WHO Prequalification of In Vitro Diagnostics
PUBLIC REPORT

Product: STANDARD Q HIV 1/2 Ab 3-Line Test
WHO reference number: PQDx 0383-117-00

The **STANDARD Q HIV 1/2 Ab 3-Line Test** with product codes **09HIV30D** and **09HIV30DM**, 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 10 June 2020.

Summary of WHO prequalification assessment for STANDARD Q HIV 1/2 Ab 3-Line Test

	Date	Outcome
Prequalification listing	10-Jun-2020	listed
Dossier assessment	25-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 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 resource limited 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 infection.*"

Assay description

According to the claim of assay description from SD Biosensor Inc, "*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."

Test kit contents

Component	**25 tests (product code 09HIV30D)**	**25 tests (product code 09HIV30DM)**
Test device (individually in a foil pouch with desiccant)	25	25
Buffer Bottle	1 x 4 mL	1 x 4 mL
Capillary tube (20µl)	Pack of 25	
Instructions for use	1	1
Sterile lancet	25	
Alcohol swab	25	

Items required but not provided

For Cat. No.: 09HIV30D

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

For Cat. No.: 09HIV30DM

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

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 1/2 Ab 3-Line Test was given priority for WHO prequalification assessment.

Dossier assessment

SD Biosensor Inc submitted a product dossier for STANDARD Q HIV 1/2 Ab 3-Line 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 25 May 2020.

Based on the product dossier screening and assessment findings, the product dossier for STANDARD Q HIV 1/2 Ab 3-Line 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 1/2 Ab 3-Line Test meets WHO prequalification requirements.

Product performance evaluation

STANDARD Q HIV 1/2 Ab 3-Line Test (SD Biosensor) was evaluated by the Institute of Tropical Medicine, Belgium, on behalf of WHO in the 4th quarter of 2019, according to protocol PQDx_030, version 10.

Clinical performance evaluation

In this limited laboratory-based evaluation of clinical performance characteristics, a panel of 1200 serum/plasma specimens was used. The specimens were characterized using the following reference algorithm: Vironostika HIV Ag/Ab (bioMérieux) and Enzygnost Anti-HIV 1/2 Plus (Siemens Healthcare Diagnostics); followed by INNO-LIA HIV I/II Score (Fujirebio) for initially reactive results.

Clinical performance characteristics in comparison with an agreed reference standard		
	Initial (95% CI)	**Final (95% CI)**
Sensitivity % (N=470)	100 (99.2-100)	100 (99.2-100)
Specificity % (N=730)	99.2 (98.2-99.7)	99.3 (98.4-99.8)
Invalid rate % (N=1200)	0.08	
Inter-reader variability % (N=1200)	2.1	

Among 449 HIV-1 positive specimens, STANDARD Q HIV 1/2 Ab 3-Line Test showed the presence of both HIV 1 and HIV-2 lines in 63 (14 %) specimens, although in most cases (n=60), 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.

Among 21 HIV-2 positive specimens, STANDARD Q HIV 1/2 Ab 3-Line Test showed the presence of both HIV-1 and HIV-2 lines in 18 (86 %) specimens, with medium to strong reactivity in most cases (n=14).

For inter-reader variability, disagreements (n=25) mostly concerned the HIV-2 line in HIV-1 positive specimens (n=21), or the HIV-1 line in HIV-2 positive specimens (n=2) or in negative specimens (n=2).

Analytical performance evaluation

Analytical performance characteristics	
Sensitivity during seroconversion on 8 seroconversion panels in comparison with a benchmark assay (Enzygnost Anti-HIV 1/2 Plus)	Of a total of 52 specimens, 23 were detected by the assay under evaluation; versus 21 specimens detected by the benchmark assay. Seroconversion sensitivity index of -0.25, therefore detection is 0.25 specimens earlier than the benchmark assay.
Analytical sensitivity on a mixed titer panel (PRB205, SeraCare)	All 25 specimens were correctly classified.
Analytical sensitivity on the 1st International Reference Panel for anti-HIV (NIBSC code 02/210)	All 6 HIV subtypes/groups in the panel were detected.
Lot to lot variation on a dilution panel	Lot to lot variation was within +/- 1 two-fold dilutions for 8 dilution series. For the other 2 dilution series, the last dilution tested was reactive on both lots, so the end-point could not be determined.

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 (for serum/plasma/venous whole blood)
Time to result	12 minutes
Endpoint stability (interval)	10 minutes (the test can be read between 10 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 1/2 Ab 3-Line Test meets the WHO prequalification requirements.

Labelling

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

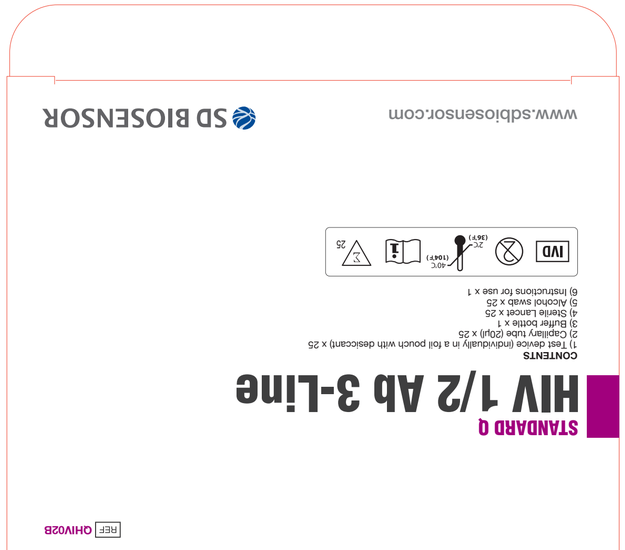
1.1 Outer box labels

STANDARD Q

HIV 1/2 Ab 3-Line 25T

Unit : mm

자재명	Package	도수	3도 (먹, Pantone 2415C, 202C)
문안번호	B25HIV3ML4R0-WHO	후가공	유광코팅 / 3면접착
크기	W155 * H71 * D124	작업일자	2020.06.04
용지/질량	로얄아이보리/300g	담당부서	디자인팀, 마케팅팀



STANDARD Q
HIV 1/2 Ab 3-Line Test

25 TESTS KIT

ES -25 PRUEBAS/KIT-
CONTENIDO
1) Dispositivo de prueba (individualmente en una bolsa de aluminio con descante) 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

DE -25 TESTGERÄT/KIT-
INHALT
1) Testgerät (einzeln in einem Folienbeutel mit Trockenmittel) x 25
2) Kapillarenröhrchen (20μl) x 25
3) Puffer flasche x 1
4) Sterile Lanzette x 25
5) Alkoholtupfer x 25
6) Gebrauchsanweisung x 1

FR -25 TESTS/KIT-
CONTENU
1) Dispositif de test (emballage individuel dans un sachet en aluminium avec un desiccant) 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

IT -25 TESTS/KIT-
CONTENUTO
1) Dispositivo di test (confezione individuale in un sacchetto di alluminio con un essiccante) 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

PT -25 TESTES/KIT-
CONTEÚDO
1) Dispositivo de teste (individualmente em uma bolsa de alumínio com dessecante) x 25
2) Tubo capilar (20μl) x 25
3) Frasco de buffer x 1
4) Lanceta estéril x 25
5) Zaragatoa com álcool x 25
6) Instruções de uso x 1

STANDARD Q
HIV 1/2 Ab 3-Line Test

Cat. No.: 09HIV30D

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

25 TESTS KIT

STANDARD Q
HIV 1/2 Ab 3-Line
STANDARD™ Q HIV 1/2 Ab 3-Line Test

www.sdbiosensor.com

SD BIOSENSOR

B25HIV3ML4R0-WHO
Issue date: 2020.06

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STANDARD Q
HIV 1/2 Ab 3-Line Test

STANDARD™

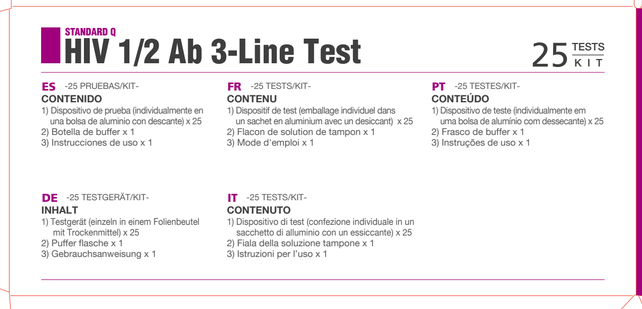
Manufactured by
SD Biosensor, Inc.
Head office
C-401&536, 16, Deogyeong-daero 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, REPUBLIC OF KOREA
Manufacturing site
74, Osingsaengmyeong 4-ro, Ozong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, REPUBLIC OF KOREA
+82-31-300-0400 www.sdbiosensor.com

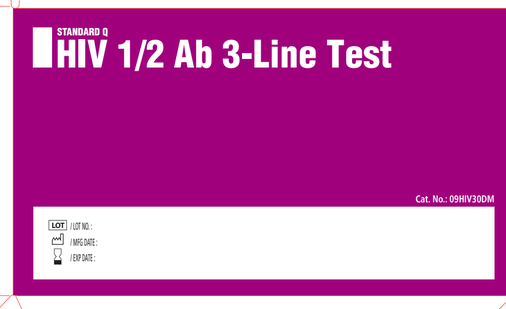
STANDARD Q

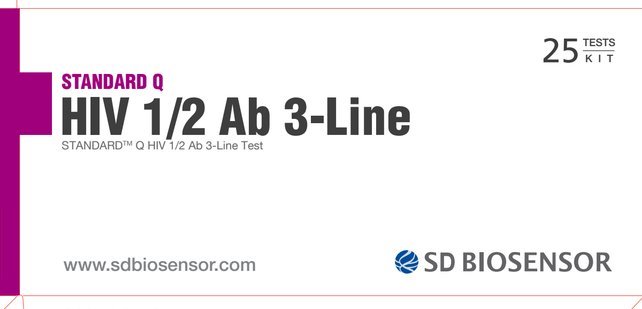
HIV 1/2 Ab 3-Line 25T

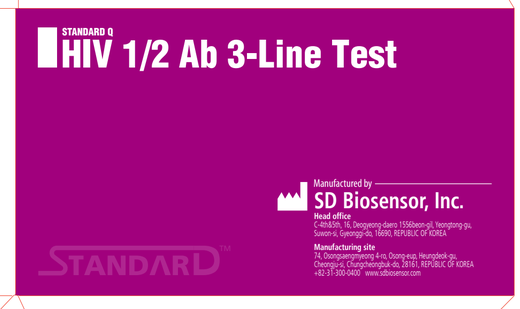
Unit : mm

자재명	Package	도수	3도 (먹, Pantone 2415C, 202C)
문안번호	B25HIV3MML4R0-WHO	후가공	유광코팅 / 3면접착
크기	W155 * H71 * D124	작업일자	2020.06.04
용지/질량	로얄아이보리/300g	담당부서	디자인팀, 마케팅팀









B25HIV3MML4R0-WHO
Issue date: 2020.06

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1.2 Foil pouch label

1Test

STANDARD Q

Rapid Test

IVD

2°C (36°F) 40°C (104°F)

STANDARD™

/ Item

REF / REF No.

LOT / LOT No.

/ MFG DATE

/ EXP DATE

STANDARD Q HIV 1/2 Ab 3-Line

QHIV02B / Cat No.: 09HIV30DM

XXXXXX

YYYY.MM.DD.

YYYY.MM.DD.

#Buffer Lot: XXXXXXXX

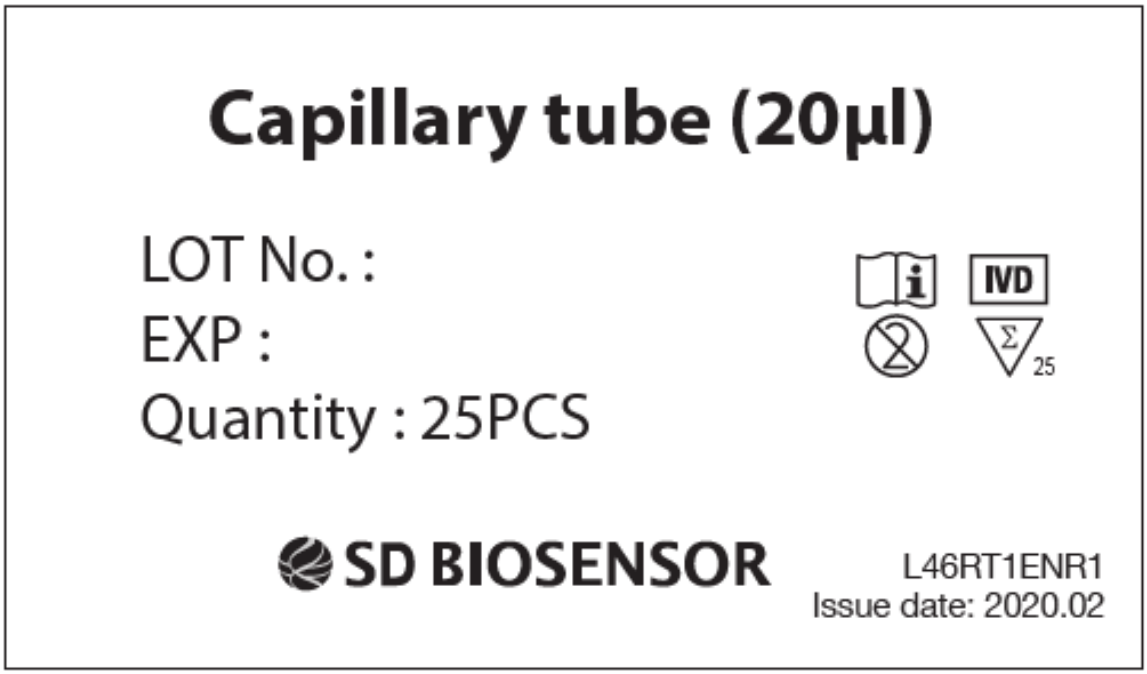
Manufactured by

SD BIOSENSOR 에스디 바이오센서(주)

www.sdbiosensor.com

1.3 Buffer label

1.4 Capillary tube label



1.5 Sterile lancet label

1.6 Alcohol swab label

Front

Back

1.7 Test device

2.0 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.

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 BACK PAGE CAREFULLY BEFORE YOU PERFORM THE TEST

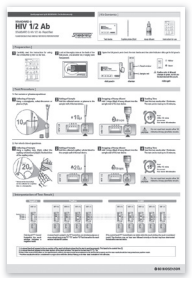
SD BIOSENSOR

[Kit Contents]

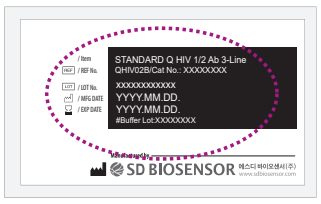
Test device (individually in a foil pouch with desiccant) | Capillary tube (20µl, Option) | Buffer bottle | Sterile lancet (Option) | Alcohol swab (Option) | Instructions for use

[Preparation]

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

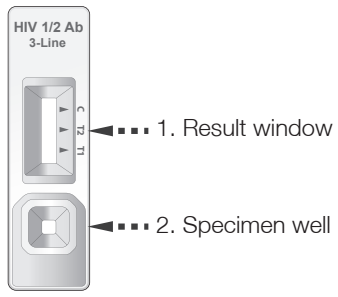


2 Check the expiry date at the back of the foil pouch. Use another lot, if expiry date has passed.



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

<Foil pouch>



<Test device>

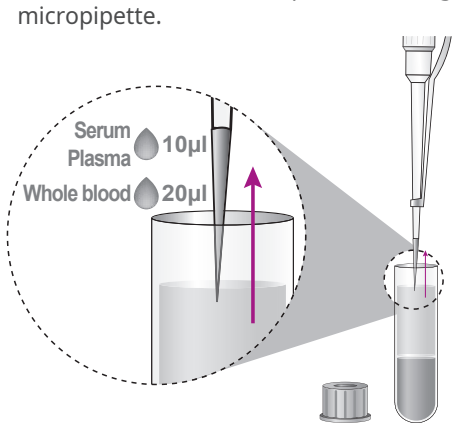
<Desiccant>

[Test Procedure]

1 Collecting of Specimen

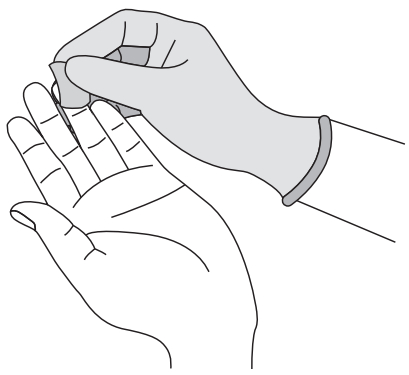
1-1. For serum/plasma/venous whole blood specimen

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

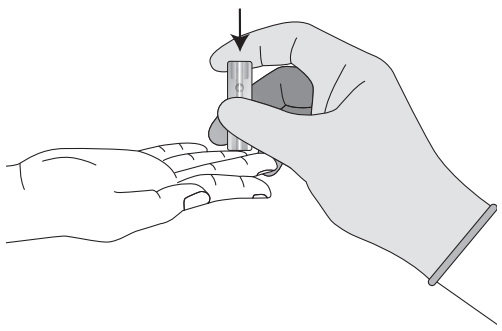


1-2. For capillary whole blood specimen

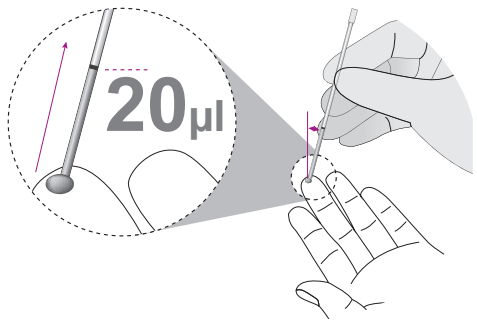
① Select the finger that is not calloused and clean the fingertip by wiping with an alcohol swab.



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



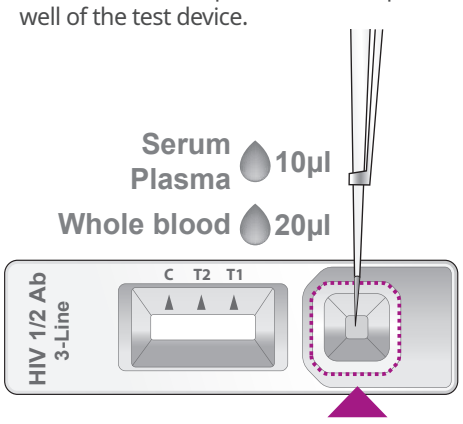
③ Gently squeeze capillary tube and immerse open end in the center of a blood drop and release the capillary tube slowly to draw up the blood up to the 20µl black marking line on the capillary tube.



2 Adding of Specimen

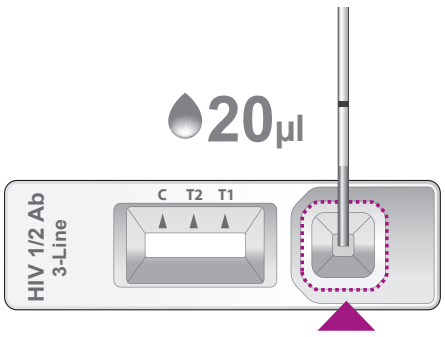
2-1. For serum/plasma/venous whole blood specimen

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



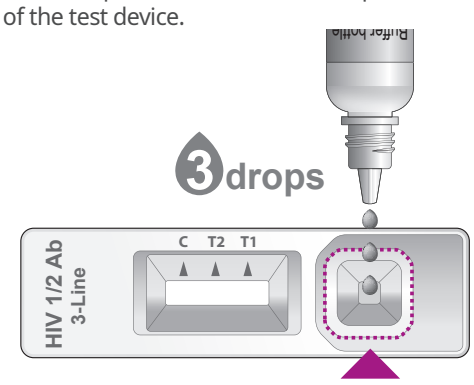
2-2. For capillary whole blood specimen

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

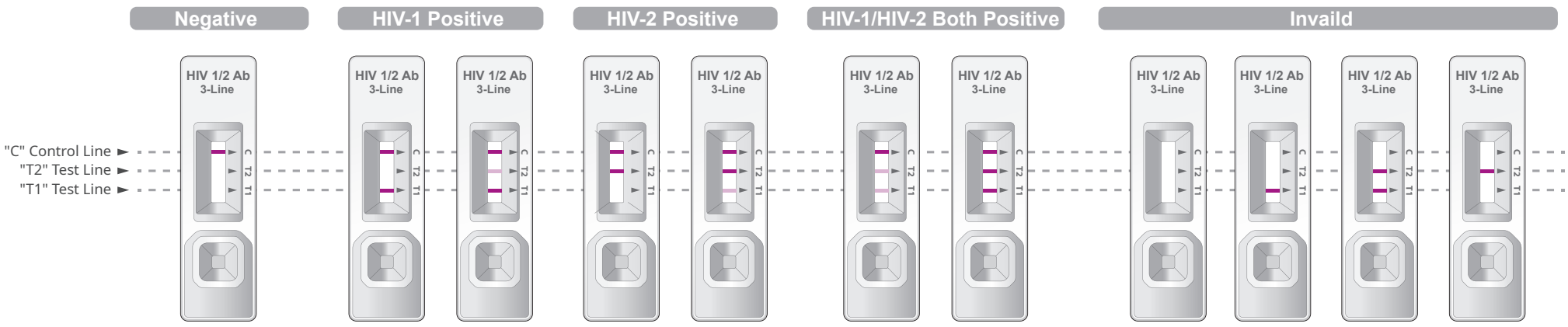


4 Reading Time

Read the test results between 10 to 20 minutes after adding buffer.

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

[Interpretation of Test Result]



SD BIOSENSOR

STANDARD™ Q HIV 1/2 Ab 3-Line Test

SD BIOSENSOR

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 resource-limited 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 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 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 contents]

- **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

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[6].
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 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.

CAUTION

- 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.

TEST PROCEDURE

[Preparation]

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]

- **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 specimen well of the test device. Let the end of the capillary tube to touch the pad, then press down lightly.
3. Hold the buffer bottle at 90º 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. Read the test results between 10 to 20 minutes after adding buffer.

- **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. Hold the buff er bottle at 90º angle to the test device without touching the specimen well to avoid contamination of the buffer. Add 3 drops of the buff er into the specimen well of the test device.
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 20μl black marking line on the capillary tube.
4. 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.
5. Hold the buffer bottle at 90º 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.
6. Read the test results between 10 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 "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.

HIV-1 and HIV-2 Both Positive Result

- 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.

CAUTION

- Interpret faint lines of "T1" and/or "T2" as the positive for HIV-1 and HIV-2.

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 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.

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.

PERFORMANCE CHARACTERISTICS

1. 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%	

2. 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 specimens	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%	

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. 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

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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