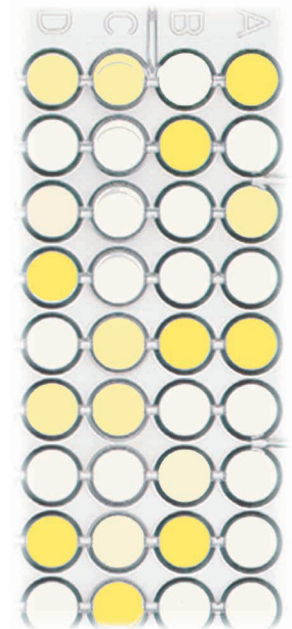


## recomWell Treponema IgG recomWell Treponema IgM

Enzyme immunoassay with recombinant antigens 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 through 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). During pregnancy the pathogen can be transmitted to the fetus (Syphilis *connata*). In approximately 40 % of the cases infection results in abortion or death of the child shortly after birth. The probability of infection in utero is around 40-70 %.

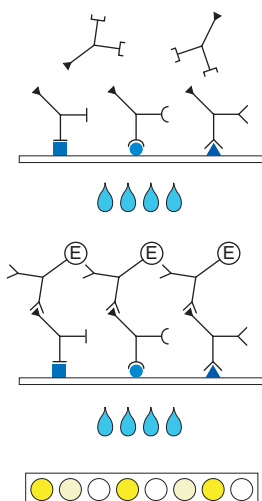
The serodiagnosis of syphilis is performed in steps. As a rule, the *T. pallidum* hemagglutination assay (TPHA) is used as an antibody screening test. As modern screening test system, the *recomWell* Treponema IgG, IgM is an excellent alternative. The main advantages of the *recomWell* Treponema tests are the possibility to distinguish between IgG and IgM antibodies and the capacity to process large numbers of samples accompanied by an automated readout. In addition, by the use of purified, recombinant antigens, the *recomWell* Treponema tests offer a reproducible higher specificity with maximum sensitivity.



### ■ Test Principle and Procedure

Indirect sandwich test.

Recombinant antigens are bound to the solid phase.



**1<sup>st</sup> Incubation:** Add patient samples diluted 1:101 (sample: 10 µl of serum or plasma), incubate for **1 h** at **37 °C**.

*Wash 4 times*

**2<sup>nd</sup> Incubation:** Add peroxidase conjugated anti-human IgG or IgM antibodies (conjugate), incubate for **30 min** at **37 °C**

*Wash 4 times*

**Color reaction:** Add ready-to-use TMB solution and incubate for **30 min** at room temperature. Stop the substrate reaction with  $H_3PO_4$  and measure the extinction at 450 nm.

## Product Advantages

- **Recombinant antigens**, therefore
  - Highest sensitivity and specificity
  - No cross reactions
- Separate detection of IgG and IgM antibodies possible
- Identical procedure for IgG and IgM determination
- No RF absorbance necessary in the case of IgM determination
- Easy to quantify
- Easy test procedure; automation possible
- Break-a-parts: single sample examination possible
- CE label: The *recomWell* Treponema tests meet the high standard of the EC directive 98/79/EC on in vitro diagnostic medical devices

## Recombinant Antigens

Recombinant Antigen	Function	Size [kDa]
TP 47 <sup>(1, 2)</sup>	Membrane protein	47
TP 17 <sup>(1, 3)</sup>	Membrane protein	17
TP 15 <sup>(1, 2)</sup>	Membrane protein	15

1) Norris SJ and the Treponema Pallidum Polypeptide Research Group **Polypeptides of *Treponema pallidum*: Progress toward Understanding Their Structural, Functional, and Immunologic Roles.** *Microbiol. Rev.* 1993, 57(3), 750-79

2) Chamberlain NR, Brandt ME, Erwin AL, Radolf, JD and Norgard MV **Major integral membrane protein immunogens of *Treponema pallidum* are proteolipids.** *Infect. Immun.* 1989, 57, 2872-7

3) Atkins DR, Purcell BK, Mitra MM, Norgard MV and Radolf JD **Lipid modification of the 17-kilodalton membrane immunogen of *Treponema pallidum* determines macrophage activation as well as amphiphilicity.** *Infect. Immun.* 1993, 61, 1202-10

## Evaluation

### Sensitivity - clinically defined sera

Clinically defined sera	<i>recomWell</i> Treponema		
	IgG	IgM	IgG/IgM
Primary syphilis (n = 19)	17 (89,5 %)	17 (89,5 %)	17 (89,5 %)
Secondary syphilis (n = 24)	24 (100 %)	0	24 (100 %)
Early latent syphilis (n = 67)	67 (100 %)	0	67 (100 %)
Late syphilis (n = 4)	4 (100 %)	0	4 (100 %)

### Screening sera and negative sera

Screening sera (n = 400) Unselected samples for routine screening for syphilis; hospital, Bologna, Italy	<i>recomWell</i> Treponema	
	IgG	IgM
negative	387 (96,8 %)	392 (98 %)
positiv or equivocal	13 (3,2 %)	8 (2 %)
of these, positive in western blot	8	6
negative in western blot	3 [Tp47] 2 [Tp47, Tp17]	2 [Tp47]
<b>Negative sera/blood donors (n = 200)</b> Sera from a blood bank in Bologna, Italy		
negative	200 (100 %)	200 (100 %)
positive	0	0

## Storage and Shelf Life

At 4 °C 18 months from the date of production

## Commercial Product

Article No. 5104 ***recomWell* Treponema IgG**  
Reagents for 96 determinations  
(Mikrotiter plates: 12 x 8 wells)

Article No. 5105 ***recomWell* Treponema IgM**  
Reagents for 96 determinations  
(Mikrotiter plates: 12 x 8 wells)

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**MIKROGEN** GmbH

Floriansbogen 2-4 · D-82061 Neuried · Germany · Tel.: +49 (0)89 54801-0 · Fax: +49 (0)89 54801-100  
Internet: www.mikrogen.de · eMail: mikrogen@mikrogen.de