

**REFERENCES**

1. Ebel A; Bachelart L; Alonso JM. Evaluation of a new competitive immunoassay (BioElisa *Syphilis*) for screening for *Treponema pallidum* antibodies at various stages of *syphilis*. J Clin Microbiol, 1998; 36(2):358-61.
2. Young H; Moyes A; Seagar L; McMillan A. Novel recombinant-antigen enzyme immunoassay for serological diagnosis of *syphilis*. J Clin Microbiol 1998; 36(4):913-7.
3. Young H. *Syphilis*. Serology. Dermatol Clin 1998; 16(4):691-8.
4. Zrein M, Maure I, Boursier F, Soufflet L. Recombinant antigen-based enzyme immunoassay for screening of *Treponema pallidum* antibodies in blood bank routine. J Clin Microbiol 1995;33:525-7.
5. Silletti RP. Comparison of CAPTIA syphilis G enzyme immunoassay with rapid plasma reagin test for detection of syphilis. J Clin Microbiol 1995;33:1829-31.
6. Stienstra S, Peeters T, van der Straaten AM, Kadir N. *Treponema pallidum* membrane protein A ELISA: a new test for screening and diagnosis of syphilis. Beitr Infusionsther 1992;30:85-91.
7. Byrne RE, Laska S, Bell M, Larson D, Phillips J, Todd J. Evaluation of a *Treponema pallidum* Western immunoblot assay as a confirmatory test for syphilis. J Clin Microbiol 1992;30:115-22.
8. Bromberg K, Rawstron S, Tannis G. Diagnosis of congenital syphilis by combining *Treponema pallidum*-specific IgM detection with immunofluorescent antigen detection for *T. pallidum*. J Infect Dis 1993;168:238-42.
9. Reisner BS, Mann LM, Tholcken CA, Waite RT, Woods GL. Use of the *Treponema pallidum*-specific captia syphilis IgG assay in conjunction with the rapid plasma reagin to test for syphilis. J Clin Microbiol 1997;35:1141-3.

2017-04-17



## Treponema Pallidum IgG ELISA

Catalog No. TP076G (96 Tests)

**INTENDED USE**

The Calbiotech *Treponema pallidum* IgG ELISA Kit is intended for the detection of IgG antibody to *Treponema pallidum* in human serum or plasma.

**SUMMARY AND EXPLANATION**

*Treponema pallidum* is the causative agent of syphilis a contagious and infectious systemic disease characterized by periods of active florid manifestations and by years of symptomless latency. Syphilis is traditionally classified as acquired or congenital, each being further subdivided on the basis of the natural course of the disease. In acquired syphilis, infection is usually transmitted by sexual intercourse. The incubation period of syphilis can vary from 1 to 13 weeks, but usually from 3 - 4 weeks. Untreated patients with primary or secondary syphilis having active lesions are the most infectious, and the risks of contagion are greatest during the first 2 years of infection. Virtually every organ and tissue of the body is affected, including most body fluids. Over 80% of patients have mucocutaneous lesions, 50% have generalized enlargement of the lymph nodes, and about 10% have lesions of the eyes, bones and joints, meninges, liver, and spleen. Mild constitutional symptoms of malaise, headache, anorexia, nausea, aching pains in the bones, and fatigability are often present. Congenital syphilis is the result of passage of *T. pallidum* across the placenta. Clinical manifestations may be present at birth but are more often seen at 3 weeks to 6 months of age. Two types of antibodies are produced by *T. pallidum*: nontreponemal antibodies (reagin) and treponemal antibodies. ELISA for detection of IgG and IgM antibodies is becoming the Gold standard for the diagnosis of syphilis.

**PRINCIPLE OF THE TEST**

Diluted patient serum is added to wells coated with purified antigen. IgG specific antibody, if present, binds to the antigen. All unbound materials are washed away and the enzyme conjugate is added to bind to the antibody-antigen complex, if present. Excess enzyme conjugate is washed off and substrate is added. The plate is incubated to allow the hydrolysis of the substrate by the enzyme. The intensity of the color generated is proportional to the amount of IgG specific antibody in the sample.

Cat#: TP076G (96 Tests)  
 For Order and Inquiries, please contact  
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[www.calbiotech.com](http://www.calbiotech.com)

MATERIALS PROVIDED	96 Tests
1. Microwells coated with <i>T. pallidum</i> antigen	12x8x1
2. Sample Diluent: 1 bottle (ready to use)	22 ml
3. Calibrator: 1 Vial (ready to use)	1ml
4. Positive Control: 1 vial (ready to use)	1ml
5. Negative Control: 1 vial (ready to use)	1ml
6. Enzyme conjugate: 1 bottle (ready to use)	12ml
7. TMB Substrate: 1 bottle (ready to use)	12ml
8. Stop Solution: 1 bottle (ready to use)	12ml
9. Wash concentrate 20X: 1 bottle	25ml

**MATERIALS NOT PROVIDED**

1. Distilled or deionized water
2. Precision pipettes
3. Disposable pipette tips
4. ELISA reader capable of reading absorbance at 450nm
5. Absorbance paper or paper towel
6. Graph paper

**STORAGE AND STABILITY**

1. Store the kit at 2-8° C.
2. Keep microwells sealed in a dry bag with desiccants.
3. The reagents are stable until expiration of the kit.
4. Do not expose test reagents to heat, sun or strong light.

**WARNINGS AND PRECAUTIONS**

1. For Research Use Only. Not for use in diagnostic procedures.
2. For Laboratory Use.
3. Potential biohazardous materials:  
The calibrator and controls contain human source components which have been tested and found non-reactive for hepatitis B surface antigen as well as HIV antibody with FDA licensed reagents. However, there is no test method that can offer complete assurance that HIV, Hepatitis B virus or other infectious agents are absent. These reagents should be handled at the Biosafety Level 2, as recommended in the Centers for Disease Control/National Institutes of Health manual, "Biosafety in Microbiological and Biomedical Laboratories." 1984.
4. Optimal results will be obtained by strict adherence to the test protocol. Precise pipetting as well as following the exact time and temperature requirements is essential.
5. Do not pipette by mouth. Do not smoke, eat, or drink in the areas in which specimens or kit reagents are handled.
6. The components in this kit are intended for use as an integral unit. The components of different lots should not be mixed.
7. Control sera and sample diluent contain preserved with sodium azide. Sodium azide may react with lead and copper plumbing to form explosive metal azide. On disposal, flush with a large volume of water.

**SPECIMEN COLLECTION AND HANDLING**

1. Collect blood specimens and separate the serum.
2. Typically, specimens may be refrigerated at 2–8 °C for up to seven days or frozen for up to six months. Avoid repetitive freezing and thawing.

**REAGENT PREPARATION**

Prepare 1X Wash buffer by adding the contents of the bottle (25 ml, 20X) to 475 ml of distilled or deionized water. Store at room temperature (20-25°C).

**ASSAY PROCEDURE**

Bring all specimens and kit reagents to room temperature (20-25°C) and gently mix.

1. Place the desired number of coated strips into the holder.
2. Negative control, positive control, and calibrator are ready to use. Prepare 1:21 dilution of specimens, by adding 10 µl of the sample to 200 µl of sample diluent. Mix well.
3. Dispense 100 µl of diluted sera, calibrator and controls into the appropriate wells. For the reagent blank, dispense 100µl sample diluent in 1A well position. Tap the holder to remove air bubbles from the liquid and mix well. Incubate for 20 minutes at room temperature.
4. Remove liquid from all wells. Wash wells three times with 300 µl of 1X wash buffer. Blot on absorbance paper or paper towel.
5. Dispense 100 µl of enzyme conjugate to each well and incubate for 20 minutes at room temperature.
6. Remove enzyme conjugate from all wells. Wash wells three times with 300 µl of 1X wash buffer. Blot on absorbance paper or paper towel
7. Dispense 100 µl of TMB substrate and incubate for 10 minutes at room temperature.
8. Add 100 µl of stop solution.
9. Read O.D. at 450 nm using ELISA reader within 15 min. A dual wavelength is recommended with reference filter of 600-650 nm.

**CALCULATION OF RESULTS**

1. Check Calibrator Factor (CF) value on the calibrator bottle. This value might vary from lot to lot. Make sure you check the value on every kit.
2. Calculate the cut-off value: Calibrator OD x Calibrator Factor (CF).
3. Calculate the Ab (Antibody) Index of each determination by dividing the O.D. value of each sample by cut-off value.

**LIMITATIONS OF THE TEST**

1. Lipemic or hemolyzed samples may cause erroneous results.