EN REF QSPH01B

STANDARD Q

Syphilis Ab

STANDARD™ Q Syphilis Ab Test

PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST

SD BIOSENSOR

KIT CONTENTS



Test device
(individually in a foil pouch with desiccant)

Capillary tube
(20µl)



Buffer bottle



Lancet



Alcohol swab



Instructions for use

SPECIMEN COLLECTION AND PREPARATION

■ Serum

1. Collect the whole blood into the commercially available plain tube, NOT containing anti-coagulants such as heparin, EDTA or sodium citrate, by venipuncture and leave to settle for 30 minutes for blood coagulation and then centifuge 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 -40°C/-40°F.
3. They should be brought to room temperature prior to use.
4. Sensitivity can be affected if more than one Freeze-thaw cycle is made.

■ Plasma

1. Collect the venous blood into the commercially available anti-coagulant tube such as heparin, EDTA or sodium citrate by venipuncture and centrifuge blood to get plasma specimen of supernatant.
2. If plasma in an anti-coagulant tube is stored in a refrigerator at 2-8°C/36-46°F, the specimen can be used for testing within 1 week after collection. Using the specimen in the long-term keeping more than 1 week can cause non-specific reaction. For prolonged storage, it should be at below -40°C/-40°F.
3. They should be brought to room temperature prior to use.
4. Sensitivity can be affected if more than one Freeze-thaw cycle is made.

■ Whole blood

[Capillary whole blood]

1. Capillary whole blood should be collected aseptically by fingertip.
2. Clean the area to be lanced with an alcohol swab.
3. Squeeze the end of the fingertip and pierce with a sterile lancet.
4. Collect the capillary whole blood to the black line of the specimen collector for the testing.
5. The capillary whole blood must be tested immediately after collection.

[Venous Whole blood]

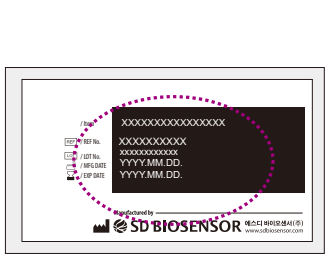
1. Collect the venous whole blood into the commercially available anti-coagulant tube such as heparin, EDTA or sodium citrate by venipuncture.
2. If venous whole blood in an anti-coagulant tube is stored in a refrigerator at 2-8°C/36-46°F, the specimen can be used for testing within 1-2 days after collection.
3. Do not use hemolyzed blood specimens.

⚠
- Anticoagulants such as heparin, EDTA or sodium citrate do not affect the test result.
- As known relevant interference, hemolytic 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.

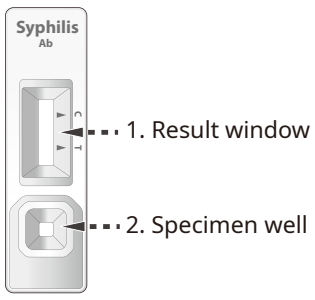
PREPARATION AND TEST PROCEDURE

■ Preparation

1. Carefully read instructions for using the STANDARD Q Syphilis Ab Test.
2. Check the expiry date at the back of the foil pouch. Do not use the kit, if expiry date has passed.
3. Open the foil pouch, and check the test device and the desiccant pack in the foil pouch.



Foil pouch



Test device

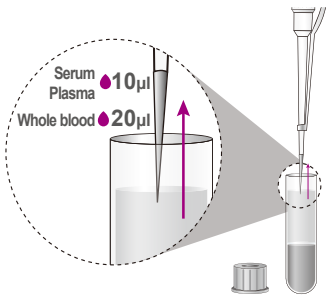


Desiccant

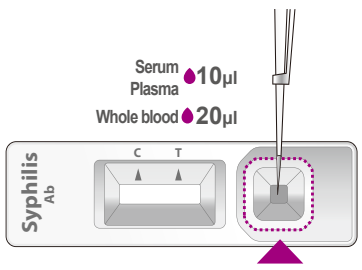
■ Test Procedure

[For serum/plasma/venous whole blood specimen]

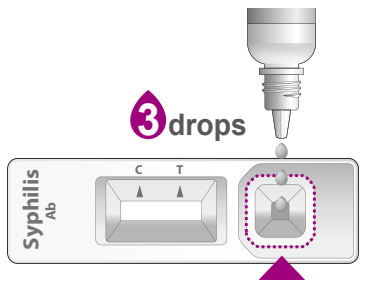
1. Collect the 10µl of serum/plasma or 20µl of venous whole blood specimen using a micropipette.



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



3. Add 3 drops of buffer bottle into the specimen well of the test device.



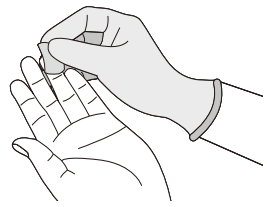
4. Read the test results after 5 minutes. Test can be read up to 20 minutes



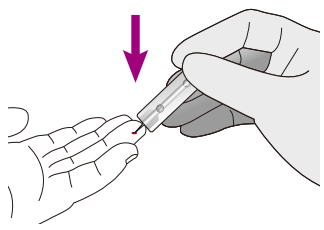
⚠
- Do not read test results after 20 minutes. It may give false results.
- If the T line does not appear until 5 minutes, make sure to observe the appearance of the T line until 20 minutes.

[For capillary whole blood specimen]

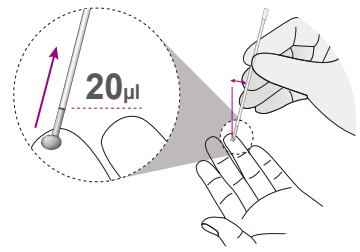
1. Clean a fingertip by wiping with an alcohol swab.



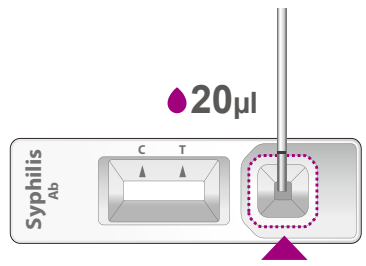
2. Dry and pierce the wiped fingertip with a lancet to bleed.



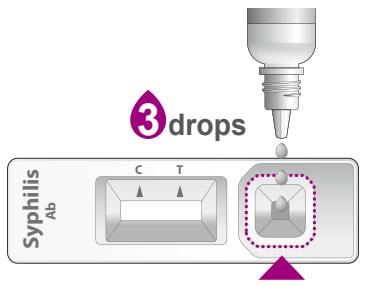
3. Collect the 20µl of capillary whole blood to the black line of the capillary tube (20µl).



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



5. Add 3 drops of buffer bottle into the specimen well of the test device.

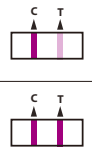
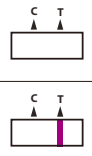


6. Read the test results after 5 minutes. Test can be read up to 20 minutes



⚠
- Do not read test results after 20 minutes. It may give false results.
- If the T line does not appear until 5 minutes, make sure to observe the appearance of the T line until 20 minutes.

INTERPRETATION OF RESULT

Test result	Example	Description
Negative		Only band (“C” Control line) within the result window indicates a negative result.
Positive		Two colored bands (“C” Control line and “T” Test line) within the result window indicate anti-syphilis positive.
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 or the test may have deteriorated. Re-test with a new test device.

⚠
- Positive results should be considered in conjunction with the clinical history and other data available.
- The presence of any line no matter how faint it is, should be considered as a line formed.
- This test is for screening purposes. Confirmatory testing according to national guidelines is recommended to confirm the infection status.

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EXPLANATION AND SUMMARY

■ Introduction

Syphilis is a sexually transmitted infection (STI) caused by a type of bacteria known as *Treponema pallidum* (TP). It is transmissible by sexual contact with infectious lesions, from mother to fetus in utero, via blood product transfusion, and occasionally through breaks in the skin that come into contact with infectious lesions. To diagnose the syphilis, the recombinant TP membrane protein is usually used for the detection of syphilis antibodies in human blood. The TP membrane protein has the strong immunity to the syphilis antibodies, especially 4 major antigens of TP membrane of which sizes are MW 47, 42, 17, and 15kDa are reported to generate the definite immunoreaction. STANDARD Q Syphilis Ab Test provides significantly fast, easy and accurate system to identify the target antibody from human blood specimen by recombinant syphilis p17.

■ Intended use

STANDARD Q Syphilis Ab Test is a rapid chromatographic immunoassay for the qualitative detection of anti-syphilis from human serum, plasma or whole blood. This test is for professional *in vitro* diagnostic use and intended as an aid to early diagnosis of syphilis infection. Positive results should be considered in conjunction with the clinical history and other data available.

■ Test principle

STANDARD Q Syphilis Ab Test contains a membrane, which is pre-coated with recombinant syphilis p17 on test region. The recombinant syphilis p17-gold, patient specimen and buffer moves along the membrane chromatographically to the test line and control line. The anti-syphilis in patient specimen combined with the recombinant syphilis p17-gold is captured by the recombinant syphilis p17 coated on test region and forms a visible line as the antigen-antibody-antigen gold particle complex forms. When the syphilis antibodies are absent in the specimen, no visible colored band in the test region. Simultaneously, recombinant syphilis p17-gold also binds to the anti-syphilis p17 on control region directly and the control line should always appear if the test procedure is performed properly.

KIT STORAGE AND STABILITY

Store the kit at room temperature, 2-40°C / 36-104°F, out of direct sunlight. Kit materials are stable until the expiration date printed on the outer box. Do not freeze the kit.

WARNINGS AND PRECAUTIONS

1. Do not re-use the test kit.
2. Do not use the test kit if the pouch is damaged or the seal is broken.
3. Do not use the 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 when 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 of all specimens and materials used to perform the test as bio-hazard waste. Laboratory chemical and bio-hazard wastes must be handled and discarded in accordance with all local, state, and national regulations.
10. Desiccant in foil pouch is to absorb moisture and keep humidity from affecting products. If the moisture indicating Desiccant beads change from yellow to green, the test device in the pouch should be discarded.

PERFORMANCE CHARACTERISTICS

■ Clinical Evaluation

The sensitivity of STANDARD Q Syphilis Ab Test Total 56 specimens were evaluated for sensitivity. The STANDARD Q Syphilis Ab Test Kit got a high correlation with TPHA test.

Reference		STANDARD Q Syphilis Ab		Total Result
		Positive	Negative	
TPHA	Positive	56	0	56
	Negative	0	0	0
Total Result		56	0	56
Sensitivity		56/56 (100.0%)		

The specificity of STANDARD Q Syphilis Ab Test Total 447 specimens were evaluated for specificity. The STANDARD Q Syphilis Ab Test Kit got a high correlation with TPHA test.

Reference		STANDARD Q Syphilis Ab		Total Result
		Positive	Negative	
TPHA	Positive	0	0	0
	Negative	4	443	447
Total Result		4	443	447
Specificity		443/447 (99.1%)		

LIMITATION OF TEST

1. The test should be used for the detection of anti-syphilis in human serum, plasma or whole blood specimens.
2. Neither the quantitative value nor the rate of anti-syphilis 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 negative 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.

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4. Alexander, JM; Sheffield, JS; Sanchez, PJ; Mayfield, J; Wendel GD, Jr (January 1999). "Efficacy of treatment for syphilis in pregnancy.". Obstetrics and gynecology 93 (1): 5-8.
5. A Gerber et al., Recombinant Treponema pallidum antigens in syphilis serology. Immunobiology. 196(5):535-49, 1996-1997.

CE IVD

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