

1. INTENDED USE

The Biokits Syphilis Ab Rapid Test is an in-vitro diagnostic, immunochromatographic assay for the qualitative detection of antibodies to *Treponema pallidum* in human serum, or plasma. This test is intended for professional use only.

2. INTRODUCTION

Syphilis is a sexually transmitted infection caused by *Treponema pallidum* and can progress through primary, secondary, latent, and tertiary stages if left untreated. Early detection and treatment are critical to prevent long-term complications and transmission. Detection of antibodies to *T. pallidum* is widely used for screening and diagnosis of syphilis infection. The Biokits Syphilis Ab Rapid Test provides a rapid qualitative result to assist in the screening of syphilis infection.

3. PRINCIPLE OF THE TEST

The Biokits Syphilis Ab Rapid Test is a lateral-flow immunochromatographic assay with a two-line detection system consisting of a test line (T) and a control line (C). Antibodies to *Treponema pallidum* present in the specimen bind to colloidal gold-conjugated recombinant *T. pallidum* antigens and migrate along the nitrocellulose membrane by capillary action. The immune complexes are captured by immobilized *T. pallidum* antigens at the test line region, producing a visible colored line when syphilis antibodies are present. The control line is coated with polyclonal antibodies and reacts with a colored control conjugate, producing a visible line independent of the presence of syphilis antibodies, thereby confirming proper sample flow, reagent integrity, and test validity.

4. KIT COMPONENTS

Each kit contains:

1. Individually pouched Syphilis Ab Test Devices with desiccant
2. Assay Diluent / Buffer vial(s)
3. Sample Dropper
4. Instructions for Use (IFU)

5. KIT STORAGE AND STABILITY

1. Store at 2–30°C. Do not freeze.
2. Protect from direct sunlight and humidity.
3. Use the device immediately after opening the foil pouch.
4. Do not use if the pouch is damaged or the seal is broken.
5. Do not mix components from different lots.
6. Use before the expiry date printed on the packaging.

6. PRECAUTIONS

1. For In-Vitro Diagnostic Use Only.
2. Do not reuse the test device.
3. Avoid testing hemolytic, lipemic, or icteric specimens.
4. Use separate droppers or pipette tips for each specimen to prevent cross-contamination.
5. Wear gloves and adhere to standard laboratory biosafety practices.
6. Do not eat, drink, or smoke in the testing area.
7. Dispose of all used materials as per biomedical waste regulations.
8. Ensure all reagents and specimens are at room temperature before testing.

7. LIMITATIONS

1. This test is qualitative and does not determine antibody concentration.
2. A negative result does not exclude syphilis infection, particularly in early stages of infection.
3. Positive results may persist after successful treatment and should be interpreted with clinical findings and patient history.
4. Clinical decisions should not be based solely on this test; additional laboratory tests may be required.
5. The test is validated only for human whole blood, serum, or plasma.

8. SAFETY INFORMATION

1. Handle all specimens as potentially infectious.
2. Use appropriate PPE such as gloves, lab coat, and eye protection.
3. Clean spills thoroughly with suitable disinfectants.
4. Dispose of used test components according to biomedical waste disposal guidelines.
5. Do not pipette by mouth.

9. REFERENCES

1. World Health Organization. *WHO guidelines for the treatment of Treponema pallidum (syphilis)*. WHO Press, Geneva.

SPECIMEN COLLECTION AND STORAGE

Category	Details
Accepted Specimens	<ul style="list-style-type: none"> ✓ Serum ✓ Plasma (EDTA, citrate, heparin)
Collection	<ul style="list-style-type: none"> ✓ Collect blood into a tube without anticoagulant. Allow the blood to clot completely, then centrifuge to separate the serum. ✓ Collect blood into an anticoagulant tube (EDTA, citrate, or heparin) and centrifuge to obtain plasma.
Storage	<ul style="list-style-type: none"> ✓ Test as early as possible ✓ Store at 2–8°C for up to 3 days ✓ For longer storage, freeze serum/plasma at –20°C Avoid freeze–thaw cycles

TEST PROCEDURE



Add 2 Drops (50 ul) of Serum/Plasma into the Sample Well "S"

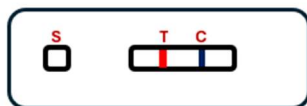
Read Results at 5-20 Minutes

Note: Do not read results after 20 min- it may give incorrect results !

RESULT INTERPRETATION



Syphilis Negative



Reactive for Syphilis Antibodies



Invalid Test Pattern

PERFORMANCE CHARACTERISTICS

- ✓ Clinical Sensitivity: 100%
- ✓ Clinical Specificity: 99.7%