ASPEN® Syphilis

Syphilis Rapid Test Strip (Serum/Plasma/WB) Package Insert

A rapid test for the diagnosis of Syphilis to detect antibodies (IgG and IgM) to Treponema Pallidum (TP) qualitatively in serum/plasma/whole blood. For professional in vitro diagnostic use only.

INTENDED USE

The Aspen Syphilis Rapid Test strip (Serum/Plasma/Whole blood) is a rapid chromatographic immunoassay for the qualitative detection of antibodies (IgG and IgM) to Treponema Pallidum (TP) in serum, plasma or whole blood to aid in the diagnosis of Syphilis.

SUMMARY

Treponema Pallidum (TP) is the causative agent of the venereal disease Syphilis. TP is a spirochete bacterium with an outer envelope and a cytoplasmic membrane.[1] Relatively little is known about the organism in comparison with other bacterial pathogens. According to the Center for Disease Control (CDC), the number of cases of Syphilis infection has markedly increased since 1985.[2] Some key factors that have contributed to this rise include the crack cocaine epidemic and the high incidence of prostitution among drug users. One study reported a substantial epidemiological correlation between the acquisition and transmission of the HIV virus and Syphilis.

Multiple clinical stages and long periods of latent, asymptomatic infection are characteristic of Syphilis. Primary Syphilis is defined by the presence of a chancre at the site of inoculation. The antibodies response to the TP bacterium can be detected within 4 to 7 days after the chancre appears. The infection remains detectable until the patient receives adequate treatment.[3]

The Syphilis Rapid Test strip (Serum / Plasma / whole blood) utilizes a double antigen combination of a Syphilis antigen coated particle and Syphilis antigen immobilized on membrane to detect TP antibodies (IgG and IgM) qualitatively and selectively in serum / plasma / whole blood.

PRINCIPLE

The Aspen Syphilis Rapid Test strip (Serum /Plasma /Whole blood) is a qualitative membrane based immunoassay for the detection of TP antibodies (IgG and IgM) in whole blood, serum or plasma. In this test procedure, recombinant Syphilis antigen is immobilized in the test line region of the test. After specimen is added to the specimen well of the test strip, it reacts with Syphilis antigen coated particles in the test. This mixture migrates chromatographically along the length of the test and interacts with the immobilized Syphilis antigen. The double antigen test format can detect both IgG and IgM in specimens. If the specimen contains TP antibodies, a colored line will appear in the test line region, indicating a positive result. If the specimen does not contain TP antibodies, a colored line will not appear in this region, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENT

The test contains Syphilis antigen coated particles and Syphilis antigen coated on the membrane.

PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after expiration date. Do not use test if pouch is damaged.
- Do not eat, drink or smoke in the area where the specimens or test strips are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing, disposable gloves and eye protection when specimens are assayed.
- The used tests, specimens and potentially contaminated materials should be discarded according to the local regulations.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

The test is stable through the expiration date printed on the sealed pouch 2-30°C. DO NOT FREEZE. Do not use after the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- The Aspen Syphilis rapid test strip can be performed using Serum / Plasma / Whole blood.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimen at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C.
- Bring specimen to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimen should not be frozen and thawed repeatedly.

MATERIAL PROVIDED

- Test strips
- Droppers
- Strip support
- Buffer
- Package insert

Material required but not provided

Specimen Collection containers, Centrifuge, Timer, Test tubes

DIRECTIONS FOR USE

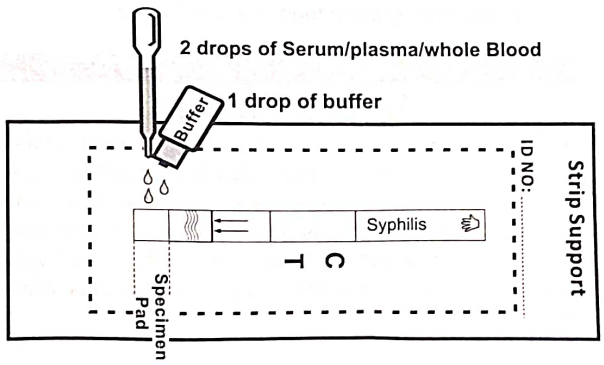
Note: Bring the test device, specimen and buffer to the room temperature if stored at 2-8°C.

Remove the strips from the sealed pouch.

- Peel off the tape from the strip support and stick the test strip in middle of the strip support as shown in below picture.

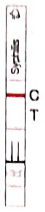
1. Add **2 drops** (50µl) of **Serum/ Plasma / Whole blood** to the specimen pad of the test strip using dropper/ pipette.

2. Add **1 drop** of **buffer** (40µl). Read result at **10 minutes**. (Do not interpret the result after 30 minutes).

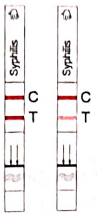


INTERPRETATION OF RESULTS

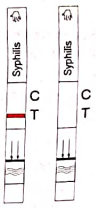
NEGATIVE : Pink/Purple line at **C** only



POSITIVE : Pink/Purple lines at **C & T**



INVALID : If control line does not appear, the test is invalid. In this case, please repeat the test using another device following the test procedure correctly.



QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms adequate membrane wicking.

LIMITATIONS

1. The Aspen Syphilis Rapid Test strip (Serum /Plasma /Whole blood) is for in vitro diagnostic use only. The test should be used for the detection of TP antibodies in serum, plasma or whole blood specimens only. Neither the quantitative value nor the rate of increase in TP antibodies can be determined by this qualitative test.
2. The Aspen Syphilis Rapid Test strip (Serum /Plasma /Whole blood) will only indicate the presence of TP antibodies in the specimen and should not be used as the sole criteria for the diagnosis of TP infection.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of TP infection.

EXPECTED VALUES

The Aspen Syphilis Rapid Test Strip (Serum/Plasma/Whole blood) has been compared with a leading commercial TPPA Syphilis test, demonstrating an overall accuracy greater than or equal to 99.8%.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The Aspen Syphilis Rapid Test strip (Serum /Plasma /Whole blood) has correctly identified specimens of a performance panel and has been compared to a leading commercial TPPA Syphilis test using clinical specimens. The results show that the relative sensitivity of the Syphilis Rapid Test strip is >99.9% and the relative specificity is 99.7%.

Method		TPPA		Total Result
Aspen Syphilis Rapid Test Strip(serum/Plasma/WB)	Results	Positive	Negative	
	Positive	130	1	131
	Negative	0	299	299
Total Result		130	300	430

Relative sensitivity: >99.9% (95%CI*: 97.7%~100.0%);
Relative specificity: 99.7% (95%CI*: 98.2%~100.0%);
Accuracy: 99.8% (95%CI*: 98.2%~100.0%).
*Confidence Intervals

Precision

Intra-Assay

Within-run precision has been determined by using 15 replicates of four specimens: a negative, a low positive, a medium positive and a high positive. The negative, low positive, medium positive and high positive values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 15 independent assays on the same four specimens: a negative, a low positive, a medium positive and a high positive. Three different lots of the Syphilis Rapid Test strip (Serum/Plasma/WB) have been tested over a 3-day period using negative, low positive, medium positive and high positive specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

The Aspen Syphilis Rapid Test Strip (Serum/Plasma/WB) has been tested by HAMA, RF, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb,HCV, HIV, H. Pylori, MONO, CMV, Rubella and TOXO positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following potentially interfering substances were added to Syphilis negative and positive specimens.

Acetaminophen: 20 mg/dL
Acetylsalicylic Acid: 20 mg/dL
Ascorbic Acid: 2g/dL
Creatin: 200 mg/dL
Bilirubin: 1g/dL
Caffeine: 20 mg/dL
Gentisic Acid: 20 mg/dL
Albumin: 2 g/dL
Hemoglobin 1.1 mg/dL
Oxalic Acid: 600mg/dL

None of the substances at the concentration tested interfered in the assay.

BIBLIOGRAPHY

1. Fraser CM. Complete genome sequence of Treponema Pallidum, the Syphilis spirochete, Science (1998); 281 July: 375-381.
2. Center for Disease Control. Recommendations for diagnosing and treating Syphilis in HIVinfected patients. MMWR Morb. Mortal Wkly Rep. (1988); 37: 601.
3. Johnson PC. Testing for Syphilis. Dermatologic Clinic (1994); 12 Jan: 9-17.

Number: RP5155505
Effective date: 2017-05-26

For in vitro diagnostic use only

STANDARD Q® HBsAg

STANDARD Q HBsAg Rapid Test

PLEASE READ COMPLETE KIT INSERT CAREFULLY BEFORE YOU PERFORM THE TEST

STANDARD®

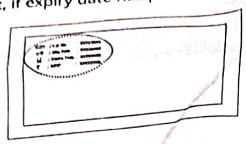
[Materials Provided]

DO NOT USE COMPONENT OF ANY OTHER KIT

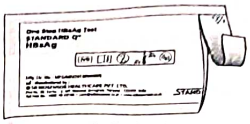
[Preparation]

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

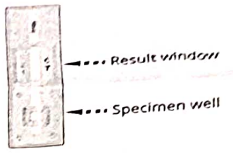
2 Look at the expiry date at the back of the Cassette Package. Use another lot, if expiry date has passed.



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



<Cassette Packaging>



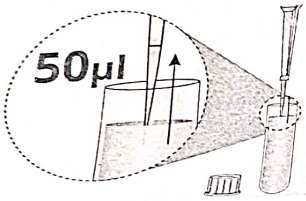
<Cassette>

<Silica gel>

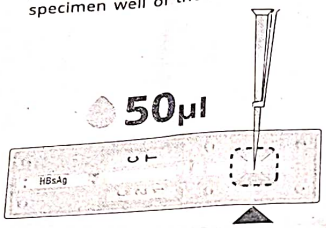
[Test Procedure]

1. Using a micropipette

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 the test results after 20 minutes.
The test can be read up to 30 minutes.

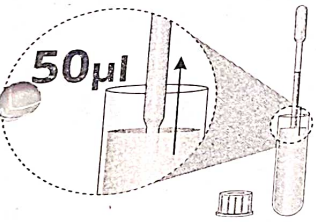
Read
After 20 mins
Can be read
Up to 30 mins

20 mins

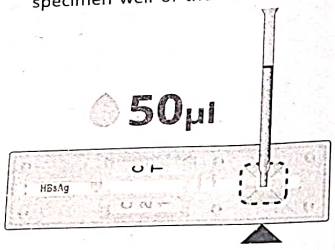
CAUTION Do not read test result after 30 minutes. It may give false results.

2. Using Specimen transfer device (50µl)

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



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



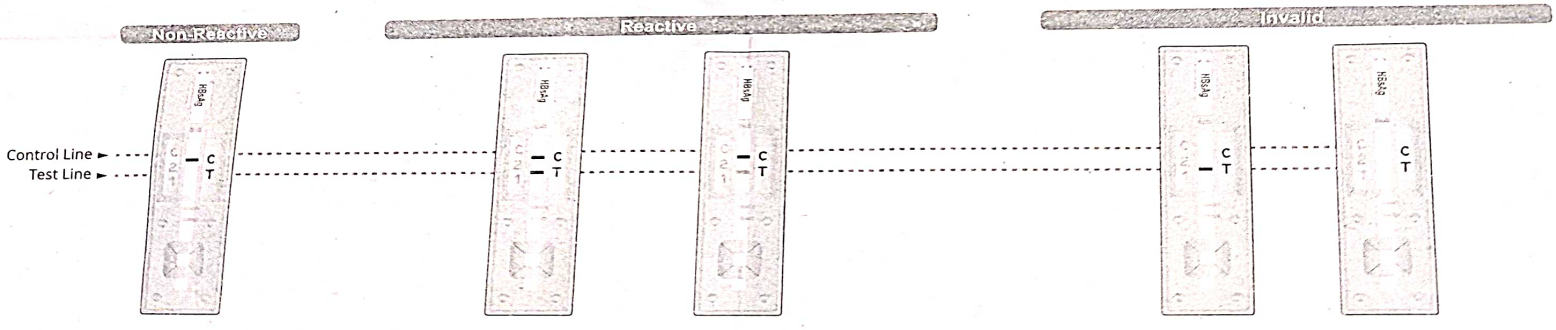
3 Reading Time
Read the test results after 20 minutes.
The test can be read up to 30 minutes.

Read
After 20 mins
Can be read
Up to 30 mins

20 mins

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

Interpretation of Test Result]



HBsAg Non-Reactive

HBsAg Reactive

Invalid, Re-test with a new cassette.

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).
A colored band will appear in the lower section of the result window. This band is the test line (T).
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.

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 or plasma. 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	

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.

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 the instruction for using the STANDARD Q HBsAg 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.*
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 serum or plasma (50µl) till the marking 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/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 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. 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 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

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

Sensitivity - 100% | Specificity - 99.74%

QUALITY CONTROL

[Internal Quality Control]

STANDARD Q HBsAg 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.

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 smoke, drink or eat while handling specimen.
4. Do not smoke, drink or eat while handling kit reagents. Wash hands thoroughly afterwards.
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 prevent humidity from affecting products.
11. For *in vitro* diagnostic use only.
12. Do not use the kit contents beyond the expiry date printed on the outside the box.
13. Immediately perform the test after removing the test device from the cassette package.
14. 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, Oon 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 flag; 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 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.

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 | 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

In House Evaluation :

In an In house evalu...

For *in vitro* diagnostic use only

STANDARD Q®

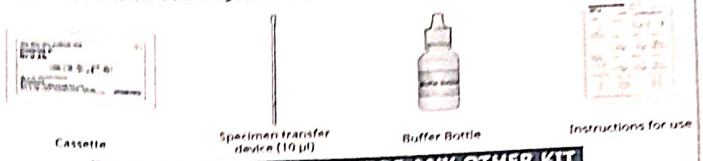
HCV Ab

STANDARD Q HCV Ab Rapid Test

PLEASE READ COMPLETE KIT INSERT CAREFULLY BEFORE YOU PERFORM THE TEST

STANDARD®

[Materials Provided]

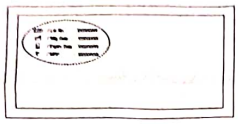


DO NOT USE COMPONENT OF ANY OTHER KIT

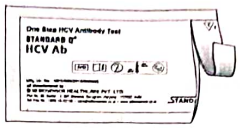
[Preparation]

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

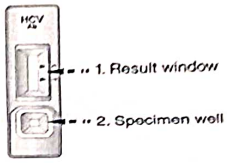
2 Look at the expiry date at the back of the cassette package. Use another lot, if expiry date has passed.



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



<Cassette Packaging>



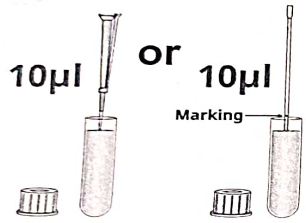
<Cassette>

<Silica gel>

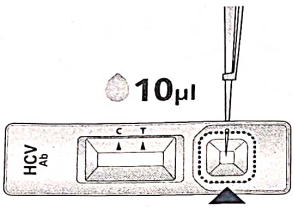
[Test Procedure]

1. For Serum or Plasma specimen

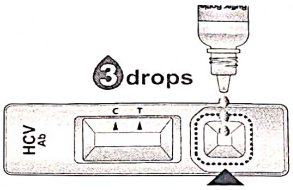
1 Specimen Collection
Using a micropipette or specimen transfer device collect 10µl (till marking) of serum or plasma.



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.



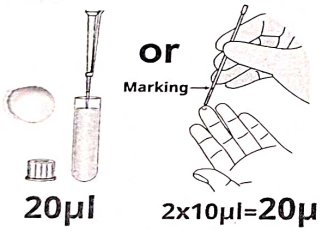
4 Reading Time
Read the test results after 5 minutes.
The test can be read up to 20 minutes.

Read
After 5 mins
Can be read
Up to 20 mins

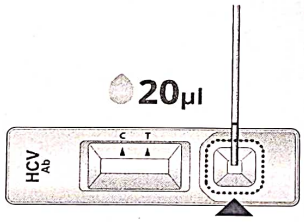
CAUTION Do not read test result after 20 minutes. It may give false results.

2. For Whole Blood specimen

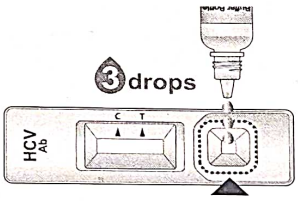
1 Specimen Collection
Collect 20µl of whole blood by using a micropipette or collect two times 10µl of whole blood till the marking of specimen transfer device.



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.

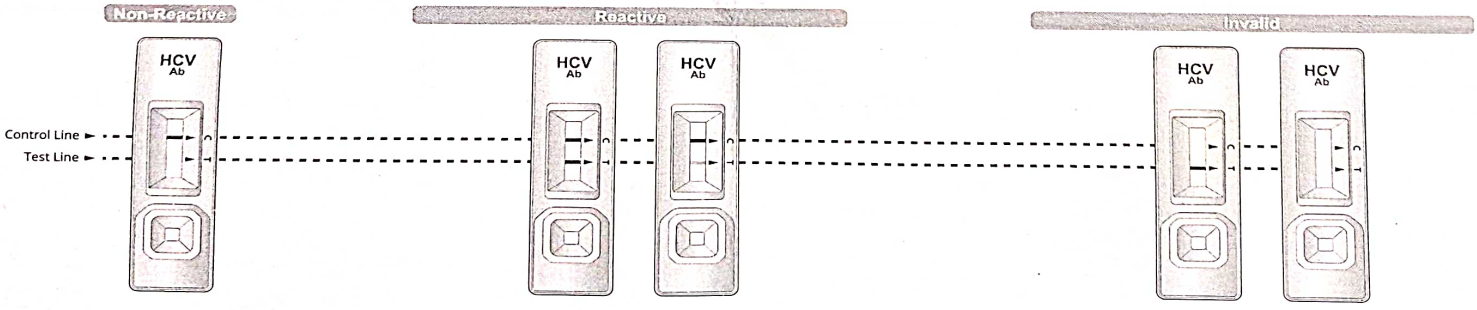


4 Reading Time
Read the test results after 5 minutes.
The test can be read up to 20 minutes.

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 first 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.

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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.

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 or consequential arising out of or related to an incorrect diagnosis, whether reactive or non reactive, in the use of this product.

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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