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

STANDARD Q

HBsAg

STANDARD Q HBsAg Rapid Test

50µl Specimen

STANDARD

PLEASE READ BACK PAGE CAREFULLY BEFORE YOU PERFORM THE TEST

[Materials Provided]

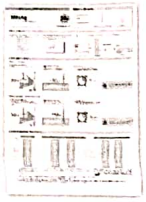
Cassette

Specimen Transfer Device (50µl)

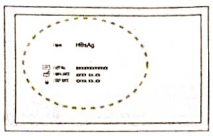
Instruction for use

[Preparation]

1 Carefully read the instruction for using the STANDARD Q HBsAg Test.



2 Look at the expiry date at the back of the Cassette Packaging. Use another lot, if expiry date has passed



3 Open the Cassette Packaging and check the cassette and the color indicator silica gel.

<Cassette Packaging>

Result window

Specimen well

<Cassette>

Yellow

Green

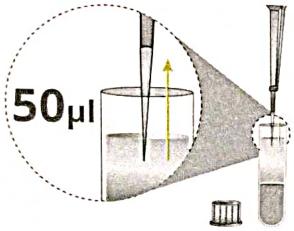
If yellow color of silica gel changes to green, do not use the cassette in the Cassette Packaging.

<Silica gel>

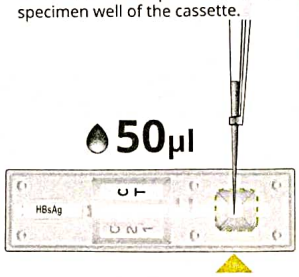
[Test Procedure]

1. Using a micropipette

1 Specimen Collection
Collect serum or plasma (50µl).



2 Specimen Addition
Add the collected specimen to the specimen well of the cassette.



3 Reading Time
Read test results after 20 minutes.
Test can be read up to 30 minutes.

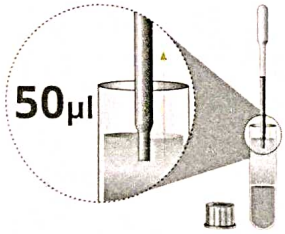
Read
After 20 mins
Do not read
After 30 mins

CAUTION

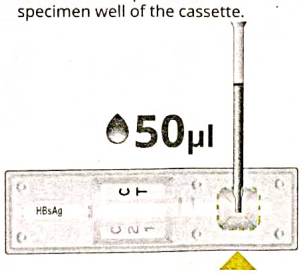
Do not read test results after 30 minutes. It may give false results.

2. Using Specimen transfer device (50µl)

1 Specimen Collection
Collect serum or plasma (50µl) till the black line of the specimen transfer device.



2 Specimen Addition
Add collected specimen to the specimen well of the cassette.



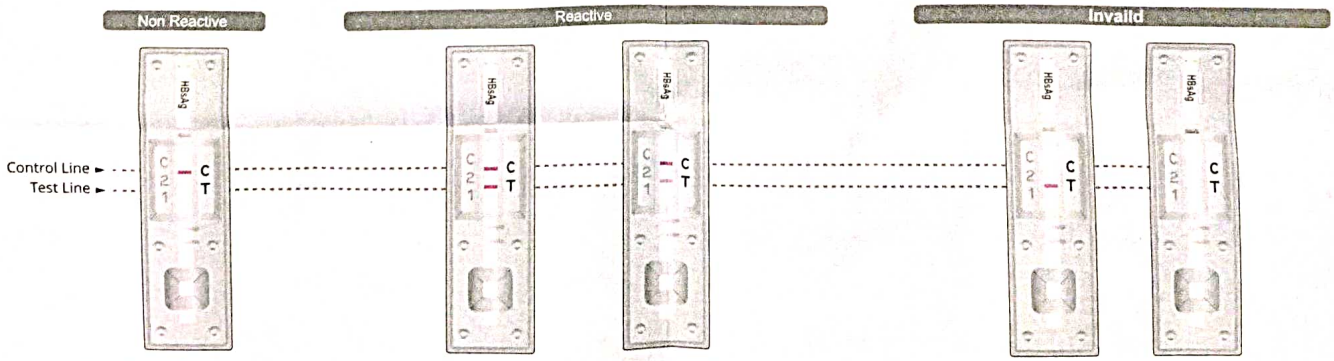
3 Reading Time
Read the test results after 20 minutes.
Test can be read up to 30 minutes.

Read
After 20 mins
Do not read
After 30 mins

CAUTION

Do not read test results after 30 minutes. It may give false results.

[Interpretation of Test Result]



The presence of only one colored band ("C" Control line) within the results window indicates a non reactive result.

The presence of two colored bands ("C" Control line and "T" Test line) within the results window, no matter which band appears first, indicates a reactive result.

If the control band ("C" Control line) is not visible within the result window, the result is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. Re-test with a new patient specimen and a new cassette.

1. A colored band will appear in the top section of the result window to show that the test is working properly. This band is the control line (C).
2. A colored band will appear in the lower section of the result window. This band is the test line (T).
3. Even if the control line is faint, or the test line isn't uniform, the test should be considered to be performed properly and the test result should be interpreted as reactive result.

* Reactive results should be considered in conjugation with the clinical history and other data available to the physician.

EXPLANATION AND SUMMARY

[Introduction]

Hepatitis B virus (HBV) is one of several hepatitis viruses that can cause inflammation of the liver. It is currently endemic worldwide and commonly transmitted via body fluids such as blood, semen, and vaginal secretions. Acute HBV infection is a short-term viral infection, illness that occurs within the first 6 months after the person is exposed to the HBV. Acute HBV infection can be either asymptomatic or develop the signs and symptoms of viral hepatitis become noticeable. Most infected persons recover, but 5%-10% are unable to clear the virus and become chronically infected. Many chronically infected persons have mild liver disease with little or no long-term morbidity or mortality. Other individuals with chronic HBV infection develop active disease, which can progress to cirrhosis and liver cancer. According to the World Health Organization, an estimated 240 million people are chronically infected with HBV and more than 780,000 people die every year due to complications of HBV infection, including cirrhosis and liver cancer. Given this urgent situation, rapid and accessible detection of HBV is important for efficient prevention and prompt treatment of it. Diagnosis of acute or chronic HBV infection is based on the presence of hepatitis B surface antigen (HBsAg), a protein on the surface of HBV, which can be detected in high levels during acute or chronic HBV infection. STANDARD Q HBsAg Test provides significantly fast, easy and accurate system to detect HBsAg in human serum, plasma or whole blood. It is essential for the reliable clinical diagnosis of HBV infection and enables supportive treatment decisions.

[Intended use]

STANDARD Q HBsAg Test is a rapid chromatographic immunoassay for the qualitative detection of Hepatitis B surface antigen (HBsAg) present in serum or plasma. This test is for in vitro professional diagnostic use and intended as an aid to early diagnosis of HBV infection in patient with clinical symptoms with HBV infection. It provides only an initial screening test result. More specific alternative diagnosis methods should be performed in order to obtain the confirmation of HBV infection.

[Test principle]

STANDARD Q HBsAg Test contains two pre-coated lines, "C" (Control line) and "T" (Test line) on the surface of the nitrocellulose membrane. Both the control line and test line in the result window are not visible before applying any samples. Monoclonal anti-Chicken IgY is coated on the control line region and monoclonal anti-HBS is coated on the test line region. Monoclonal anti-HBS conjugated with colloidal gold particles is used as a detector for HBsAg. During the test, Hepatitis B surface antigen (HBsAg) in the sample interacts with anti-HBS conjugated with colloidal gold particles making anti-HBS-HBsAg gold particle complex. This complex migrates on the membrane via capillary action until the test line, where it will be captured by monoclonal anti-HBS. A violet test line would be visible in the result window if HBsAg is present in the specimen. The intensity of violet test line will vary depending upon the amount HBsAg present in the specimen. If HBsAg is not present in the specimen, then no color appears in the test line. The control line is used for procedural control, and should always appear if the test procedure is performed properly and the test reagents of the control line are working.

ACTIVE INGREDIENTS OF MAIN COMPONENT

[Materials Provided]

Components	
Cassette	Specimen transfer device (50µl)
Instruction for use	

[Reagents composition]

Components	Composition
Cassette	· Gold conjugates - Monoclonal anti-HBS-gold - Chicken IgY-gold · Test line - Monoclonal anti-HBS · Control line - Monoclonal anti-Chicken IgY

KIT STORAGE AND STABILITY

Store the RDT Box at room temperature, 2-40°C / 36-104°F out of direct sunlight. Materials provided are stable until the expiration date printed on the RDT box. Do not freeze.

SPECIMEN COLLECTION AND PREPARATION

[Serum]

1. Collect the whole blood into the commercially available plain tube NOT containing anti-coagulant such as heparin or EDTA by venipuncture and leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant.
2. If serum in the plain tube is stored in a refrigerator at 2-8°C / 36-46°F, the specimen can be used for testing within 1 week after collection. Using the specimen in the long-term keeping more than 1 week can cause non-specific reaction. For prolonged storage, it should be at below -20°C / -4°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 or EDTA 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 -20°C / -4°F.
3. It should be brought to room temperature prior to use.

CAUTION

- Anticoagulants such as heparin or EDTA do not affect the test result.
- As known relevant interference, haemolytic specimen, rheumatoid factors-contained specimen and lipaemic, icteric specimen can lead to impair test results.
- Use separate disposable materials for each specimen in order to avoid cross-contamination which can cause erroneous results.

TEST PROCEDURE

[Preparation]

1. Carefully read the instruction for using the STANDARD Q HBsAg Test.
2. Look at the expiry date at the back of the cassette packaging. Use another lot, if expiry date has passed.
3. Open the cassette package, and check the cassette and the color indicator silica gel in cassette packaging.
4. Methods for following steps can be changed depending on the type of specimen and specimen transfer device.

[Test Procedure]

- **Using micropipette**

1. Collect 50µl of serum or plasma.
2. Add the collected specimen to the specimen well of the cassette.
3. Read the test results after 20 minutes. Test can be read up to 30 minutes.

- **Using specimen transfer device (50µl)**

1. Collect 50µl of serum or plasma till black line of the specimen transfer device.
2. Add the collected specimen to the specimen well of the cassette.
3. Read the test results after 20 minutes. Test can be read up to 30 minutes.

CAUTION

- Do not Read the test result after 30 minutes. It may give false results.

INTERPRETATION OF TEST RESULTS

1. **Non reactive result**: The presence of only one colored band ("C" Control line) within the result window indicates a non reactive result.

2. **Reactive result**: The presence of two colored bands ("C" Control line and "T" Test line) within the result window, no matter which band appears first, indicates a reactive result. Even if the control line is faint, or the test line isn't uniform, the test should be considered to be performed properly and the test result should be interpreted as a reactive result.

3. **Invalid result**: If the control band ("C" Control line) is not visible within the result window, the result is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. Re-test with a new cassette.

CAUTION

- Reactive results should be considered in conjunction with the clinical history and other data available to the physician.

LIMITATION OF TEST

1. The test should be used for the detection of HBsAg in human serum or plasma specimens.
2. Neither the quantitative value nor the concentration of HBsAg can be determined by this qualitative test.
3. Failure to follow the test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results.
4. A non-reactive test result may occur if the level of extracted antigen in a specimen is below the sensitivity of the test or if a poor-quality specimen is obtained.
5. For more accuracy of immune status, additional follow-up testing using other laboratory methods is recommended.
6. The test result must always be evaluated with other data available to the physician.

PERFORMANCE CHARACTERISTICS

1. Sensitivity : In this multi-site evaluation of 43 specimen, we found the relative sensitivity is 100% (43/43). The results are summarized in the following table.

Reference		STANDARD Q HBsAg Test		Total Result
		Reactive	Non reactive	
CLIA Analyzer	Positive	43	0	43
	Negative	0	0	0
Total Result		43	0	43
Sensitivity		43/43 x 100=100%		

2. Specificity : In this multi-site evaluation of 162 specimen, we found the relative specificity is 100% (162/162). The results are summarized in the following table.

Reference		STANDARD Q HBsAg Test		Total Result
		Reactive	Non reactive	
CLIA Analyzer	Positive	0	0	0
	Negative	0	162	162
Total Result		0	162	162
Specificity		162/162 x 100=100%		

WARNINGS

1. Do not re-use the kit.
2. Do not use the kit if the cassette package is damaged or the seal is broken.
3. Do not use the kit after expiration date.
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 afterwards.
6. Clean up spills thoroughly using an appropriate disinfectant.
7. Handle all specimens as if they contain infectious agents.
8. Observe established precautions against microbiological hazards throughout testing procedures.
9. Dispose off 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 cassette packaging is to absorb moisture and keep humidity from affecting products. If the moisture indicating silica gel beads change from yellow to green, the cassette in the cassette packaging should be discarded.
11. Discard the cassette immediately after reading result.

BIBLIOGRAPHY

1. Tabor E, Gerety RJ, Smallwood LA, Barker LF. Coincident hepatitis B surface antigen and antibodies of different subtypes in human serum. J Immunol 1977;118:369-70.
2. Mesenas SJ, Chow WC, Zhao Y, Lim GK, Ooi CJ, Ng HS. Wild-type and "a" epitope variants in chronic hepatitis B virus carriers positive for hepatitis B surface antigen and antibody. J Gastroenterol Hepatol 2002; 17:148-52.
3. Shiels MT, Taswell HF, Czaja AJ, Nelson C, Swenke P. Frequency and significance of concurrent hepatitis surface antigen and antibody in acute and chronic hepatitis B virus. Gastroenterology 1987; 93:675-80.
4. Voller A, Bartlett A, and Bidwell D. Zuckerman AJ. Viral hepatitis with special reference to hepatitis B. Immunoassays for the 80's. eds University Park Press. 1981;361-373.
5. Weinbaum, C.M., Williams, I., Mast, E.E., Wang, S.A., Finelli, L., Wasley, A. et al, Recommendations for identification and public health management of persons with chronic hepatitis B virus infection. MMWR Recomm Rep. 2008; 57:1-20.
6. Randrianirina, F., Carod, J.F., Ratsima, E., Chretien, J.B., Richard, V., Talarmin, A. Evaluation of the performance of four rapid tests for detection of hepatitis B surface antigen in Antananarivo, Madagascar. J Virol Methods. 2008; 151:294-297.

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 reactive or non reactive, in the use of this product.

Issue date : 2018. 06

SD/026/IN/01-00

Manufactured by

SD BIOSENSOR HEALTHCARE PVT. LTD.

Corporate Office
Unit No-202 A-D, 2nd Floor, Tower-A, Unitech Signature Towers, South City 1, Gurugram, Haryana-122001, India

Manufacturing site
Plot No. 38, Sector - 4, IMT Manesar, Gurugram, Haryana-122052, India

Any inquiries regarding the instruction provided should be addressed to:
care@sdbiosensor.co.in

www.sdbiosensor.com

Toll Free No.
1800-10-23105

For *in vitro* diagnostic use only

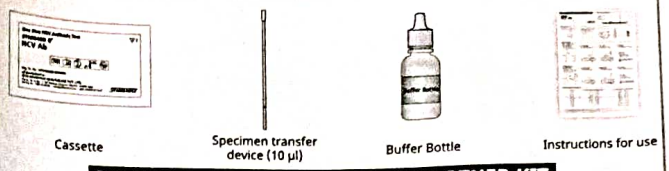
STANDARD Q®
HCV Ab

STANDARD Q HCV Ab Rapid Test

PLEASE READ COMPLETE KIT INSERT CAREFULLY BEFORE YOU PERFORM THE TEST

STANDARD®

[Materials Provided]



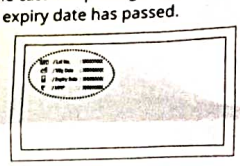
Cassette | Specimen transfer device (10 µl) | Buffer Bottle | Instructions for use

DO NOT USE COMPONENT OF ANY OTHER KIT

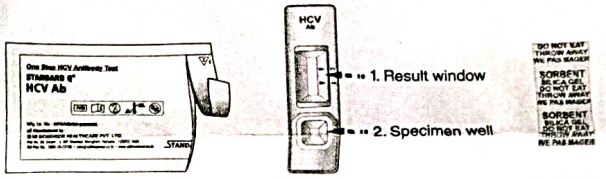
[Preparation]

1 Carefully read the instruction for using the STANDARD Q HCV Ab Test.

2 Look at the expiry date at the back of the cassette package. Use another lot, if expiry date has passed.



3 Open the cassette package & check for the cassette & silica gel.

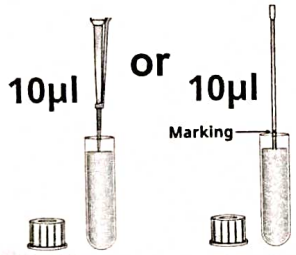


<Cassette Packaging> <Cassette> <Silica gel>

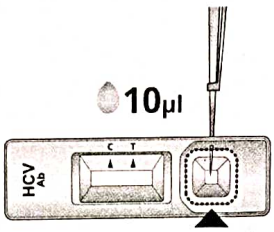
[Test Procedure]

1. For Serum or Plasma specimen

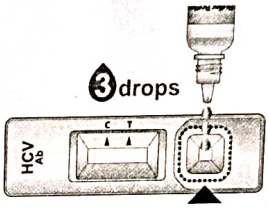
1 Specimen Collection
Using a micropipette or specimen transfer device collect 10µl (till marking) of serum or plasma.



2 Specimen Addition
Add the collected serum or plasma to the specimen well of the cassette.



3 Buffer Addition
Add 3 drops of buffer into specimen well of the cassette.



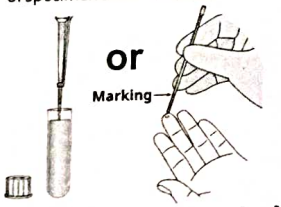
4 Reading Time
Read the test results after 5 minutes.
The test can be read up to 20 minutes.

Read
After 5 mins
Can be read
Up to 20 mins

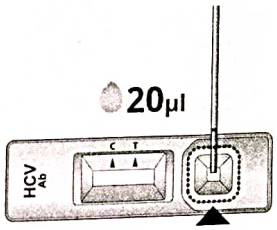
CAUTION Do not read test result after 20 minutes. It may give false results.

2. For Whole Blood specimen

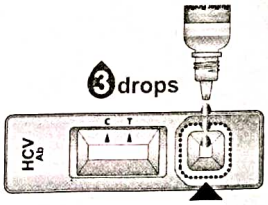
1 Specimen Collection
Collect 20µl of whole blood by using a micropipette or collect two times 10µl of whole blood till the marking of specimen transfer device.



2 Specimen Addition
Add the collected whole blood to the specimen well of the cassette.



3 Buffer Addition
Add 3 drops of buffer into specimen well of the cassette.

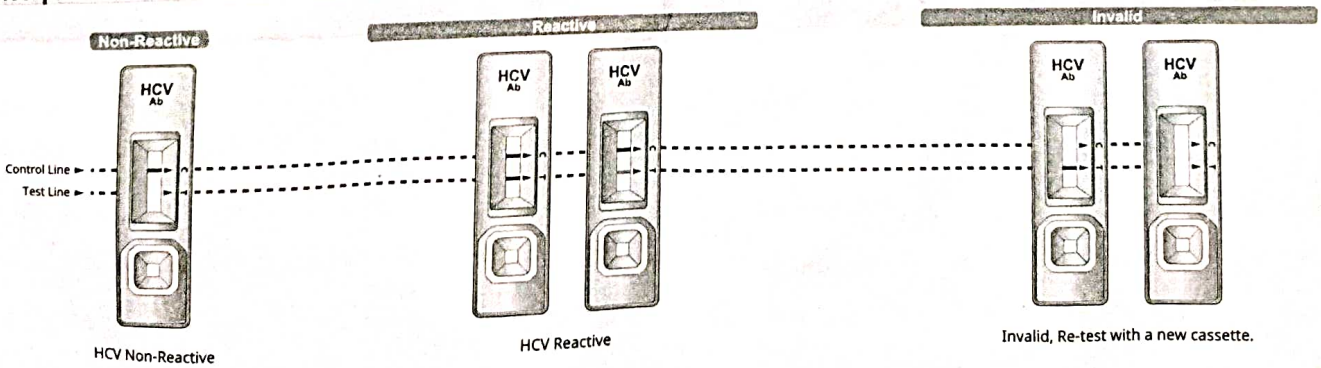


4 Reading Time
Read the test results after 5 minutes.
The test can be read up to 20 minutes.

Read
After 5 mins
Can be read
Up to 20 mins

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

[Interpretation of Test Result]



HCV Non-Reactive | HCV Reactive | Invalid, Re-test with a new cassette.

1. A colored band will appear in the top section of the result window to show that the test is working properly. This band is the control line (C).
2. A colored band will appear in the lower section of the result window. This band is the test line (T).
3. **Even if the control line/test line is faint, or the test line is not uniform, the test should be considered to be performed properly and the test result should be interpreted as a reactive result.**

* Reactive results should be considered in conjunction with the clinical history and other data available to the physician.

STANDARD Q® HCV Ab Test

SD BIOSENSOR HEALTHCARE PVT. LTD.

EXPLANATION AND SUMMARY

[Introduction]

Hepatitis C virus (HCV) is one of several hepatitis viruses that can cause inflammation of the liver. It is a bloodborne virus and is most commonly transmitted through unsafe injection practices, inadequate sterilization of medical equipment and the transfusion of unscreened blood and blood products. HCV can cause both acute and chronic hepatitis infection. Acute HCV infection is a short-term viral infection, and is usually asymptomatic. About 15-45% of infected persons spontaneously improve or resolve the infection within just several months without treatment. However, the remaining 55-85% of infected persons will develop chronic HCV infection. The chronic HCV infection is a serious disease that it can result in long-term problems in the liver, including liver damage and liver cancer, even death. According to the World Health Organization, about 130-150 million people globally have chronic HCV infection, with more than 350,000 people dying from Hepatitis C-related liver diseases each year. Antiviral medicines can cure approximately 90% of persons with HCV, thereby reducing the risk of death, but access to diagnosis and is low. To establish best practices for early diagnosis for HCV infection can prevent health problems that may result from infection and prevent transmission of the virus. STANDARD Q HCV Ab Test provides significantly fast, easy and accurate system to detect the specific antibodies HCV in human serum, plasma or whole blood. It is essential for the reliable clinical diagnosis of HCV infection and enables supportive treatment decisions.

[Intended use]

STANDARD Q HCV Ab Test is a rapid chromatographic immunoassay for the qualitative detection of specific antibodies to HCV present in human serum, plasma or whole blood. This test is for *in vitro* professional diagnostic use and intended as an aid to early diagnosis of HCV infection in patient with clinical symptoms with HCV infection. It provides only an initial screening test result. More specific alternative diagnosis methods should be performed in order to obtain the confirmation of HCV infection.

[Test principle]

STANDARD Q HCV Ab Test contains two pre-coated lines, "C" (Control line), "T"(Test line) on the surface of the nitrocellulose membrane. Both the control line and test line in the result window are not visible before applying any specimens. Monoclonal anti-NS3 and monoclonal anti-Core are coated on the control line region and monoclonal anti-human IgG is coated on the test line region. Four recombinant HCV antigens from the Core, NS3, NS4 and NS5 regions conjugated with colloidal gold particles are used as detectors for HCV antibodies. During the test, HCV antibodies in the specimen interacts with recombinant HCV antigens conjugated with colloidal gold particles making antibody-antigen gold particle complex. This complex migrates on the membrane via capillary action until the test line, where it will be captured by the monoclonal anti-human IgG. A violet test line would be visible in the result window if HCV antibodies are present in the specimen. The intensity of violet test line will vary depending upon the amount HCV antibodies present in the specimen. If HCV antibodies are not present in the specimen, then no color appears in the test line. The control line is used for procedural control, and should always appear if the test procedure is performed properly and the test reagents of the control line are working.

[Materials Provided]

Components	
Cassette	Specimen transfer device
Buffer Bottle	Instruction for use

KIT STORAGE AND STABILITY

Store the RDT Box at room temperature, 2-40°C / 36-104°F out of direct sunlight. Materials provided are stable until the expiry date printed on the RDT box. DO NOT FREEZE.

SPECIMEN COLLECTION AND PREPARATION

[Serum]

1. Collect the whole blood into the commercially available plain tube NOT containing anti-coagulant such as heparin or EDTA by venipuncture and leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant.
2. If serum in the plain tube is stored in a refrigerator at 2-8°C/36-46°F, the specimen can be used for testing within 1 week after collection. Using the specimen in the long-term keeping more than 1 week can cause non-specific reaction. For prolonged storage, it should be at below -20°C / -4°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 or EDTA 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 -20°C/-4°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 till the marking of the specimen transfer device 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 or EDTA 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 day after collection.
3. Do not use hemolyzed blood specimen.

CAUTION

- Anticoagulants such as heparin or EDTA 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.
- Use separate disposable materials for each specimen in order to avoid cross-contamination which can cause erroneous results.

TEST PROCEDURE

[Preparation]

1. Carefully read instructions for using the STANDARD Q HCV Ab Test.
2. Look at the expiry date at the back of the cassette package. Use another lot, if expiry date has passed.
3. Allow the RDT kit to come at room temperature before opening the cassette package.
4. Open the cassette package & check for the cassette & silica gel.
5. Methods for following steps can be changed depending on the specimen or specimen transfer device.

[Test Procedure]

- **For serum or plasma specimen**

1. Using a micropipette or specimen transfer device collect 10µl (till the marking) of serum or plasma.
2. Add the collected serum or plasma to the specimen well of the cassette.
3. Add 3 drops of buffer into the specimen well of the cassette.
4. Read the test results after 5 minutes. Test can be read up to 20 minutes.

- **For whole blood specimen**

1. Collect 20µl of whole blood by using a micropipette or collect two times 10µl of whole blood till the marking of specimen transfer device.
2. Add the collected whole blood to the specimen well of the cassette.
3. Add 3 drops of buffer into the specimen well of the cassette.
4. Read the test results after 5 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

1. **Non-reactive:** The presence of only one colored band ("C" Control line) within the result window indicates a non-reactive result.
2. **Reactive:** The presence of two colored bands ("C" Control line and "T" Test line) within the result window, no matter which band appears first, indicates a reactive result. Even if the control line/test line is faint, or the test line isn't uniform, the test should be considered to be performed properly and the test result should be interpreted as a reactive result.
3. **Invalid:** If the control band ("C" Control line) is not visible within the result window, the result is considered invalid. The directions may not have been followed correctly. In such case, it is recommended to retest the specimen with a new cassette.

CAUTION

- Even if the control line/test line is faint, or the test line isn't uniform, the test should be considered to be performed properly and the test result should be interpreted as a reactive result.
- Reactive result should be considered in conjunction with the clinical history and other data available to the physician.

LIMITATION OF TEST

1. The test should be used for the detection of HCV antibodies in human serum, plasma or whole blood specimen.
2. Neither the quantitative value nor the rate of HCV antibodies concentration can be determined by this qualitative test.
3. Failure to follow the test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results.
4. A non-reactive test result may occur if the level of extracted antibody in a specimen is below the sensitivity of the test or if a poor-quality specimen is obtained.
5. For more accuracy of immune status, additional follow-up testing using other laboratory methods is recommended.
6. The test result must always be evaluated with other data available to the physician.

QUALITY CONTROL

[Internal Quality Control]

STANDARD Q HCV Ab Kit has test line and control line on the surface of each cassette. All the test line and control line in result window are not visible before applying specimen. The control line is used for procedural control. It will appear if the test has been performed correctly and the reagents are functional. If it does not appear, the test results are not valid and the test must be repeated. In addition, good laboratory practice recommends the daily use of control materials to confirm the test procedure and to verify proper test performance.

PERFORMANCE CHARACTERISTICS

As per the evaluation conducted at different sites in India, the performance characteristics of STANDARD Q HCV Ab is found to be:

Sensitivity - 100% | Specificity - 99.74%

WARNINGS AND PRECAUTIONS

1. Do not re-use the kit.
2. Do not use the kit if the cassette package is damaged or the seal is broken.
3. Do not use the buffer bottle 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 off 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 cassette packaging is to absorb moisture and prevent humidity from affecting products.
11. Buffer contain sodium azide as a preservative. If these materials are to be disposed off through sink or other common plumbing system, flush with generous water to prevent accumulation of potentially explosive compound.
12. For *in vitro* diagnostic use only.
13. Do not use the kit contents beyond the expiry date printed outside the box.
14. Immediately perform the test after removing the test device from the cassette package.
15. Discard the cassette immediately after reading result.

BIBLIOGRAPHY

1. Smith BD, Teshale E, Jewett A, Weinbaum CM, Neaigus A, Hagan H, et al. Performance of premarket rapid hepatitis C virus antibody assays in 4 national human immunodeficiency virus behavioral surveillance system sites. Clin Infect Dis. 2011;53:780–786.
2. Lee SR, Yearwood GD, Guillon GB, Kurtz LA, Fischl M, Friel T, et al. Evaluation of a rapid, point-of-care test device for the diagnosis of hepatitis C infection. J Clin Virol. 2010;48:15–17.
3. Perz, J.F., Armstrong, G.L., Farrington, L.A., Hutin, Y.J., Bell, B.P. The contributions of hepatitis B virus and hepatitis C virus infections to cirrhosis and primary liver cancer worldwide. J Hepatol. 2006;45:529–538.
4. Larrat, S., Bourdon, C., Baccard, M. et al, Performance of an antigen–antibody combined assay for hepatitis C virus testing without venipuncture. J Clin Virol. 2012;55:220–225.
5. Shah DO, Chang CD, Jiang LX, et al. Combination HCV core antigen and antibody assay on a fully automated chemiluminescence analyzer. Transfusion 2003;43:1067-74.

SD/018/IN/01-03

Issue date : 2022.03

Manufactured by

SD BIOSENSOR HEALTHCARE PVT. LTD.

Manufacturing site: Plot No. 38, Sector - 4, IMT Manesar, Gurugram, Haryana - 122052, India

Head Office: Unit No - 202 A-D, 2nd Floor, Tower A, Unitech Signature Towers, South City 1, Gurugram, Haryana - 122001, India

Any inquiries regarding the instruction provided should be addressed to: care@sdbiosensor.co.in or call at - **1800-10-23105**

www.sdbiosensor.co.in

CAT Catalogue number | IVD *in vitro* Diagnostics | Consult Instructions for Use | Contains Sufficient for <n> Tests | Caution | To indicate the temperature limitations in which the transport package has to be kept and handled. | 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 | This way up

For *in vitro* diagnostic use only

STANDARD Q®

HIV 1/2 Ab

STANDARD Q HIV 1/2 Ab Test

PLEASE READ COMPLETE KIT INSERT CAREFULLY BEFORE YOU PERFORM THE TEST

STANDARD®

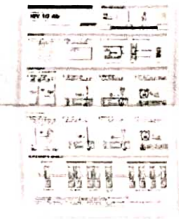
[Materials Provided]

Cassette | Specimen transfer device (10 µl) | Buffer Bottle | Instructions for use

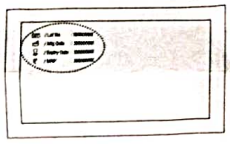
DO NOT USE COMPONENT OF ANY OTHER KIT

[Preparation]

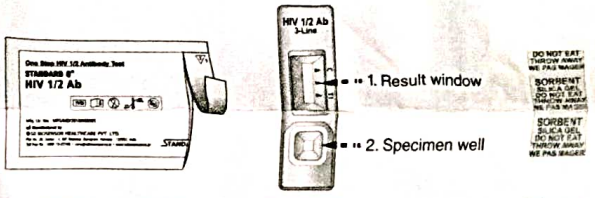
1 Carefully read the instruction for using the STANDARD Q HIV 1/2 Ab Test.



2 Look at the expiry date at the back of the cassette package. Use another lot, if expiry date has passed.



3 Open the cassette package & check for the cassette & silica gel.

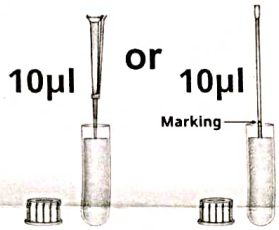


<Cassette Packaging> <Cassette> <Silica gel>

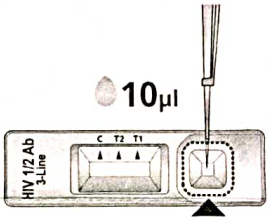
[Test Procedure]

1. For Serum or Plasma specimen

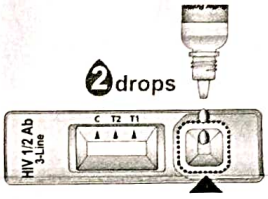
1 Specimen Collection
Using a micropipette or specimen transfer device collect 10µl (till the marking) of serum or plasma.



2 Specimen Addition
Add the collected serum or plasma to the specimen well of the cassette.



3 Buffer Addition
Add 2 drops of buffer into the specimen well of the cassette.



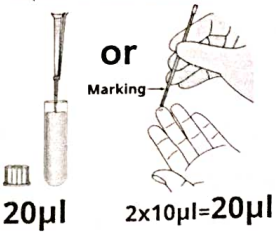
4 Reading Time
Read the test results after 10 minutes. The test can be read up to 20 minutes.

Read
After 10 mins
Can be read
Up to 20 mins

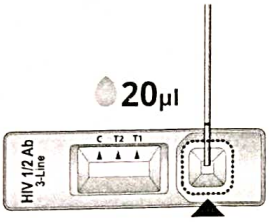
CAUTION **Do not read test result after 20 minutes. It may give false results.**

2. For whole blood specimen

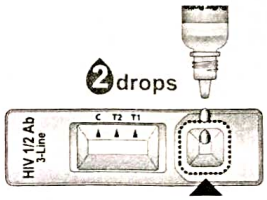
1 Specimen Collection
Collect 20µl of whole blood by using a micropipette or collect two times 10µl of whole blood till the marking of specimen transfer device.



2 Specimen Addition
Add the collected whole blood to the specimen well of the cassette.



3 Buffer Addition
Add 2 drops of buffer into the specimen well of the cassette.

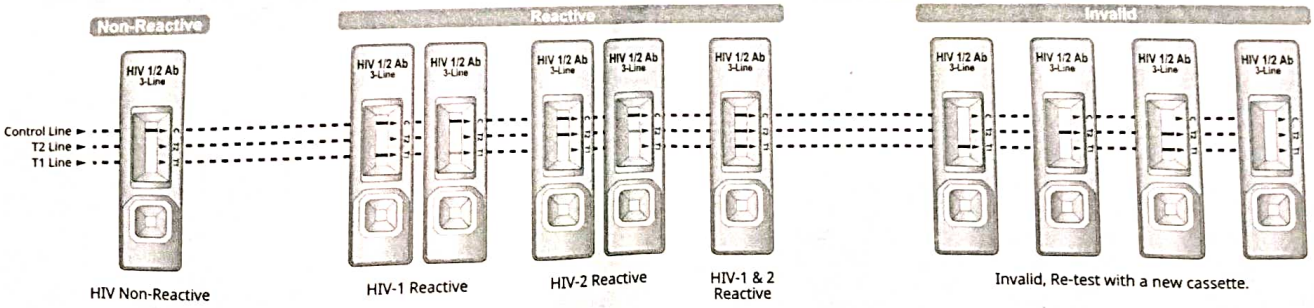


4 Reading Time
Read the test results after 10 minutes. The test can be read up to 20 minutes.

Read
After 10 mins
Can be read
Up to 20 mins

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

[Interpretation of Test Result]



1. A colored band will appear in the top section of the result window to show that the test is working properly. This band is the control line (C).
2. Colored bands will appear in the lower section of the result window. These bands are test lines (T1 and T2).
3. **Even if the control line/test line is faint, or the test line is not uniform, the test should be considered to be performed properly and the test result should be interpreted as a reactive result.**

* Reactive results should be considered in conjunction with the clinical history and other data available to the physician.

STANDARD Q® HIV 1/2 Ab Test

SD BIOSENSOR HEALTHCARE PVT. LTD.

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 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 Test is helpful to prevent future transmission during extremely infectious stage.

[Intended use]

STANDARD Q HIV 1/2 Ab Test is a rapid immunochromatographic 3rd generation test for the detection of antibodies (IgM, IgG & IgA) against HIV 1 & HIV 2 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 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 IgG 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 HIV antigens on the test regions (T1 and T2). If the antibodies against HIV 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.

[Materials Provided]

Components	
Cassette	Specimen transfer device
Buffer Bottle	Instruction for use

KIT STORAGE AND STABILITY

Store the RDT Box at room temperature, 2-40°C / 36-104°F out of direct sunlight. Materials provided are stable until the expiration date printed on the RDT box. Do not freeze.

SPECIMEN COLLECTION AND PREPARATION

[Serum]

1. Collect the whole blood into the commercially available plain tube, NOT containing anti-coagulant such as heparin, EDTA or sodium citrate, by venipuncture and leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant.
2. If serum in the plain tube is stored in a refrigerator at 2-8°C/36-46°F, the specimen can be used for testing within 1 week after collection. Using the specimen in the long-term keeping more than 1 week can cause non-specific reaction. For prolonged storage, it should be at below -20°C / -4°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 -20°C/-4°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 till the marking of the specimen transfer device for 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 day after collection.
3. Do not use hemolyzed blood specimen.

CAUTION

- Anticoagulants such as heparin or EDTA 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.
- Use separate disposable materials for each specimen in order to avoid cross-contamination which can cause erroneous results.

TEST PROCEDURE

[Preparation]

1. Carefully read instructions for using the STANDARD Q HIV 1/2 Ab Test.
2. Look at the expiry date at the back of the cassette package. Use another lot, if expiry date has passed.
3. Allow the RDT kit to come at room temperature before opening the cassette package.
4. Open the cassette package & check for the cassette & silica gel.
5. Methods for following steps can be changed depending on the specimen or specimen transfer device.

[Test Procedure]

- **For serum or plasma specimen**

1. Using a micropipette or specimen transfer device collect 10µl (till the marking) of serum or plasma.
2. Add the collected serum or plasma to the specimen well of the cassette.
3. Add 2 drops of buffer into the specimen well of the cassette.
4. Read the test results after 10 minutes. Test can be read up to 20 minutes.

- **For whole blood specimen**

1. Collect 20µl of whole blood by using a micropipette or collect two times 10µl of whole blood till the marking of specimen transfer device.
2. Add the collected whole blood to the specimen well of the cassette.
3. Add 2 drops of buffer into the specimen well of the cassette.
4. 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

Non-Reactive

The presence of only control line (C) within the result window indicates that the specimen is non-reactive for antibodies to HIV-1 and/or HIV-2.

Reactive

1) The presence of two lines as control line (C) and test line (1) within the result window indicates that the specimen is reactive for antibodies to HIV-1.
2) The presence of two lines as control line (C) and test line (2) within the result window indicates that the specimen is reactive for antibodies to HIV-2.
3) The presence of three lines as control line (C) , test line (1) and test line (2) within the result window indicates that the specimen is reactive for antibodies to HIV-1 and HIV-2.

Invalid

If the control band ("C" Control line) is not visible within the result window, the result is considered invalid. The directions may not have been followed correctly. In such case, it is recommended to retest the specimen with a new cassette.

CAUTION

- There is an homology in the amino acid sequence between HIV-1 and HIV-2 due to which they have a cross reactivity of 30-70%. Hence, appearance of test lines for both HIV-1 and HIV-2 antibodies on the cassette does not necessarily imply co-infection from HIV-1 & HIV-2. To determine the virus type or diagnose a co-infection accurately, a confirmatory test such as Western Blot or PCR must be performed.

LIMITATION OF TEST

1. The test should be used for the detection of antibodies to HIV in human serum, plasma or whole blood specimen.
2. Neither the quantitative value nor the rate of antibodies to HIV concentration can be determined by this qualitative test.
3. Failure to follow the test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results.
4. A non-reactive test result may occur if the level of extracted antibody in a specimen is below the sensitivity of the test or if a poor-quality specimen is obtained.
5. For more accuracy of immune status, additional follow-up testing using other laboratory methods is recommended.
6. The test result must always be evaluated with other data available to the physician.

QUALITY CONTROL

[Internal Quality Control]

STANDARD Q HIV 1/2 Ab Kit has test line and control line on the surface of each cassette. All the test lines and control line in result window are not visible before applying specimen. The control line is used for procedural control. It will appear if the test has been performed correctly and the reagents are functional. If it does not appear, the test results are not valid and the test must be repeated. In addition, good laboratory practice recommends the daily use of control materials to confirm the test procedure and to verify proper test performance.

PERFORMANCE CHARACTERISTICS

As per the evaluation conducted at different sites in India, the performance characteristics of STANDARD Q HIV 1/2 Ab is found to be:

Sensitivity - 100% | Specificity - 99.49%

WARNINGS AND PRECAUTIONS

1. Do not re-use the kit.
2. Do not use the kit if the cassette package is damaged or the seal is broken.
3. Do not use the buffer bottle 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 off 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 cassette packaging is to absorb moisture and prevent humidity from affecting products.
11. Buffer contain sodium azide as a preservative. If these materials are to be disposed off through sink or other common plumbing system, flush with generous water to prevent accumulation of potentially explosive compound.
12. For *in vitro* diagnostic use only.
13. Do not use the kit contents beyond the expiry date printed outside the box.
14. Immediately perform the test after removing the test device from the cassette package.
15. Discard the cassette immediately after reading result.

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.

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 HEALTHCARE PVT. LTD. 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 HEALTHCARE PVT. LTD. 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 reactive or non reactive, in the use of this product.

SD/057/IN/04-00

Issue date : 2022.03

Manufactured by
SD BIOSENSOR HEALTHCARE PVT. LTD.
Manufacturing site: Plot No. 38, Sector - 4, IMT Manesar, Gurugram, Haryana - 122052, India
Head Office: Unit No - 202 A-D, 2nd Floor, Tower A, Unitech Signature Towers, South City 1, Gurugram, Haryana - 122001, India

Any inquiries regarding the instruction provided should be addressed to: care@sdbiosensor.co.in or call at - **1800-10-23105**
www.sdbiosensor.co.in

CAT Catalogue number | IVD *in vitro* Diagnostics | Consult Instructions for Use | Contains Sufficient for <n> Tests | Caution | To indicate the temperature limitations in which the transport package has to be kept and handled. | Do not re-use. | Use Dry | 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 | This way up