



For the rapid detection of *Treponema pallidum* infection in serum, plasma or whole blood samples.

Not for sale in USA

INTENDED USE

The American Bionostica Rapid Syphilis Test is an in vitro, qualitative immunochromatographic assay for the detection of *Treponema pallidum* infection in human serum. The test is intended for use as a screening test. The diagnosis of syphilis should not be made on a single reactive result without the support of a positive history or clinical evidence.

(Validation with serum specimens completed, whole blood studies not yet completed)

PRINCIPLE

The American Bionostica Rapid Syphilis Test utilizes an indirect solid-phase antigen immunoassay technology for the qualitative detection of *T. pallidum* antibodies in human serum. In the test procedure, 5 ul of serum, plasma, or whole blood is added to port A in the test cassette. Then the Syphilis Test Buffer Solution is added to port B. As the test serum antibody and gold-conjugate, followed by the Syphilis Test Buffer Solution move by capillary action along the membrane strip, the test line will appear when the gold-conjugate-bound-*Treponema* specific antibodies in the serum are captured by the solid phase antigen on the Test line. The Control line will produce a colored band regardless of the presence of *T. pallidum* antibodies in the sample. Therefore, the presence of two colored bands, one at the test line and the other at the control line, indicates a positive result, while the absence of a colored band in the test area indicates a negative result.

MATERIALS REQUIRED BUT NOT SUPPLIED

1. Timer, sample container and gloves, pipette or other device for delivering specimen to strip
2. No other equipment or reagents are needed.

WARNINGS AND PRECAUTIONS

1. This test is for in-vitro diagnostic use by professionals only.
2. Do not pipette any material by mouth. Do not smoke, eat or drink in areas where specimens or kits are handled.
3. Individuals performing the test should wear protective clothing such as laboratory coats and disposable gloves while collecting and testing samples and thoroughly wash hand afterwards.
4. All spills should be wiped up thoroughly with a suitable disinfectant.
5. Treat all materials in the test as if they were infectious. Dispose of all specimens and used assay materials as if they contained infectious agents. Preferred methods are autoclaving for 60 minutes at 121o or incineration.
6. Avoid any contact of hands with eyes and nose during specimen collection and testing.
7. Prior to use, ensure that the product has not expired by verifying that the date of use is prior to the expiration date on the foil pouch.
8. The foil pouch containing the test strip must remain completely sealed before use. Do not use if the foil pouch seal is not intact.
9. Follow proper handling and disposal procedures because blood specimens are potentially infectious.
10. Avoid cross-contamination of specimens by using a new pipette or dropper for each specimen.

STABILITY AND STORAGE

The American Bionostica Rapid Syphilis Test should be stored at 4-25°C in the sealed pouch or desiccant vial. The test kit is stable until the expiration date stamped on the pouch when stored under these conditions. Do not use the test if the pouch is damaged or the seal is broken. Keep the test in the sealed pouch until ready for use.

The American Bionostica Rapid Syphilis Test should be stored at room temperature (15°C to 30°C) or refrigerated (2°C to 8°C). The Syphilis Test Strip, Syphilis Test Buffer and specimens must be warmed to room temperature before use.

SPECIMEN COLLECTION AND HANDLING

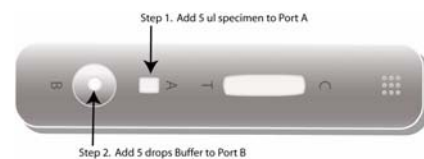
1. Test strips, buffer solution and specimens should be at room temperature before using.

2. Handle and dispose of specimens as if they were infectious and capable of transmitting infection. Avoid contact, inhalation or ingestion.

ASSAY PROCEDURE

1. Using the included disposable 5 ul pipette, add approximately 5 ul serum to the sample port (See step 1.) on the test cassette. With moderate finger pressure squeeze the pipette near the mid section. Insert the open end of the pipette in to the specimen and draw up the specimen to the calibrated line by releasing pressure. Touch the lower (open) end of the pipette to the upper area of the test cassette sample pad and transfer the specimen to the test cassette sample pad by applying pinch pressure to the middle section of the pipette.
2. Add 110 ul (4-5 drops) of the Syphilis Test Buffer to the Buffer Port (See step 2) of the cassette. Read the test result after 15 minutes and not longer than 20 minutes. If solution does not flow up the membrane, add 1 or 2 more drops of Buffer Solution.

INTERPRETATION OF RESULTS



1. Positive Result

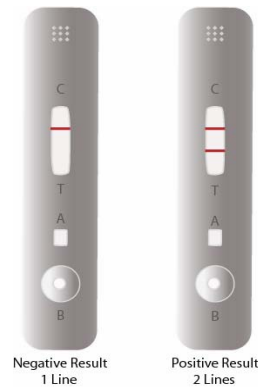
Two colored lines appear in the result window - one in the Control Line area and one in the Test Line area. This indicates the presence of antibodies to *Treponema pallidum* in the specimen. The test result can be read as soon as a distinctive pink-purple line appears in the Test Line area. In most strong positive cases, the Test Line appears before the Control Line. The Test line may appear after the Control Line in some weak positive cases, and the Control Line may become darker than the Test Line.

2. Negative Result

Only one colored line appears in the results window, in the Control Line area, with no distinctive colored line in the Test Line area. This indicates that no active *M. tuberculosis* infection was detected.

3. Invalid Result

A distinct colored line should always appear in the Control Line area. The test is invalid if no Control Line appears.



KIT PERFORMANCE

The American Bionostica Rapid Syphilis Test was performed on clinical serum specimens previously tested by the RPR (Rapid Plasma Reagin) method.

Test Status	Negative Specimens	Positive Specimens
Clinical Results (RPR method))	10	20
ABI Syphilis Test Results	10	19
Sensitivity		95%
Specificity	100%	