



recomLine Toxoplasma IgG [Avidity] recomLine Toxoplasma IgM [IgA]

Strip-Immunoassay with antigens produced by recombinant techniques for the detection of IgG, IgM and IgA antibodies against *Toxoplasma gondii*

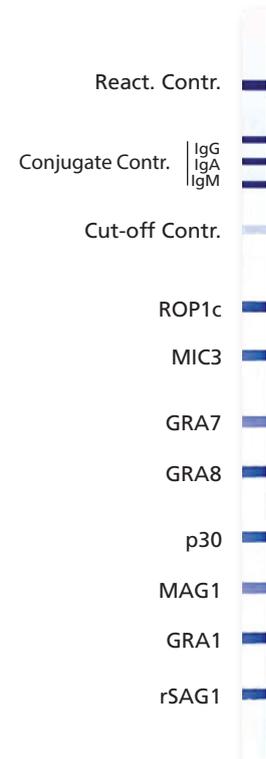
Toxoplasma gondii shows the highest incidence of any human pathogenic parasite in central Europe. As a rule, the course of the infection is asymptomatic or mild and confers lifelong immunity on immunocompetent persons. Initial contact with the pathogen during pregnancy can result in transmission of the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

The main task of routine diagnostics is therefore a preventive testing before or during pregnancy. Due to the frequently sub clinical course and the mostly uncharacteristic clinical picture, a clinical diagnosis is impossible without laboratory tests and is mainly based on serological methods with its main interest to differentiate acute infections from past infections. It is well known that *Toxoplasma* specific IgM antibodies can persist for month or even years after initial contact – so a positive IgM finding is not sufficient for the diagnosis of an acute toxoplasmosis. Much more of importance is to determine the avidity of *Toxoplasma* specific IgG antibodies.

The *recomLine Toxoplasma* is worldwide the only test system which meets the requirements for the special diagnosis of toxoplasmosis especially for pregnancy. The optimized combination of using recombinant antigens for IgG and IgM and also 4 different phase specific avidity antigens is unique on the market for the determination of the status of a *Toxoplasma* infection.

Product advantages

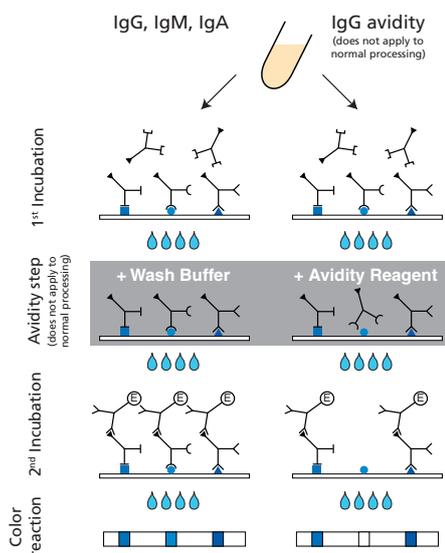
- Recombinant antigens
 - High sensitivity and specificity
 - Easy and clear interpretation due to easy to read bands
- Easy test procedure; automation possible
- Easy and objective evaluation and documentation by *recomScan* software
- Test procedure and reagents identical in all MIKROGEN strip tests - reagents exchangeable
- Safe evaluation due to strip specific controls (cut-off and conjugate control)
- Separate detection of IgG, IgM and IgA antibodies possible
- Easy and reliable determination of avidity possible
- CE label: The *recomLine Toxoplasma* tests meet the high standard of the EC directive 98/79/EC on in vitro diagnostic medical devices
- **Most accurate determination of stage of infection**



Recombinant Toxoplasma antigens in use

Antigen	Origin
ROP1c	Tachyzoite and bradyzoite antigen
MIC3	Tachyzoite antigen
GRA7	Tachyzoite and bradyzoite antigen
GRA8	Tachyzoite and bradyzoite antigen
p30	Tachyzoite antigen
MAG1	Tachyzoite antigen
GRA1	Tachyzoite and bradyzoite antigen
rSAG1	Tachyzoite antigen

Test Principle and Procedure



1st Incubation

One (two*) strip loaded with *Toxoplasma* antigens is incubated with diluted serum or plasma in a dish for **1 hour**.

wash 3 (1*) times

Avidity step*

(IgG only - does not apply to normal processing)

Wash buffer is added to one strip and the dissolved avidity reagent is added to the other strip, followed by a **3 minute** incubation. Low avidity antibodies will be "washed off" by the avidity reagent.

wash 3 times

2nd Incubation

Peroxidase conjugated anti-human antibodies (IgG, IgM or IgA specific) (IgG specific only*) are added. Incubate for **45 minutes**.

wash 3 times

Color reaction

8 minutes after addition of the coloring solution, insoluble colored bands develop at the sites on the test strips occupied by antibodies. (By direct comparison of the intensity of the corresponding bands on the two strips, the avidity of individual anti-*Toxoplasma* IgG antibodies can be determined.*)

(* processing of avidity determination)

Data

Toxoplasmosis Infection Phases

	Phase I			Phase II			Phase III			Phase IV					
	suspicious of < 3 months p.i.			suspicious of > 2 months p.i.			suspicious of > 3 months p.i.			suspicious of > 6 months p.i.			suspicious of > 12 months p.i.		
	IgG	IgG Avi	IgM	IgG	IgG Avi	IgM	IgG	IgG Avi	IgM	IgG	IgG Avi	IgM	IgG	IgG Avi	IgM
Conjugate Ctr.	[Diagram showing conjugate control bands for IgG, IgA, and IgM]														
Cut-off Ctr.	[Diagram showing cut-off control bands]														
ROP1c	[Diagram showing ROP1c bands]														
MIC3	[Diagram showing MIC3 bands]														
GRA7	[Diagram showing GRA7 bands]														
GRA8	[Diagram showing GRA8 bands]														
Avidity Marker	[Diagram showing p30, MAG1, GRA1, and rSAG1 bands]														
	No antibodies with high avidities detectable			Antibodies with high avidity for p30			Antibodies with high avidity for GRA1			Antibodies with high avidity for rSAG1 together with positive IgM			Antibodies with high avidity for rSAG1 together with negative IgM		

Article-No

- 5972 **recomLine Toxoplasma IgG [Avidity]**
Reagents for 20 determinations
- 5973 **recomLine Toxoplasma IgM [IgA]**
Reagents for 20 determinations
- 11010 **Blot, Line - avidity reagent**
Reagent for 25 avidity determinations
- 10016 **Anti-Human-Conjugate IgA**
500 µl
*[] optional available as additional reagent

Storage and Shelf Life

At +2°C - +8°C
10 months from the date of production