RapidTech Syphilis Ab test strips

INTENDED USE

The RapidTech Syphilis Ab test is intended for the qualitative detection of antibodies against Treponema pallidum in human serum as an aid in the diagnosis of syphilis.

INTRODUCTION

Syphilis is a sexually transmitted disease caused by the spirochete *Treponema pallidum* (TP). As this organism cannot be cultured on artificial media, the diagnosis of syphilis depends on the correlation of clinical data with the specific antibody demonstrated by serological tests. Serological screening tests for syphilis utilizing cardiolipin and lecithin as antigens are simple to perform but biological false positive (BFP) reactions occur frequently because the tests use non-treponemal antigens.

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 TPI and FTA-Abs tests utilize pathogenic TP as the antigen but these tests present some difficulties for routine serodiagnosis. The TPI test requires living pathogenic microorganisms and the FTA-ABS test requires a fluorescence microscope. Both tests require a high level of expertise.

PRINCIPLE

The method employs a unique combination of anti-human immunoglobulins dye conjugate and highly purified TP recombinant protein to specifically detect anti TP antibodies. The test mainly detects IgG and IgA, but IgM also react if present at high concentrations.

As the samples flow through the absorbent device, the anti human immunoglobulins dye conjugate binds to the human IgG antibodies forming an antibody-antigen complex. This complex binds to the recombinant protein in the positive reaction at the Test region and produces a purple-pink colour band. In the absence of TP antibodies, there is no line in the positive reaction. The reaction mixture continues flowing through the absorbent device past the reaction area and Control region. Unbound conjugate binds to the reagents in the Control region, producing a purple-pink colour band, demonstrating that the reagents are functioning correctly.

PRECAUTIONS

1. For in vitro diagnostic use.
2. Handle all specimens as if they contain infectious agents. When the assay procedure is completed, dispose of specimens carefully after autoclaving them for at least one hour. Alternatively, they can be treated with 0.5 to 1% solution of sodium hypochlorite for one hour before disposal.
3. Wear protective clothing such as laboratory coats and disposable gloves while assaying samples.
4. Do not eat, drink or smoke in the area where specimens and kit reagents are handled.
5. Avoid any contact between hands and eyes or nose during specimens collection and testing.

REAGENT AND MATERIALS SUPPLIED

1. RapidTech Syphilis Ab Test strips

STORAGE AND STABILITY

All test strips should be stored at room temperature (2º to 30ºC). Do not freeze the test kit.

SPECIMEN COLLECTION

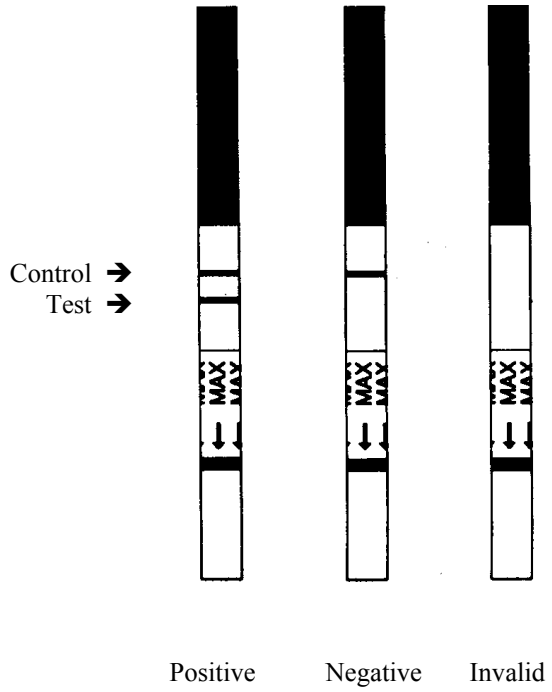
This test can be performed on human serum. Patient samples are best performed if tested immediately. Specimens containing precipitate may give inconsistent test results. Such specimens should be prior to assaying.

TEST PROCEDURE

Test strips, patient samples, controls or reference materials should be brought to room temperature (18º to 25ºC) prior to testing.

1. Tear open pouch, remove strip from package. Label the strip with patient or control identification.
2. Immerse the strip into the serum with the arrow end pointing towards the serum container. Do not immerse pass the MAX (maximum) line. You may leave the strip in the specimen or you may take the strip out after a minimum of 10 seconds and lay the strip flat on a clean, dry, non-absorbent surface.
3. Wait for coloured bands to appear. Read results in 15 minutes. Do not interpret results after 30 minutes.

INTERPRETATION OF RESULTS



NEGATIVE: Only one red coloured band appears on the control line (C) region. No apparent red coloured band on the test line (T) region.

POSITIVE: In addition to the control band (C), a distinct red coloured band also appears on the test line (T) region.

INVALID: When no coloured bands appear on the control region (C), the test should be voided since an improper test or deterioration of reagents probably occurred.

PERFORMANCE CHARACTERISTICS

A panel of 12 assayed samples has been tested with the RapidTech test. The results are summarized in the following table and show a very good correlation with ELISA or *Treponema pallidium* based assays.

50 negative samples were also tested and confirmed negative with the RapidTech Syphilis Test.

EIA Cambridge	VDRL Behring	FTA-Abs Biolab	RapidTech One Step
Pos	Neg	Pos	Pos
Pos	Neg	Pos	Pos
Pos	1/4	Pos	Pos
Pos	1/4	Pos	Pos
Pos	1/4	Pos	Pos
Pos	1/64	Pos	Pos
Pos	1/4	Pos	Pos
Pos	1/16	Pos	Pos
Pos	Neg	Pos	Pos
Pos	+1/1	Neg	Neg
Pos	Neg	Pos	Pos
Pos	1/1	Pos	Pos

LIMITATIONS OF THE TEST

1. The RapidTech Syphilis Ab Test strip is for the detection of *TP* antibodies in serum or plasma specimen. This test is for *in vitro* diagnostic use only. Neither the quantitative value nor the rate of increase in *TP* antibodies can be determined by this qualitative test.
2. This test 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. 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.
4. As it true with any diagnostic procedure, the physician should evaluate data obtained by the use of the test in light of other clinical information.

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Genix Technology
Vancouver, Canada.

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