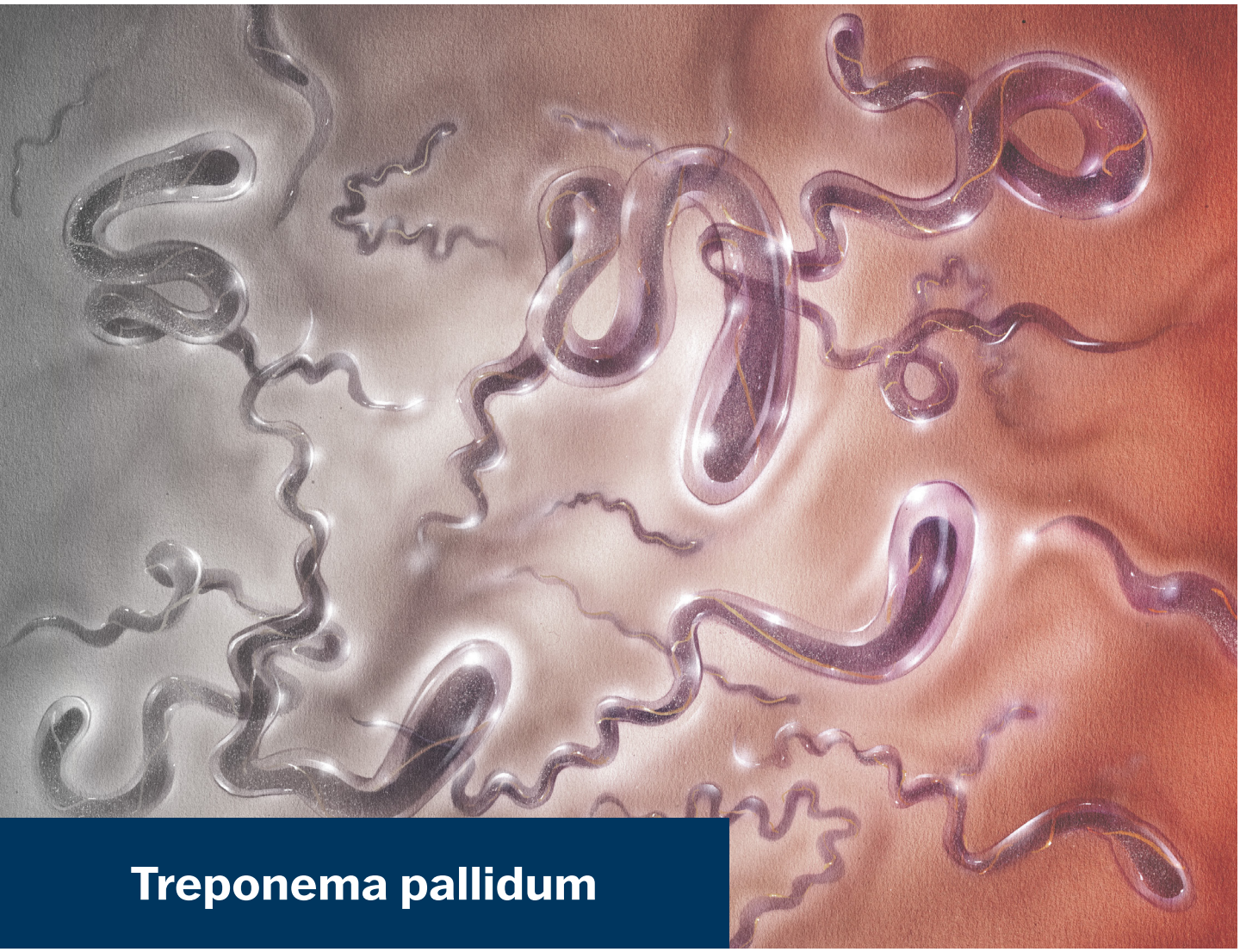


Treponema pallidum

Enzyme immunoassays for the diagnosis of syphilis

ELISA and **IMMUNOBLOT** kits are optimized and validated for detection of IgG and IgM antibodies in human serum and plasma

CE IVD

Diagnostic kits are intended for professional use in the laboratory.

BG TestLine®

Introduction

Syphilis (lues) is a sexually transmitted disease caused by spirochaeta *Treponema pallidum* subsp. pallidum. The disease is spread predominantly by sexual intercourse with an infected individual, however in approximately 5–10% of cases the infection is transmitted in another way (from mother to child, rarely by contact with infected blood or by dermal manifestations).

Syphilis proceeds in the following characteristic phases:

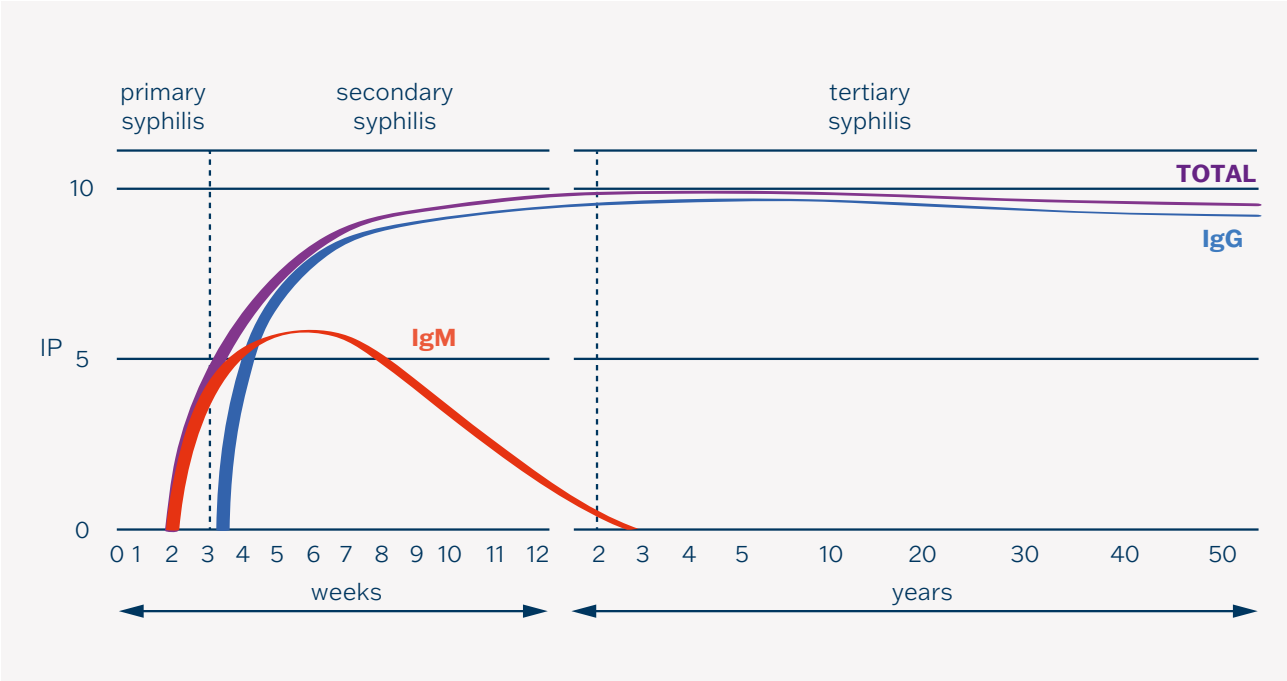
Primary syphilis: 2 or 4 weeks after exposure a hard painless ulcer appears in the place when the infection entered the organism. The ulcer disappears spontaneously after 4 to 6 weeks.

Secondary syphilis: the infection spreads in the bloodstream. Skin lesions – exanthema (rash) and highly infectious condylomata lata are characteristic for this phase of the disease; swollen lymph nodes are noted. This stage is then alternated by an asymptomatic stadium (latency) which can last for years.

Tertiary syphilis: severe skin lesions, hard alterations of organs as heart and cardiovascular system, eyes, central nervous system and spinal cord occur.

In case that an expectant mother suffers from an untreated primary or secondary acquired form of syphilis, the disease can be passed to the unborn infant which results in abortion or infection of the foetus and its severe damages (congenital syphilis).

Antibody Response

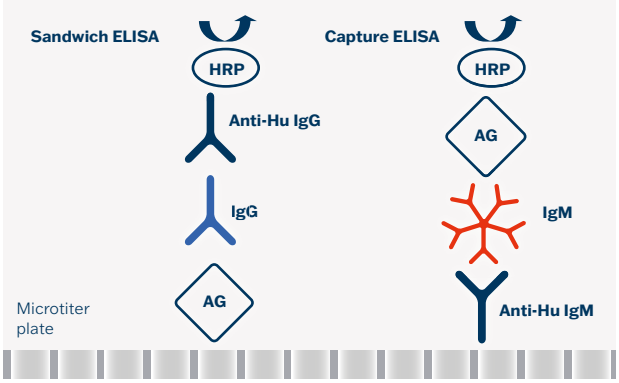


ELISA

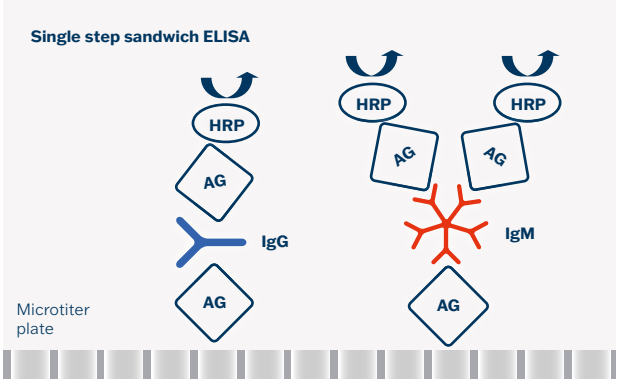
Test Principle

EIA Treponema pallidum IgG:
The assay is based on a sandwich type of ELISA method.

EIA Treponema pallidum IgM:
The assay is based on a capture type of ELISA method.



EIA Treponema pallidum TOTAL:
The assay is based on a single-step sandwich type of ELISA method.



Advantages

- Identical assay procedure
- High diagnostic specificity and sensitivity
- High reproducibility
- High dynamics of antibody response
- Short total assay time
- Not necessary to dilute test samples
- Ready for automation
- Customer support

Antigens

Combination of selected parts of the specific antigens of *Treponema pallidum*, particularly p17, p47, p41 and p15.

Clinical Application

- Highly sensitive and specific ELISA methods for detection of anti-treponema IgG and IgM antibodies are suitable for screening as well as confirmation of non-treponemal (VDRL, RPR, etc.) and treponemal (TPHA, etc.) test results.
- Determination of IgG and IgM antibodies enables one to distinguish between new and previous infections, diagnostics of congenital infection and antibiotic treatment efficiency monitoring.
- *EIA Treponema pallidum TOTAL kit enables determination of specific antibodies' presence in tested samples (qualitative test).

User Comfort

- Ready-to-use components
- Colour-coded components
- Interchangeable components
- Breakable colour-coded microplate strips
- CUT-OFF included
- *EIA Treponema pallidum TOTAL kit includes Negative and Positive control
- Semiquantitative evaluation of results (Index of Positivity)
- Easy assay procedure

Test Characteristics

ELISA	Diagnostic sensitivity	Diagnostic specificity
EIA Treponema pallidum IgG	98.6%	99.2%
EIA Treponema pallidum IgM	95,7%	95.2%
EIA Treponema pallidum TOTAL	97.8%	99.9%

Summary Protocol

EIA Treponema pallidum IgG, IgM

Step		Test steps
	1.	Dilute samples – serum/plasma 1:101 (10 µl + 1 ml)
	2.	Pipette controls and diluted samples 100 µl – blank = empty well
	3.	Incubate 30 minutes at 37 °C
	4.	Aspirate and wash the wells 5 times
	5.	Add 100 µl Conjugate – blank = empty well
	6.	Incubate 30 minutes at 37 °C
	7.	Aspirate and wash the wells 5 times
	8.	Add 100 µl Substrate (TMB-Complete) – Including blank
	9.	Incubate 30 minutes at 37 °C
	10.	Add 100 µl Stopping solution – Including blank
	11.	Read colour intensity at 450 nm

EIA Treponema pallidum TOTAL

Step		Test steps
	1.	Pipette Controls and undiluted samples 50 µl – blank = empty well
	2.	Add 50 µl Conjugate
	3.	Incubate 30 minutes at 37 °C
	4.	Aspirate and wash the wells 5 times
	5.	Add 100 µl Substrate (TMB-Complete) – Including blank
	6.	Incubate 30 minutes at 37 °C
	7.	Add 100 µl Stopping solution – Including blank
	8.	Read colour intensity at 450 nm

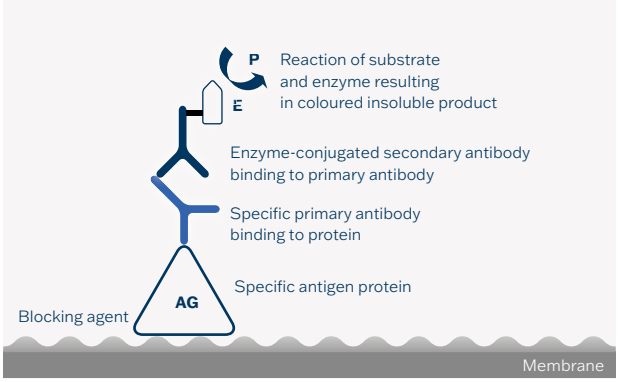
Advantages of TOTAL technique vs. TPHA

TPHA – classical treponemal tests	EIA Treponema pallidum TOTAL
Analysis of small number of samples	Investigation of large number of samples
Hand-operated only	Ready for automation
No compliance with GMP (Good Manufacturing Practice)	cCompliance with GMP (Good Manufacturing Practice)
Difficult compilation of results	Simple compilation of results

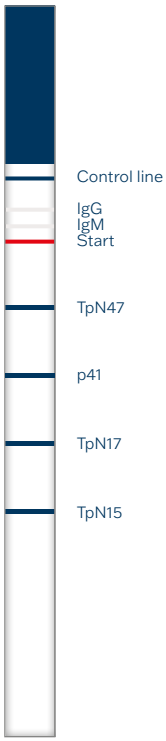
IMMUNOBLOT

Test Principle

Recombinant antigens are transferred to a nitrocellulose membrane using a micro-dispersing method.



Antigeny



Highly specific antigens:
TpN47
TpN17
TpN15

Specific antigen:
TpN41

Summary Protocol

Step		Test steps
	1.	Pipette Universal solution 2 ml
	2.	Strips soaking 10 min. at room temperature – Shaker
	3.	Aspirate
	4.	Dilute samples – serum/plasma 1:51 (30 µl + 1,5 ml)
	5.	Pipette Controls and diluted samples 1.5 ml
	6.	Incubate 30 min. at room temperature – Shaker
	7.	Aspirate samples and wash strips with 1.5 ml of Universal solution 3-times for 5 min. – Shaker
	8.	Pipette Conjugate 1.5 ml
	9.	Incubate 30 min. at room temperature – Shaker
	10.	Aspirate Conjugate and wash strips with 1.5 ml of Universal solution 3-times for 5 min. – Shaker
	11.	Pipette Substrate solution (BCIP/NBT) 1.5 ml
	12.	Incubate 15 min. at room temperature – Shaker
	13.	Aspirate Substrate solution and wash strips with 2 ml of distilled water 2-times for 5 min. – Shaker
	14.	Sticking and evaluation of strips

Clinical Application

- Confirmation of treponemal and non-treponemal tests
- Confirmation of ambiguous results
- Diagnostics of *Treponema pallidum* infection, confirmative test for ELISA

User Comfort

- Ready-to-use components
- Colour-coded strips
- Positive and Negative controls
- Control of reaction course and CUT-OFF control are present on the strip
- Interchangeable components
- Easy assay procedure

Test Characteristics

Pathogen	Diagnostic Sensitivity	Diagnostic Specificity
BLOT-LINE Treponema IgG	98.0%	100.0%
BLOT-LINE Treponema IgM	97.6%	100.0%

Advantages

- Easy interpretation and reproducibility of results
- High diagnostic specificity and sensitivity
- Easy evaluation of the test
- Compatibility with all commercial immunoblot processing systems
- Customer support

Results of Cross-Reacting Pathogens or Factors Category

The assay was evaluated for potential cross-reactivity using samples positive for selected pathogens and factors.

Category	n	Positive Result
Borrelia spp.	10	0
Chlamydia pneumoniae	12	0
EBV EBNA-1	4	0
EBV VCA	3	0
EBV EA-D	3	0
Chlamydia trachomatis	7	0
RF	8	0
Total	**47**	**0**

Ordering Information

ELISA

Cat. No	Product	No. of Tests
TpG096	EIA Treponema pallidum IgG	96
TpM096	EIA Treponema pallidum IgM	96
Tp0096	EIA Treponema pallidum TOTAL	96
SK-TpG096	SmartEIA Treponema pallidum IgG	96
SK-TpM096	SmartEIA Treponema pallidum IgM	96
SK-Tp0096	SmartEIA Treponema pallidum TOTAL	96
xxxTLN	CKS negativní (dle seznamu na www.testlinecd.cz)	3,5 ml
xxxTLP	CKS pozitivní (dle seznamu na www.testlinecd.cz)	3,5 ml

SmartEIA kits are designed for automated processing using the Agility® analyser

IMMUNOBLOT

Cat. No	Product	No. of Tests
TpGL20	BLOT-LINE Treponema IgG	20
TpML20	BLOT-LINE Treponema IgM	20
BD-TpGL24	BlueBLOT-LINE Treponema IgG	24
BD-TpML24	BlueBLOT-LINE Treponema IgM	24
SwIm03	Immunoblot Software	1 ks

BlueBLOT-LINE kits are designed for automatic processing on a BlueDiver device

Availability of some products is territorially restricted. Please, contact Trade Department.

TestLine®

TestLine Clinical Diagnostics Ltd.
Krizikova 68, 612 00 Brno, Czech Republic
+420 549 121 203
sales@testlinecd.com
www.testlinecd.com

CERTIFIED ISO 9001 · ISO 13485

Company is certified to the quality management system standards ISO 9001 and ISO 13485 for in vitro diagnostics.

V08/2022