil pouch with desiccant)

Capillary tube (20μl)

Buffer bottle

Sterile Lancet

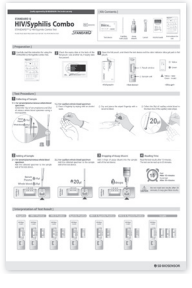
Alcohol swab



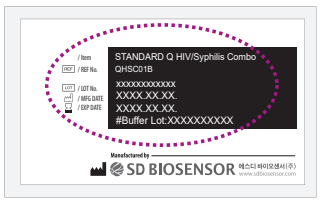
Instructions for use

[Preparation]

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

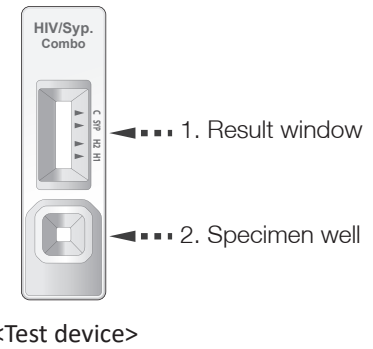


2 Check the expiry date at the back of the foil pouch. Use another lot, if expiry date has passed.

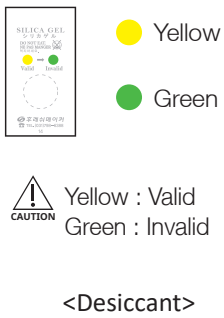


3 Open the foil pouch, and check the test device and the color indicator desiccant pack in foil pouch.

<Foil pouch>



<Test device>



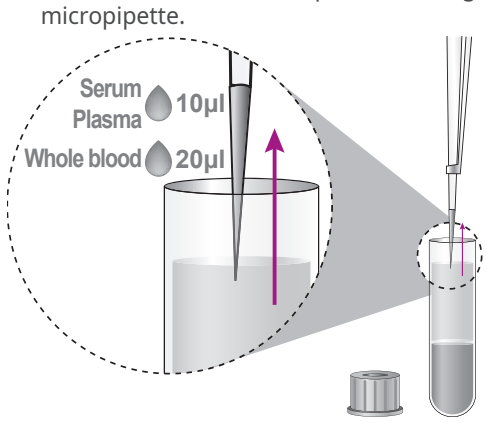
<Desiccant>

[Test Procedure]

1 Collecting of Specimen

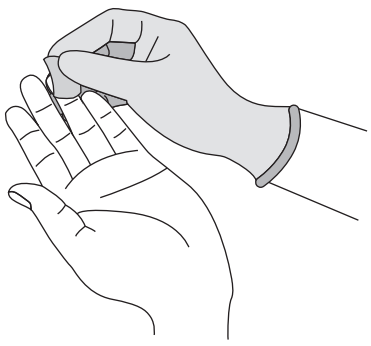
1-1. For serum/plasma/venous whole blood specimen

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

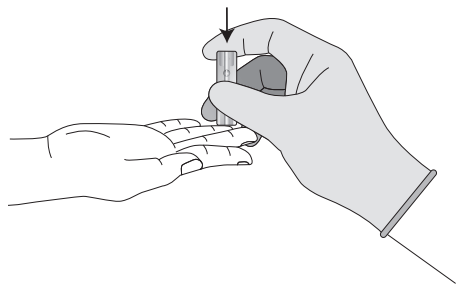


1-2. For capillary whole blood specimen

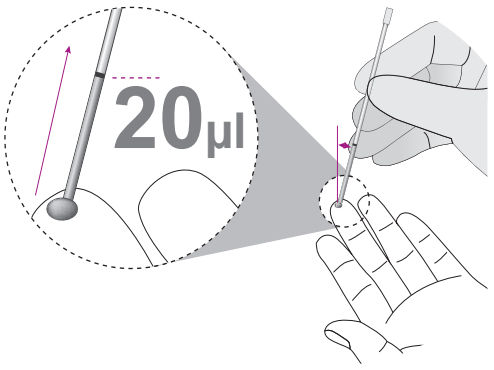
① Clean a fingertip by wiping with an alcohol swab.



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



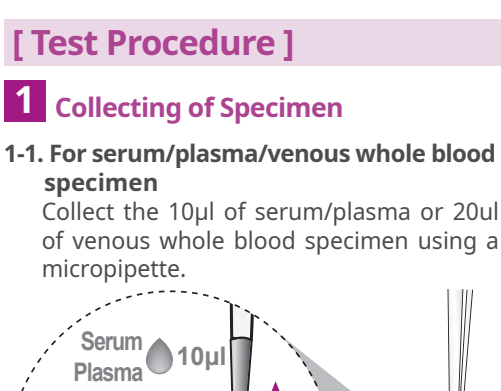
③ Collect the 20μl of capillary whole blood to the black line of the capillary tube (20μl).



2 Adding of Specimen

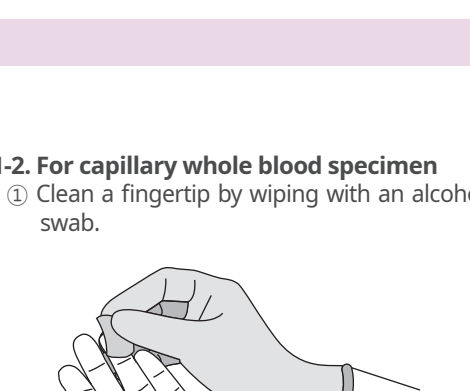
2-1. For serum/plasma/venous whole blood specimen

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.

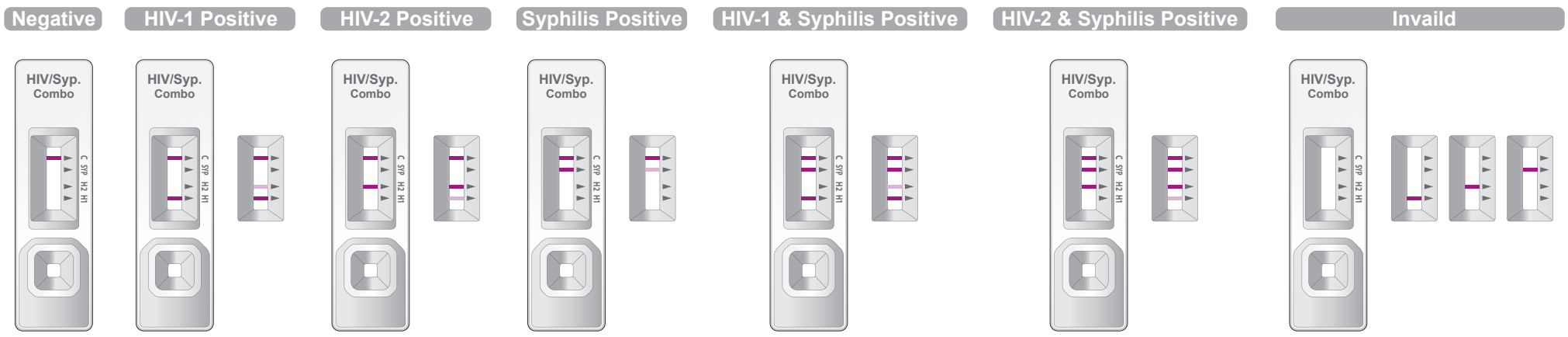
4 Reading Time

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%	

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IVD

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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