

NEW

CE 0483

ELISA

recomWell Toxoplasma IgG recomWell Toxoplasma IgM

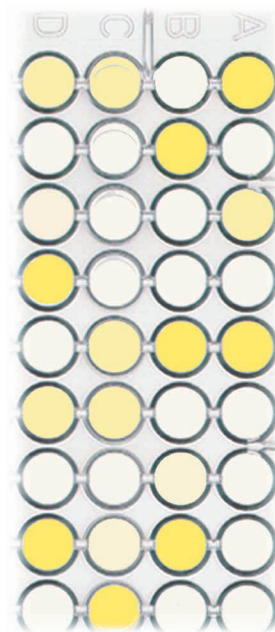
Enzyme immunoassay with recombinant antigens for the detection of IgG or IgM antibodies against *Toxoplasma gondii*.

Toxoplasma gondii shows the highest incidence of any human pathogenic parasite in central Europe. As a rule, the course of infection is asymptomatic or mild and confers lifelong immunity on immunocompetent persons. Initial contact with the pathogen during pregnancy can result in transmission of the pathogen to the foetus, leading to severe damage.

The main task of routine diagnosis is thus within the framework of preventive examinations during pregnancy. Due to the asymptomatic genesis of a toxoplasmosis in most cases, detection of Toxoplasmosis is in most cases serological. Enzyme immunoassays or immunofluorescent tests are mainly used for screening.

The *recomWell Toxoplasma IgG* assay can be initially also used as screening assay because of the high sensitivity and specificity. After a positive screening result a quantitative determination of IgM and IgG antibodies is recommended. Using the *recomWell Toxoplasma IgG* already for screening only the quantitative determination of IgM antibodies is necessary. Positive IgM and IgG results can be ideally confirmed by using the *recomLine Toxoplasma*, which also can give information about the time point of infection.

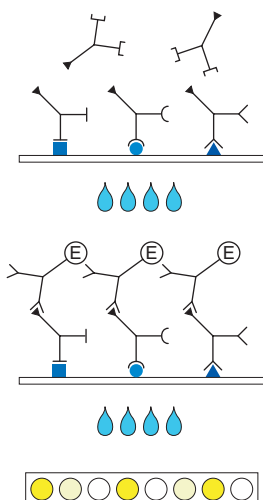
Genetically engineered immunodominant antigens of tachyzoites and bradyzoites are used in the *recomWell Toxoplasma* assay. In contrast to other ELISA systems using a total lysate antigen of *Toxoplasma gondii* different recombinant antigens - depending on the characteristics - can be utilised for the IgM and IgG assay. This results in an optimal discrimination between early and late immune response.



Test Principle and Procedure

Indirect sandwich test.

Recombinant antigens are bound to the solid phase.



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

Wash 4 times

2nd 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
 - High sensitivity and specificity
 - Excellent discrimination between negative and positive results
 - Immunodominant antigens of tachyzoites and bradyzoites
- Separate detection of IgG and IgM antibodies
- Identical procedure for IgG and IgM determination
- Test procedure is identical to other MIKROGEN ELISA tests
- No RF absorbance necessary in the case of IgM determination
- Easy test procedure; automation possible
- Easy to quantify
- Break-a-part: single sample examination possible
- CE label: The *recomWell* Toxoplasma tests meet the high standard of the EC directive 98/79/EC on in vitro diagnostic medical devices - certified by notified body 0483

■ Applied recombinant Toxoplasma antigens

Antigen	Abbreviation	Molecular weight [kDa]
Rhoptry antigen	ROP1	66
Matrix antigen	MAG1	65
Surface antigen	SAG1	30
Granular antigen	GRA7	29
Granular antigen	GRA8	35

■ Evaluation

	Positive sera (Reference ELISA and <i>recomLine</i> Toxoplasma)	
	IgG	IgM
positive/equivocal	227	50
negative	7	4
<i>Total</i>	234	54
Sensitivity	97 %	93 %

	Negative sera (Reference ELISA and <i>recomLine</i> Toxoplasma)	
	IgG	IgM
positive	2	1
negative	147	148
<i>Total</i>	149	149
Specificity	99 %	99 %

■ Storage and Shelf Life

At 4 °C 18 months from the date of production

■ Commercial Product

Article No. 5904 ***recomWell* Toxoplasma IgG**
Reagents for 96 determinations
(Mikrotiter plates: 12 x 8 wells)

Article No. 5905 ***recomWell* Toxoplasma IgM**
Reagents for 96 determinations
(Mikrotiter plates: 12 x 8 wells)

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