Ana-Chek® SYPHILIS ANTIBODY CARD

METHOD – LATERAL FLOW IMMUNOASSAY
PRODUCT CODE – RC03

ANAMOL
THE ORIGINAL MAKERS

INSTRUCTIONS FOR USE

INTENDED USE: Test for detection of Syphilis antibody in Serum or Plasma.

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. is 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.

PRINCIPLE

Ana-Chek® Syphilis Antibody Card 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.

KIT COMPONENTS

Test Device, Assay Buffer, Sample Dropper and Instructions for use.

PRECAUTIONS

1. Wear protective gloves while handling specimens wash thoroughly afterwards.
2. The device is sensitive to humidity as well as heat. Therefore, take out the device from sealed pouch just before test.
3. Do not mix reagents from different lot.
4. Dispose all the samples and kits properly as per the instruction after test in accordance to GLP.
5. Follow the testing procedure exactly as mentioned in the insert.

STORAGE & STABILITY

The kit can be stored at room temperature or refrigerated (2-30 °C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Fresh Serum or Plasma: If testing is not performed within 3 days of collection of specimens, the specimen should be refrigerated immediately at 2-8 °C.

TEST PROCEDURE

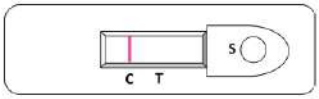
Allow test cassette, specimen, and/or controls to equilibrate to room temperature (15-30 °C) prior to testing

1. Place the test device on a clean and level surface. Add 1 drop (25 µl) of serum in sample well "S".
2. Add 1 drops of assay buffer in sample well "S".
3. Allow reaction to occur in next 15-20 minutes.
4. The test should be read between 15-20 minutes after addition of serum sample and buffer.

INTERPRETATION OF THE RESULTS

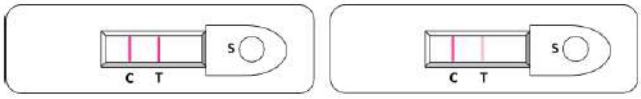
NEGATIVE RESULT:

Only one pink-purple coloured line appears at the control zone 'C' (Control line) the test result is negative



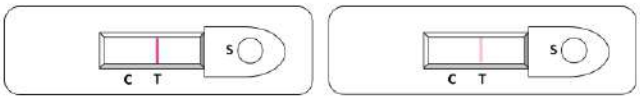
POSITIVE RESULT:

In addition to the coloured line in the control region a clearly distinguishable pink purple coloured line also appears in the test region 'T' (Test line) indicating a positive result.



INVALID TEST:

If no line appears in the control as well as the test region, the test should be repeated with fresh card.



LIMITATION OF PROCEDURE

1. Ana-Chek® Syphilis Antibody Card 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 infection can give a negative result. 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 regin test such as VDRL, RPR.
4. Ana-Chek® Syphilis Antibody Card 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.

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.

Symbol	Explanation	Symbol	Explanation
	Manufactured By		In Vitro Diagnostic Use
	Lot Number		Read Instructions Before Use
	Catalogue Number		Storage Temperature
	Manufacturing Date		Number of Tests / Volume
	Expiry Date		Do Not Reuse
	Protect from Sunlight		Keep Dry

ANAMOL LABORATORIES PVT. LTD.
61, Genesis Industrial Township, Kolgaon,
Palghar – 401 404. India.
Customer Care & WhatsApp: +91-9823388695.

admin@anamollabs.com
exports@anamollabs.com
www.anamollabs.com

ISO 9001: 2015
ISO 13485: 2016
GMP
CE

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