

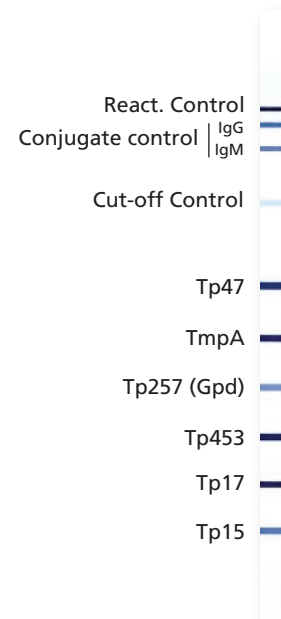


recomLine Treponema IgG recomLine Treponema IgM

Strip-Immunoassay with antigens produced by recombinant techniques for the detection of IgG or IgM antibodies against *Treponema pallidum*

Treponema pallidum subsp. *pallidum* is the causative agent of Syphilis, a chronic disease occurring only in humans. The disease progresses in several stages. After a short propagation period at the site of infection (primary stage) the hematogenic spreading of the pathogen throughout the entire organism follows (secondary stage). After the decline of acute symptoms *Treponema pallidum* can persist for years or lifetime in the human organism (stage of latency) and then can cause late complications (tertiary Syphilis and neurosyphilis). During pregnancy the pathogen can be transmitted to the fetus (Syphilis conata). An untreated syphilis can decisively affect the course of pregnancy and can lead to spontaneous abortion, stillborn or premature birth.

The serologic diagnosis of syphilis intends the use of a sensitive antibody screening assay (TPHA/TPPA, ELISA) in the first step. In the case of equivocal or positive results in the screening test a confirmation assay is performed in the second step to assure the specificity (FTA-ABS, immunoblot). Here the immunoblot plays a very important role, as only with this technique the determination of antibody production against essential *Treponema pallidum* antigens is possible. At the same time the detection of different antibody classes is possible. With the use of recombinant antigens the *recomLine* Treponema IgG, IgM meets all these requirements perfectly.



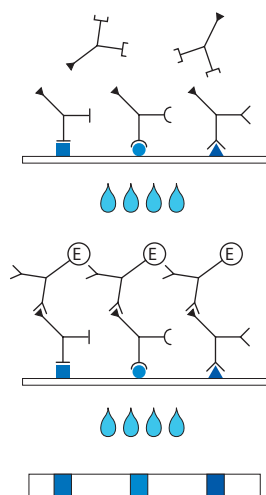
Product Advantages

- Recombinant antigens
 - Use of pathogen specific Treponema antigens Tp 47, Tp17 and Tp 15 as well as TmpA
 - Additional safety due to new antigens Tp257 (Gpd) and Tp453 with high specificity for *Treponema pallidum*
- Simple and quick interpretation by two-band criterion
- Test procedure and reagents identical in all MIKROGEN strip tests - reagents exchangeable
- Control bands on each strip
- Separate detection of IgG and IgM antibodies possible
- Easy test procedure; automation possible
- Easy and objective evaluation and documentation by *recomScan* software
- CE label: The *recomLine* Treponema tests meet the high standard of the EC directive 98/79/EC on in vitro diagnostic medical devices

Recombinant Treponema Antigens

Recombinant Antigen	Function	Size [kDa]
Tp 47	Membrane protein	47
TmpA	Membrane protein	42
Tp257 (Gpd)	Glycerophosphodiester-Phosphodiesterase, membrane protein	39
Tp453	Membrane protein	28
Tp 17	Membrane protein	17
Tp 15	Membrane protein	15

Test Principle and Procedure



- 1st Incubation** A test strip loaded with *Treponema* antigens is incubated with diluted serum or plasma in a tray for **1 hour** (3 hours as an alternative).
wash 3 times
- 2nd Incubation** Peroxidase conjugated anti-human antibodies (IgG or IgM specific) are added. Incubate for **45 minutes**.
wash 3 times
- Color reaction** **8 minutes** after addition of the colouring solution, insoluble coloured bands develop at the sites on the test strips occupied by antibodies.

Evaluation

Diagnostic sensitivity

<i>recomLine</i> Treponema	Positive findings in two reference tests			
	1h Procedure		3h Procedure	
	IgG (n = 280)	IgM (n = 90)	IgG (n = 39)	IgM (n = 38)
Negative	0	0	0	0
Borderline	2	7	1	0
Positive	278	83	38	38
Sensitivity	100 %*	100 %*	100 %*	100 %

* including borderline results

Diagnostic specificity

<i>recomLine</i> Treponema	Blood donors			
	1h Procedure		3h Procedure	
	IgG (n = 200)	IgM (n = 199)	IgG (n = 40)	IgM (n = 40)
Negative	199	196	40	38
Borderline	1	3	0	2
Positive	0	0	0	0
Specificity	99.5 %	98.5 %	100 %	95 %

Article-No

- 5172 ***recomLine* Treponema IgG**
Reagents for 20 determinations
- 5173 ***recomLine* Treponema IgM**
Reagents for 20 determinations
- 5170 ***recomLine* Treponema IgG**
Reagents for 100 determinations
- 5179 ***recomLine* Treponema IgM**
Reagents for 100 determinations

Storage

+2°C - +8°C