EN

REF QHIV02B

Cat. No.:09HIV30D, 09HIV30DM

STANDARD Q

HIV 1/2 Ab 3-Line

STANDARD™ Q HIV 1/2 Ab 3-Line Test

PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST

SD BIOSENSOR

KIT CONTENTS



Test device
(individually in a foil pouch with desiccant)

Capillary tube
(20 µl, Option)



Buffer bottle



Sterile lancet
(Option)



Alcohol swab
(Option)



Instructions for use

■ For Cat. No.: 09HIV30D

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
⑥ Instructions for use x 1

■ For Cat. No.: 09HIV30DM

① Test device (individually in a foil pouch with desiccant) x 25
② Buffer bottle x 1
③ Instructions for use x 1

MATERIALS REQUIRED BUT NOT PROVIDED

■ For Cat. No.: 09HIV30D

① Anti-coagulant tube containing heparin, EDTA or sodium citrate
② Micropipette and tip
③ PPE (Personal Protective Equipment)
④ Biohazard container

■ For Cat. No.: 09HIV30DM

① Anti-coagulant tube containing heparin, EDTA or sodium citrate
② Micropipette and tip
③ Sterile lancet
④ Alcohol swab
⑤ PPE (Personal Protective Equipment)
⑥ Biohazard container
⑦ Capillary whole blood collection tool

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 3 days after collection. For prolonged storage, it should be at below -40°C / -40°F up to 3 freeze-thaw cycles.
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 3 days after collection. For prolonged storage, it should be at below -40°C / -40°F up to 3 freeze-thaw cycles.
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 not calloused and gently rub the finger to warm it to stimulate blood circulation. And then clean the fingertip by wiping with an alcohol swab.
3. Wait until the fingertip is dried completely and squeeze the end of the fingertip and pierce the wiped fingertip with a sterile lancet to bleed.
4. Gently squeeze capillary tube and immerse open end in the center of a blood drop and release the capillary tube slowly to draw up the blood up to the 20µl black marking line on the capillary tube.
5. The capillary whole blood must be tested immediately after collection.

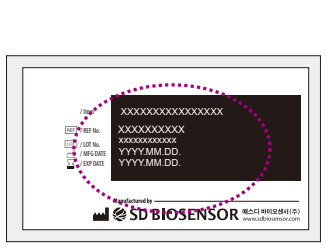
[Venous whole blood]

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 freeze venous whole blood specimen.
4. Do not use hemolyzed blood specimen.

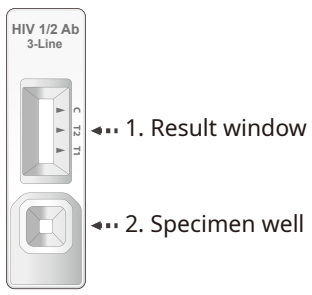
⚠
- Anticoagulants such as heparin, EDTA or sodium citrate do not affect the test result.
- As known relevant interference, haemolytic specimen, rheumatoid factors-contained specimen and lipaemic, icteric specimen can lead to impair the test results.

PREPARATION AND TEST PROCEDURE

■ Preparation



Foil pouch



Test device



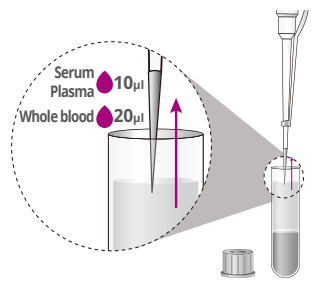
Desiccant

1. Carefully read the instructions for using the STANDARD Q HIV 1/2 Ab 3-Line Test.
2. Check that the expiry date on the back of the foil pouch has not passed.
3. Allow the STANDARD Q HIV 1/2 Ab 3-Line Test components and specimen to come to room temperature(15 ~ 30°C / 59 ~ 86°F) for 30min prior to testing.
4. Check that the test device package is not damaged. If damaged, discard the test and use another test. If a humidity indicator inside shows saturation (color changed from yellow to green), throw away the test device and take another test device packaging.
5. Procedure method should be followed for the specific specimen type being tested.

■ Test Procedure

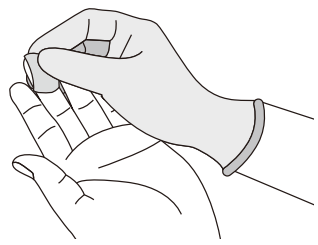
1. Collecting of Specimen
[For serum/plasma/venous whole blood specimen]

① Collect the 10 µl of serum/plasma or 20 µl of venous whole blood specimen using a micropipette.

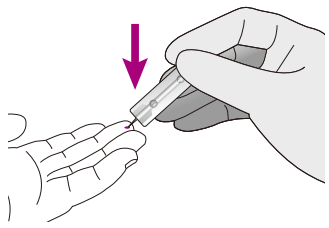


[For capillary whole blood specimen]

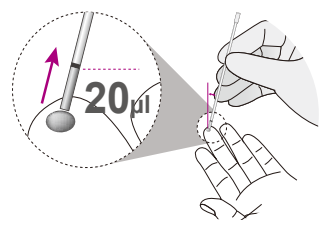
① Select the finger that is not calloused and gently rub the finger to warm it to stimulate blood circulation. And then clean the fingertip by wiping with an alcohol swab.



② Wait until the fingertip is dried completely and pierce the wiped fingertip with a sterile lancet to bleed.

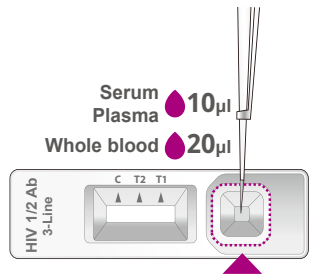


③ Gently squeeze capillary tube and immerse open end in the center of a blood drop and release the capillary tube slowly to draw up the blood up to the 20 µl black marking line on the capillary tube.



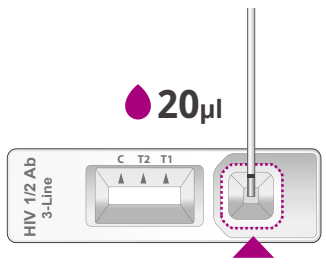
2. Adding of Specimen
[For serum/plasma/venous whole blood specimen]

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



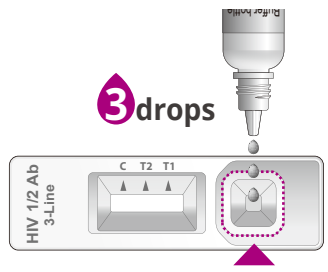
[For capillary whole blood specimen]

Add the collected specimen to the specimen well of the test device. Let the end of the capillary tube to touch the pad, then press down lightly.



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 10 to 20 minutes after adding buffer.



⚠
- Do not read test results after 20 minutes. It may give false results.
- Place the test device on the flat surface before applying the specimen.
- Use correct amount of specimen and buffer.
- If the T line does not appear until 10 minutes, make sure to observe the appearance of the T line until 20 minutes.

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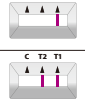
INTERPRETATION OF TEST RESULT

If the T line does not appear until 10 minutes, make sure to observe the appearance of the T line until 20 minutes.

Test result		Example	Description
Negative			The presence of only “C” line indicates a negative result.
Positive	HIV-1	 	- 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	 	-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.
	HIV-1 & HIV-2	 	The presence of three lines as “C” and equivalent intensity of “T2” and “T1”, it should be interpreted as HIV-1 and HIV-2 both positive.
Invalid		   	No presence of “C” line indicates an invalid result. It is recommended that the specimen be retested using a new device.

- Interpret faint lines of ‘T1” and/or “T2” as the positive for HIV-1 and HIV-2.
- In case the intensity of ‘T1’ and ‘T2’ line is similar, confirmatory testing is recommended to confirm the virus type or a co-infection.
- The presence of any line no matter how faint it is, should be considered as a line formed.
- Positive results should be considered in conjunction with the clinical history and other data available.
- This test is for screening purposes. Confirmatory testing according to national guidelines is recommended to confirm the infection status.

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.
3. If there is a problem with the result such as invalid result, retest with a new kit and/or specimen. If the problem is repeated, contact SD Biosensor through your local distributor.

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 antibodies to both HIV-1 and HIV-2, 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 chromatographic immunoassay for the qualitative detection of antibodies specific to HIV-1 including subtype O and HIV 2 in human serum, plasma or venous and capillary whole blood. The test is for *in vitro* diagnostic use and intended as an aid to diagnosis of HIV in symptomatic, asymptomatic populations and persons at risk of HIV infection. The test is not intended for use on neonates or infants below 2 years. 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 resourcelimited countries. The product is not for blood donor screening. The test kit is not automated and does not require any additional instruments. More specific alternative diagnosis methods should be performed in order to obtain the confirmation of HIV Virus infection.

■ Test Priniple

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 specimens interacts with the recombinant HIV-1 GP41-gold / recombinant HIV-1 subtype O GP41-gold and the anti-HIV-2 in patient specimens 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 buffer 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 specimen, visible lines are formed in the test region. The chicken IgY antibody conjugated with colloidal gold particles are used as detectors for “C” control line. The control line should always appear if the test procedure is performed properly.

KIT STORAGE AND STABILITY

1. Store the sealed pouch and the buffer provided in the kit at 2 ~ 40°C / 36 ~ 104°F out of the direct sunlight for the duration of its shelf life.
2. Do not open the foil pouch until you are ready to perform a test. Test device can be used immediately after being opened.
3. Close the buffer cap tightly after using, and then store it at 2 ~ 40°C / 36 ~ 104°F out of the direct sunlight. It is stable until the expiry date of the kit and the buffer label after opening its cap, if it is tightly closed.

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 after the expiration date.
4. Do not use the 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 after the tests are done.
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 / 59 ~ 86°F) before performing a test.
13. Follow necessary precautions when handling specimens with this test. Use personal protective equipment (PPE) consistent with current guideline.
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.

PERFORMANCE CHARACTERISTICS

■ Diagnostic Sensitivity

[Plasma]

The Diagnostic Sensitivity for anti-HIV antibody detection, calculated on 457 positive plasma specimens, is 99.78% (456 / 457) with a Wilson 95% confidence interval of [98.77% - 99.96%].

	STANDARD Q HIV 1/2 Ab 3-Line Test	
	HIV Negative	HIV Positive
Anti-HIV-1 positive	1	294
Anti-HIV-1 positive non-B subtype	0	40
Anti-HIV-2 positive	0	122
Sensitivity	456/457= 99.78%	

[Serum]

The Diagnostic Sensitivity for anti-HIV antibody detection, calculated on 623 serum specimens, is 99.84% (622 / 623) with a Wilson 95% confidence interval of [99.10% - 99.97%].

	STANDARD Q HIV 1/2 Ab 3-Line Test	
	HIV Negative	HIV Positive
Anti-HIV-1 positive	1	589
Anti-HIV-1 positive non-B subtype	0	10
Anti-HIV-2 positive	0	23
Sensitivity	622/623= 99.84%	

[Venous whole blood]

The Diagnostic Sensitivity for anti-HIV antibody detection, calculated on 101 venous whole blood positive specimens, is 99.01% (100 / 101) with a Wilson 95% confidence interval of [94.60% - 99.83%].

	STANDARD Q HIV 1/2 Ab 3-Line Test	
	HIV Negative	HIV Positive
Anti-HIV-1 positive	1	100
Sensitivity	100/101= 99.01%	

[Capillary whole blood]

The Diagnostic Sensitivity for anti-HIV antibody detection, calculated on 71 capillary whole blood positive specimens, is 100% (71 / 71) with a Wilson 95% confidence interval of [94.87% - 100.00%].

	STANDARD Q HIV 1/2 Ab 3-Line Test	
	HIV Negative	HIV Positive
Anti-HIV-1 positive	0	46
Anti-HIV-2 positive	0	25
Sensitivity	71/71=100.00%	

■ Diagnostic Specificity

1. The Diagnostic Specificity, calculated on 1177 negative plasma specimens, is 100.00% (1177 / 1177) with a Wilson 95% confidence interval of [99.67% - 100.00%] after initial testing.
2. The Diagnostic Specificity, calculated on 1277 negative serum specimens, is 99.92% (1276 / 1277) with a Wilson 95% confidence interval of [99.56% - 99.99%] after initial testing.
3. The Diagnostic Specificity, calculated on 750 negative venous whole blood specimens, is 100.00% (750 / 750) with a Wilson 95% confidence interval of [99.49% - 100.00%] after initial testing.

	STANDARD Q HIV 1/2 Ab 3-Line Test	
	HIV Negative	HIV Positive
Blood donors plasma specimens	1177	0
Blood donors serum specime	1276	1
Blood donors venous whole blood specimens	750	0
Specificity for plasma specimen	1177/1177 = 100.00%	
Specificity for serum specimen	1276/1277 = 99.92%	
Specificity for venous whole blood specimen	750/750 = 100.00%	

LIMITATION OF TEST

1. All three test lines (“T1”, “T2” 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 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.

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IVD

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Issue date: 2023.10

REF Reference number
IVD *In vitro* Diagnostics
Consult Instructions for Use
Contains Sufficient for <n> Tests
Caution
Note
Do not re-use.
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
To indicate the temperature limitations in which the transport package has to be kept and handled.