RAPID SYPHILIS

Test Device for Detection of Syphilis Antibody in Human Serum / Plasma

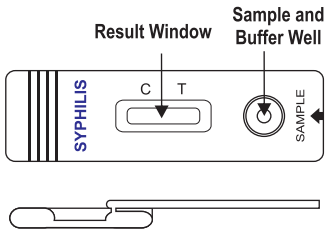
BIO LAB DIAGNOSTICS
ISO 9001:2015
ISO 13485:2016
CE

INTENDED USE

Rapid SyphilisTest is a lateral flow chromatographic immunoassay for the qualitative detection of antibodies including IgG, IgM, and IgA to *Treponema pallidum* (*Tp*) in human serum or plasma. It is intended to be used as a screening test and as an aid in the diagnosis of infection with *Tp*. Any reactive specimen with Syphilis Ab Rapid Test must be confirmed with alternative testing method(s) and clinical findings.

SUMMARY AND PRINCIPLE

Rapid SyphilisTest is a lateral flow chromatographic immunoassay. The test membrane consists of: 1) a burgundy colored conjugate pad containing recombinant *Tp* antigens conjugated with colloid gold (*Tp* conjugates) and rabbit IgG-gold conjugates, 2) a nitrocellulose membrane containing a test band (T band) and a control band (C band). The T band is pre-coated with non-conjugated recombinant *Tp* antigens, and the C band is pre-coated with goat anti-rabbit IgG antibody.



When an adequate volume of test specimen is dispensed into the sample wells of the device, the specimen migrates by capillary action across the device. *Tp* antibody, if present in the specimen will bind to the *Tp* conjugates. The immunocomplex is then captured on the membrane by the pre-coated *Tp* antigen, forming a burgundy colored band on test zone (T band), indicating a *Tp* antibody positive test result. Absence of the band on test zone suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti-rabbit IgG/rabbit IgG-gold conjugate regardless of color development on the band on test zone. Otherwise, the test result is invalid and the specimen must be retested with another device.

PRECAUTIONS

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use the components in any other type of test kit as a substitute for the components in this kit.
4. Do not use hemolized blood specimen for testing.
5. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
6. Dispose of all specimens and materials used to perform the test as biohazardous waste.
7. Handle the Negative and Positive Control in the same manner as patient specimens.
8. The testing results should be read within 10 minutes after a specimen is applied to the sample well of the device. Reading result after 20 minutes may give erroneous results.
9. Do not perform the test in a room with strong air flow, ie. an electric fan or strong airconditioning.

STORAGE AND STABILITY

The kit can be stored between 2-30°C. Shorter exposure to 40°C does not make any change in test result. DO NOT FREEZE. The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. Do not use beyond the expiration date.

MATERIAL

Materials Provided

1. Test device.
2. Desiccant
3. Sample Dispensing Device
4. Procedure Manual.

SAMPLE

Specimen can be serum, plasma or body fluids which has no sign of hemolysis. Store specimens at 2-8°C if not tested immediately. Specimens should be frozen at -20° for longer storage. Avoid multiple freeze-thaw cycles. (All samples should be handled as potential infective agents as no laboratory methods make conclusive finding for its safety. Therefore, adequate protective laboratory measures should be taken while handling such materials).

PROCEDURE

Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Mix the specimen well prior to assay.

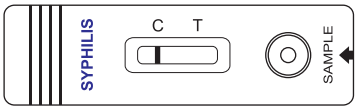
Step 2: When ready to test, open the pouch at the notch and remove the test device.

Step 3: Dispense at least 100-150 µL or 3-4 drops of serum or plasma in to sample well.

Step 4: Observe the result within 10 minutes and interpret as per result interpretation column. Do not interpret the results after 20 minutes. The lower the antibody concentration, the weaker the test band may be.

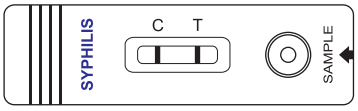
RESULT INTERPRETATIONS

1. **NEGATIVE RESULT**:



If only a band on position "C" is developed, the test indicates that no detectable *Tp* antibody is present in the specimen. The result is negative.

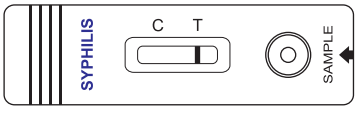
2. **POSITIVE RESULT**:



If bands are developed on positions "T" and "C" indicate presence of *Tp* antibody in the specimen. The result is positive.

Samples with positive results should be confirmed with alternative testing method(s) and correlate with clinical findings before a positive determination is made.

3. **INVALID:**



If no band is developed on position "C", the test is invalid regardless of the color development on the position "T" as indicated below. Repeat the assay with a new device.

SENSITIVITY AND SPECIFICITY

in an inhouse study using 245 negative samples 13 positive samples tested with contemporary hemagglutination and VDRL Test, it has been shown as under.

Description	Hemagglutination	VDRL	Rapid Syphilis
Negative	245	245	245
Positive	13	13	13
Total	258	258	258

% of Sensitivity = 100

% of Specificity = 100

LIMITATIONS

1. For professional *invitro* diagnostic use only.
2. Humidity and temperature can adversely affect results. Similarly avoid excessive air flow or strong air-conditioning while performing the test.
3. The Assay Procedure and the Assay Result Interpretation must be followed closely when testing the presence of *Tp* antibody in serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
4. Rapid Syphilis Test is limited to the qualitative detection of *Tp* antibody in human serum or plasma. The intensity of the test band does not indicate linear correlate with the antibody titer in the specimen.
5. A negative result for an individual subject indicates absence of detectable *Tp* antibody. However, a negative test result does not preclude the possibility of exposure to or infection with *Tp*.
6. A negative result can occur if the quantity of the *Tp* antibody present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
7. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
8. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

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