ACCUCARE®

ONE STEP SYPHILIS RAPID TEST
(Whole Blood/Serum/Plasma)

One step rapid Card Test for detection of Syphilis antibody in human Whole Blood/Serum/Plasma

For *In-Vitro Diagnostic* Use only

ORDER INFORMATION

Pack Size	REF
10 Tests	SYPC 10
25 Tests	SYPC 25
50 Tests	SYPC 50

CLINICAL SIGNIFICANCE

Syphilis is sexually transmitted (venereal) disease caused by the spirochete Treponema pallidum. The disease can also be transmitted congenitally thereby attaining its importance in antental screening. After injection the host forms non-treponemal anti lipoidal antibodies (regains) to the lipoidal material released from the damaged host cells as well as treponema specific antibodies. Serological tests for non-treponemal antibodies such as VDRL, RPR, and TRUST etc. are useful as screening tests. Test for treponema specific antibodies such as TPHA, FTA-ABS, rapid treponema antibody tests are gaining importance as screening as well as confirmatory tests because they detect the presence of antibodies specific to Treponema pallidum.

ACCUCARE® ONE STEP SYPHILIS TEST is a modified TPHA, which qualitatively detects the presence of IgM and IgG class of treponema specific antibodies of syphilis in Whole blood/Serum/Plasma specimens within 15 minutes.

PRINCIPLE

ACCUCARE® ONE STEP SYPHILIS RAPID TEST utilizes the principle of immunochromatography, a unique two-site immunoassay on a membrane. As the test conjugate forms through the membrane assembly of the test card, the recombinant Treponema antigen-colloidal gold conjugate forms a complex with Treponema specific antibodies in the sample. This complex moves further on the membrane leading to the formation of a pink to deep purple colored band at the test region which confirms a positive test result. Absence of this colored band in test region indicates a negative test result. The unreacted conjugate and the unbound complex if any along with rabbit IgG gold conjugate move further on the membrane and are subsequently immobilized by the goat anti-rabbit antibodies coated at the control region of the membrane assembly, forming a pink to deep purple coloured band. The control band serves to validate the test results.

CONTENTS

Test Device
Assay Buffer
Instruction for Use (IFU)
Disposable (Dropper) 25 µl sampling device
Desiccant

STORAGE & STABILITY

1. The kit can be stored at room temperature or refrigerated (2-30°C). The test device/strip must remain in the sealed aluminum pouch until use. DO NOT FREEZE.
2. Do not use beyond the expiration date.
3. Do not use the test device/strip, if the pouch is damaged or seal is broken.

PRECAUTIONS

1. For professional *In-vitro* diagnostic use only. Do not use after expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Handle all the specimens as potentially infectious. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens and tested device/strip.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
5. Read the Instruction for use carefully before performing the test.

LIMITATIONS

1. ACCUCARE® ONE STEP SYPHILIS RAPID TEST detects the presence of Treponemal antibodies; thus a positive result indicates a past or present infection. Positive results should be evaluated in co-relation with the clinical condition before arriving at a final diagnosis.
2. Low levels of antibodies to Treponema pallidum such as those present at a very early primary stage of infection can give a negative result. But a negative result does not exclude the possibility of exposure to or infection can give a negative result. But a negative result does not exclude the possibility of exposure to or infection with Treponema pallidum. Resting is indicated after two weeks if clinically syphilis is still suspected.
3. In order to assess the clinical response to treatment it is advisable to use a reagin test such as VDRL, RPR.
4. ACCUCARE® ONE STEP SYPHILIS RAPID TEST detects Treponemal antibodies in serum/plasma; other body fluid may not give accurate results.
5. In immunocompromised patients the test results must be interpreted with caution.

SPECIMEN COLLECTION & PREPARATION

1. The ACCUCARE® ONE STEP SYPHILIS RAPID TEST can be performed using either Whole Blood or serum or plasma.
2. Collect Whole Blood into an appropriate blood collection tube with or without anticoagulant (EDTA, citrate or heparin). If you want use serum or plasma than separate the serum or plasma from whole blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens must be used.
3. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens 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.
4. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
5. If specimens are to be shipped, it should be packed in compliance with federal regulations for transportation of etiologic agents.

ISO 13485:2016

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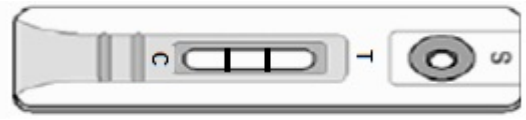
PROCEDURE

1. Allow test device, Assay Buffer and specimen equilibrates to room temperature (15-30°C) prior to testing.
2. Remove the test device from the aluminum foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
3. Place the test device on a clean and flat surface. Carefully dispense 1 drop (25 µl) of Whole Blood/Serum/Plasma in the sample well "S" using the dropper provided.
4. After that add 1 drop (appx. 40 µl) of Assay Buffer in the Sample well "S".
5. Allow reaction to occur and read the results at 15 minutes. Do not interpret the results after 20 minutes.

INTERPRETATION OF RESULTS

1. POSITIVE



If two color bands appear, one at control line 'C' and other at test line 'T', the specimen is positive for Syphilis Antibody.

2. NEGATIVE

If only one color band appear at control line 'C' as the specimen is Negative for Syphilis Antibody.

3. INVALID

If no color band appear, at control line 'C' within the stipulated time then result is invalid. Repeat the test using a fresh Test Device/Strip.

NOTE: The intensity of the color band in the test line region will vary depending on the concentration of Syphilis Antibody present in the specimen. However, neither the quantitative value nor the rate of increase in Syphilis Antibody can be determined by this qualitative test.

INTERFERING SUBSTANCES

No interference (except HIV positive specimen) in the ACCUCARE® ONE STEP SYPHILIS RAPID TEST was evident when the following substances were tested:

Sample Type	Number of Samples Tested	Positive	Negative
Clinical Specimens	100	02	98
Pregnant women	100	01	99
Other disease Samples*	100	03	97

*Other disease Samples: These are the samples that potentially interfere with HBsAg immunoassays. Details of the samples are as follow:

Sample Type	No. of Sample Tested
HCV Positive	20
HIV Positive	20
HBsAg Positive	15
Anti-HAV Positive	15
Rubella Positive	15
Anti-HTLV Positive	15
Total	**100**

PERFORMANCE CHARACTERISTICS

The ACCUCARE® ONE STEP SYPHILIS RAPID TEST has been evaluated with positive and negative samples confirmed by ELISA examination.

Specimen	Positive	Negative	Sensitivity
Positive	240	00	100 %

Specimen	Positive	Negative	Specificity
Negative	05	295	98.3 %

BIBLIOGRAPHY

1. Syphilis: New Diagnostic Direction, H. Young, international Journal of STD and AIDS, 1992, 3: 391-413.
2. Clinical Laboratory Diagnostics: Use and Assessment of Clinical Laboratory Results, Lothar Thomas, 1st Edition, 1998, TH Books.
3. AABB Technical Manual, 13th Edition, 1999.
4. Clinical Diagnosis and Diagnosis and Management by laboratory methods, John Bernard Henry, 17th Edition, 1979, W.B. Saunders Company.

GLOSSARY OF SYMBOL

	Consult Instruction for Use	LOT	Lot Number
REF	Catalog Number		Date of Manufacturing
	Store between		Use By or Expiration Date
	Manufacturer		Do not reuse
IVD	For *in vitro* Diagnostic use only		Keep Dry
Σ	Tests per Kit		Do Not Use if Damaged

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