

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*

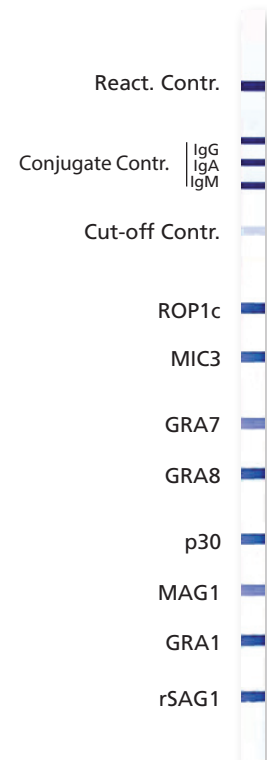
Toxoplasma gondii shows the highest incidence of any human pathogenic parasite in central Europe. As a rule, the course of the infection is asymptomatic or mild and confers lifelong immunity on immunocompetent persons. Initial contact with the pathogen during pregnancy can result in transmission of the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

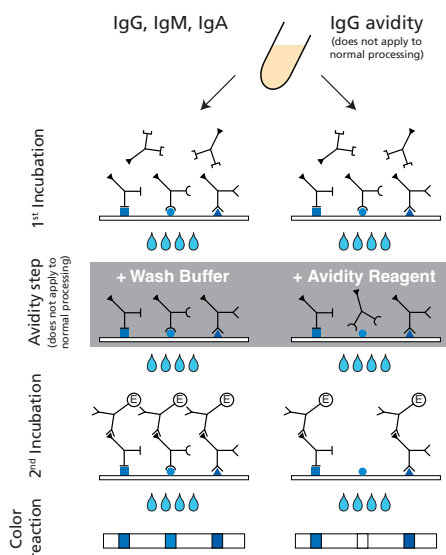
- Recombinant antigens
 - High sensitivity and specificity
 - Easy and clear interpretation due to easy to read bands
- Easy test procedure; automation possible
- Easy and objective evaluation and documentation by *recomScan* software
- Test procedure and reagents identical in all MIKROGEN strip tests - 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. | IgG | IgG | IgG | IgG | IgG | IgG | IgG | IgG | IgG | IgG | IgG | IgG | IgG | IgG | IgG |
| Conjugate Ctr. | IgA | IgA | IgA | IgA | IgA | IgA | IgA | IgA | IgA | IgA | IgA | IgA | IgA | IgA | IgA |
| Conjugate Ctr. | IgM | IgM | IgM | IgM | IgM | IgM | IgM | IgM | IgM | IgM | IgM | IgM | IgM | IgM | IgM |
| Cut-off Ctr. | | | | | | | | | | | | | | | |
| ROP1c | | | | | | | | | | | | | | | |
| MIC3 | | | | | | | | | | | | | | | |
| GRA7 | | | | | | | | | | | | | | | |
| GRA8 | | | | | | | | | | | | | | | |
| Avidity Marker | p30 | p30 | p30 | p30 | p30 | p30 | p30 | p30 | p30 | p30 | p30 | p30 | p30 | p30 | p30 |
| | MAG1 | MAG1 | MAG1 | MAG1 | MAG1 | MAG1 | MAG1 | MAG1 | MAG1 | MAG1 | MAG1 | MAG1 | MAG1 | MAG1 | MAG1 |
| | GRA1 | GRA1 | GRA1 | GRA1 | GRA1 | GRA1 | GRA1 | GRA1 | GRA1 | GRA1 | GRA1 | GRA1 | GRA1 | GRA1 | GRA1 |
| | rSAG1 | rSAG1 | rSAG1 | rSAG1 | rSAG1 | rSAG1 | rSAG1 | rSAG1 | rSAG1 | rSAG1 | rSAG1 | rSAG1 | rSAG1 | rSAG1 | rSAG1 |
| | 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