



WANTAI anti-TP ELISA

*Developing Scientifically
Focusing on the Health*

Sensitivity: **99.52%**
Specificity: **99.95%**
Specimen volume: **20 μ l**
Shelf-life: **15 months**

What is Syphilis?

Syphilis is a disease caused by Spirochete bacterium called *Treponema Pallidum* (TP). If untreated, the organisms move throughout the body and can cause damage to many organs, making syphilis a life-threatening disease if not treated early enough. People who have been infected with Syphilis experience different symptoms during the 3 stages of the disease. Early, which is defined by the presence of the chancre at the site of inoculation. Syphilis may be further divided into primary, secondary, and early latent syphilis; late syphilis includes late latent and the various forms of tertiary Syphilis. The serological response to syphilis involves production of antibodies to a wide range of antigens, including non-specific antibodies and specific anti-TP antibodies. The first detectable response to infection is the production of specific antitreponemal IgM, which can be detected within 4 to 7 days after the chancre appears and until the end of the second week of infection; antitreponemal IgG appears at about four weeks later. By the time that symptoms develop, most patients have detectable IgG and IgM.

Product Description

WANTAI anti-TP ELISA is an enzyme-linked immunosorbent assay (ELISA) for qualitative detection of antibodies to *Treponema Pallidum* in human serum or plasma samples. It is intended for screening of blood donors and as an aid in the diagnosis of clinical conditions related to infection with *Treponema Pallidum*.



Clinical Study 1

Wantai Syphilis ELISA was evaluated in 8 blood banks in China. The accumulative results from the studies indicate that

- **Sensitivity is 99.52%** (413/415)
- **Specificity is 99.95%** (3859/3861) and,
- **Coincidence rate with TPPA is 99.9%**.

Blood Bank	Sensitivity	TPPA	Specificity
	POS / Total	POS / Total	NEG Total
1	14/14	-	2888/2890
2	6/6	-	521/521
3	76/76	4/6	59/59
4	8/8	0/2	148/148
5	90/90	1/1	13/13
6	80/80	-	12/12
7	2/2	0/2	148/148
8	137/139	5/6	70/70

Clinical Study 2

Serum specimens collected from 222 syphilis patients (including 1st period, 2nd period, 3rd period and latent period Syphilis), 42 non-syphilis, autoimmune diseases patients, and 270 healthy blood-donors, were tested with RPR, TPPA and Wantai TP-ELISA.

The positive rates of

- **Wantai TP-ELISA was 97.30%** (216/222),
- **TPPA was 95.95%** (213/222) and,
- **RPR was 90.54%**(201/222).

Samples	No.	Wantai TP ELISA		TRUST/PRP		TPHA	
		+	-	+	-	+	-
Syphilis	No.						
1st period	66	60	6	55	11	59	7
2nd period	140	140	0	131	9	138	2
3rd period	2	2	0	2	0	2	0
latent period	14	14	0	13	1	14	0
TOTAL	222	216	6	201	21	213	9
Atrophic arthritis	42	0	42	42	0	0	42

Conclusion: WANTAI TP Antibody ELISA Kit has both **high sensitivity** and **high specificity** in diagnosis of syphilis. It can be taken as tool for blood donor screening and confirmatory test for large number of clinical samples.