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

STANDARD Q

HIV 1/2 Ab 3-Line

REF QHIV02B

STANDARD™ Q HIV 1/2 Ab 3-Line Test

PLEASE READ BACK PAGE CAREFULLY BEFORE YOU PERFORM THE TEST

STANDARD™

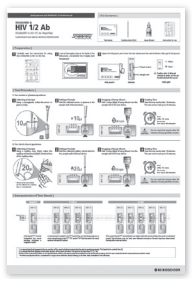
Digitally signed by Bolea Petru
Date: 2021.05.31 16:20:19 EEST
Reason: MoldSign Signature
Location: Moldova

[Kit Contents]

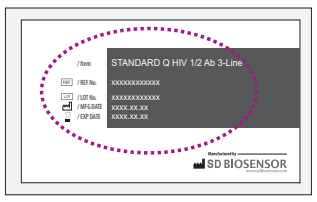
Test device | Capillary tube (20µl) | Assay diluent | Lancet | Alcohol swab | Instructions for use

[Preparation]

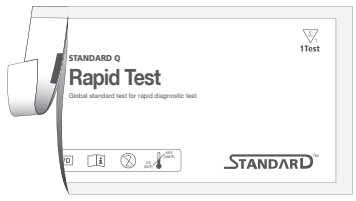
1 Carefully read instructions for using the STANDARD Q HIV 1/2 Ab 3-Line Test.



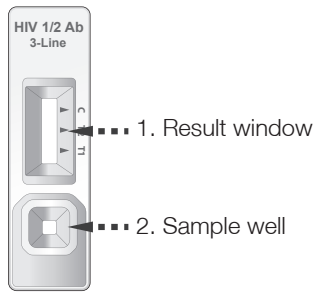
2 Check the expiry date at the back of the foil pouch. Use another lot, if expiry date has passed.



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



<Foil pouch>



<Test device>

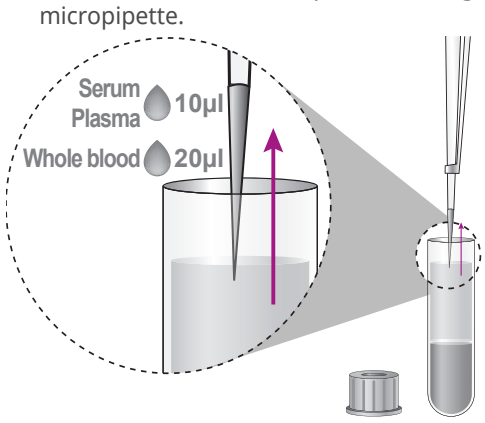
<Silica gel>

[Test Procedure]

1 Collecting of Sample

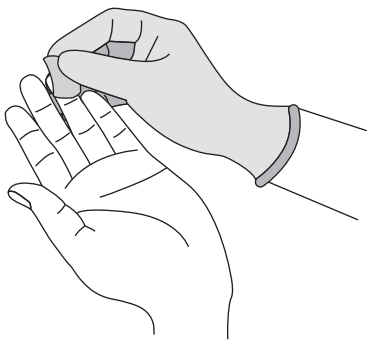
1-1. For serum/plasma/venous whole blood specimen

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

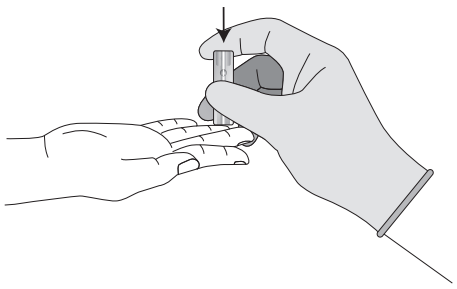


1-2. For capillary whole blood specimen

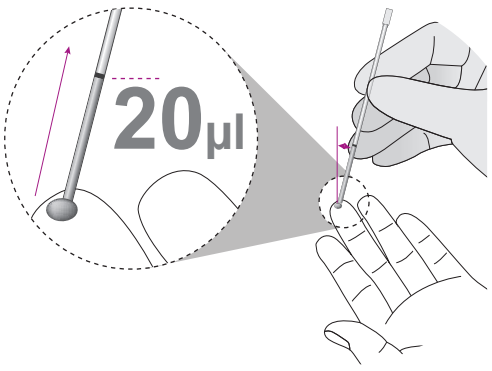
① Clean a fingertip by wiping with an alcohol swab.



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



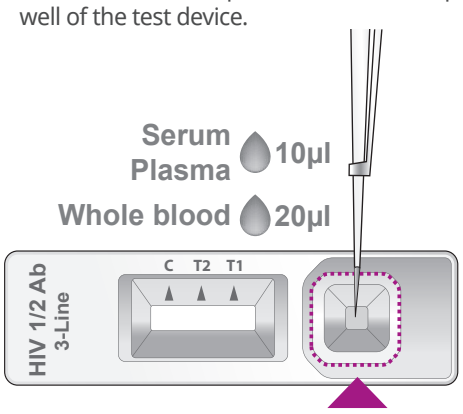
③ Collect the 20µl of capillary whole blood to the black line of the capillary tube (20µl).



2 Adding of Sample

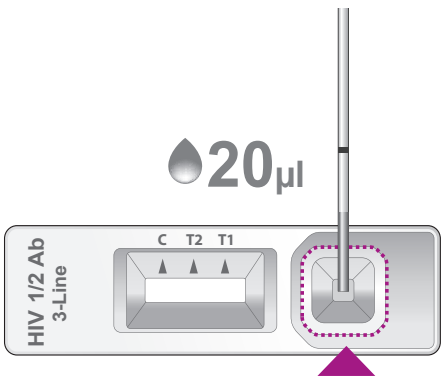
2-1. For serum/plasma/venous whole blood specimen

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



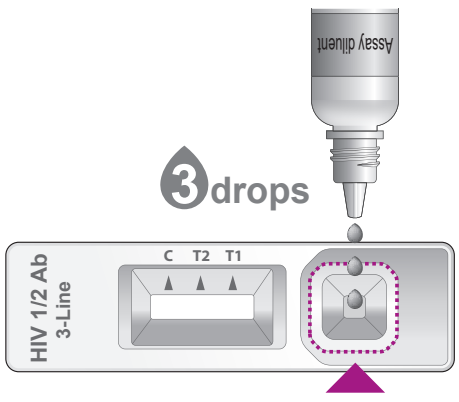
2-2. For capillary whole blood specimen

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.



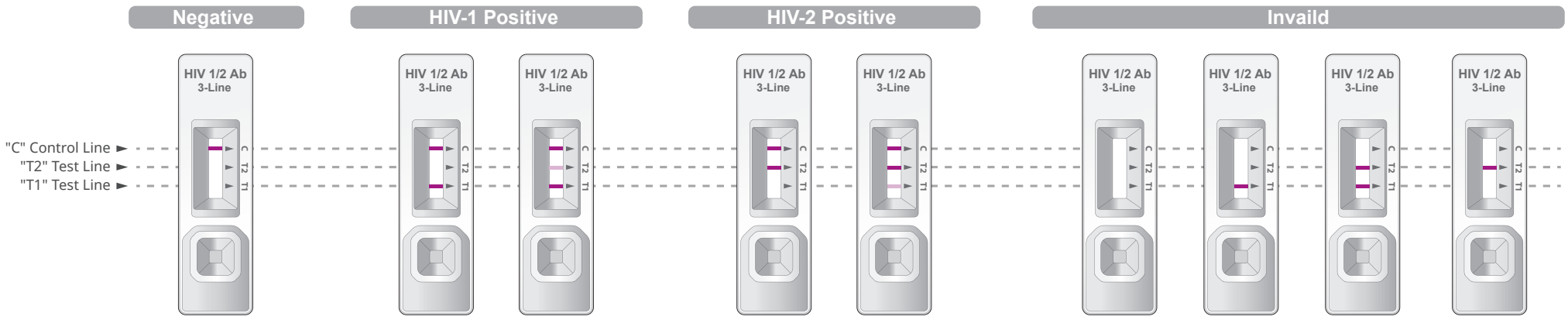
4 Reading Time

Read the test results after 10 minutes.
The test can be read up to 20 minutes.

Read
After 10 mins
Do not read
After 20 minutes

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

[Interpretation of Test Result]



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STANDARD™ Q HIV 1/2 Ab 3-Line Test

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EXPLANATION AND SUMMARY

[Introduction]

AIDS is caused by two known types of HIV (human immunodeficiency virus) , HIV type 1 and HIV type 2. HIV type 1 (HIV-1) is found in patients with AIDS, AIDS-related complex (ARC), and asymptomatic infected individuals at high risk for AIDS. The virus is transmitted by sexual contact, by exposure to infected blood or blood products, or from an infected mother to her fetus or infant. The infection of HIV type 2 (HIV-2) is endemic only in West Africa, and it has been identified in individuals who had sexual relations with individuals from that geographic region. HIV-2 is similar to, but distinct from, HIV-1. Both viruses have similar morphology and lymphotropism, and the modes of transmission appear to be identical. Within the two major HIV types, there is significant variation. HIV-1 has been divided into four groups: group M (for major)-including at least ten subtypes, group O (for outlier), group P, and group N (for non-M, non-O). Similarly, the HIV-2 strains have been classified into at least five subtypes (A through E). STANDARD Q HIV 1/2 Ab 3-Line Test can detect both HIV-1 antibody and HIV-2 antibody, which first appear significantly later, 20-45 days after infection. Detecting HIV earlier with STANDARD Q HIV 1/2 Ab 3-Line Test is helping to prevent future transmission during extremely infectious stage.

[Intended use]

STANDARD Q HIV 1/2 Ab 3-Line Test is a rapid, qualitative immunoassay to detect circulating antibodies against HIV in human serum, plasma or whole blood. The test is for *in vitro* diagnostic use and is intended as an aid to early diagnosis of HIV infection. This is intended for professional use, only for an initial screening test.

[Test principle]

STANDARD Q HIV 1/2 Ab 3-Line Test has "T1", "T2" and "C" line pre-coated with recombinant HIV-1 GP41 protein / recombinant HIV-1 subtype O GP41, recombinant HIV-2 GP36 protein and monoclonal anti-chicken IgY 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 complex of gold conjugated antigens and antibodies moves along the membrane chromatographically to the membrane with assay diluent and is captured by the recombinant HIV-1 and HIV-2 antigens on the test regions (T1 and T2). If the antibodies against HIV-1/2 are in the patient sample, visible lines are formed in the test region. The control line should always appear if the test procedure is performed properly.

[Kit contents]

① Test device ② Capillary tube (20µl) ③ Assay diluent 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 at 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 re-use the test kit.
2. Do not use the test kit if the pouch is damaged or the seal is broken.
3. Do not use the 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 after the tests are done.
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 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. Carefully read instructions for using the STANDARD Q HIV 1/2 Ab 3-Line 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 silica gel pack in the foil pouch.
4. 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 20µl 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 10 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 10 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 "T1" line indicates a positive result for HIV-1.
- In case of the presence of three lines as "C", "T1" and "T2", if the intensity of the "T1" line is stronger than "T2" line, it should be interpreted as HIV-1 positive.

HIV-2 Positive Result

- The presence of two lines as "C" and "T2" line indicates a positive result for HIV-2.
- In case of the presence of three lines as "C", "T2" and "T1", if the intensity of the "T2" line is stronger than "T1" line, it should be interpreted as HIV-2 positive.

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 'T1' and 'T2' 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 ("T1", "T2" 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 and/or HIV-2. However, a positive result does not indicate a conclusive HIV 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. The STANDARD Q HIV 1/2 Ab 3-Line Test may not detect extremely low concentration of the antibody to HIV 1/2. 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. For overall clinical diagnosis, results must be interpreted 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

The Diagnostic Sensitivity for anti-HIV antibody detection, calculated on 501 positive samples, is 99.8% (500 / 501) with a Wilson 95% confidence interval of [98.9% - 100.0%].

	STANDARD Q HIV 1/2 Ab 3-Line Test	
	HIV Negative	HIV Positive
Anti-HIV-1 positive	1	360
Anti-HIV-1 positive non-B subtype	0	40
Anti-HIV-2 positive	0	100
Sensitivity	500/501 = 99.8%	

2. Diagnostic Specificity

The Diagnostic Specificity, calculated on 1500 negative samples, is 100% (1500 / 1500) with a Wilson 95% confidence interval of [99.7% - 100.0%] after initial testing.

	STANDARD Q HIV 1/2 Ab 3-Line Test	
	Negative	Positive
Blood donors EDTA-K3 plasma samples	500	0
Blood donors EDTA-K3 whole blood samples	1000	0
Specificity	1500/1500 = 100%	

BIBLIOGRAPHY

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3. 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.
4. 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.
5. 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.
6. Charneau P, Borman AM, Quillant C, et al: Isolation and envelope sequence of a highly divergent.

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.
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

Any inquiries regarding instructions provided should be addressed to: sales@sdbiosensor.com
or you can also contact us through www.sdbiosensor.com

L23HIV3ENR5
Issue date: 2018.08

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