



SERION ELISA *classic*

# Toxoplasma gondii IgG/IgM

## Intended use

- Qualitative and quantitative detection of human IgG and IgM antibodies in serum, plasma or cerebrospinal fluid (IgG) directed against *Toxoplasma gondii*
- Demonstration of IgM antibodies as an initial assay for the detection of acute infections
- Detection of IgG antibodies for the determination of immune status
- Determination of IgG antibody avidity, by using the corresponding avidity reagent, in order to differentiate between acute and past infections

## Diagnostic Efficiency

For validation of the SERION ELISA *classic* Toxoplasma gondii IgG test 994 sera from pregnant women were analyzed in comparison to an indirect immunofluorescence test. Discrepant sera were further analyzed in the Sabin-Feldman-Test.

For the evaluation of sensitivity and specificity of the SERION ELISA *classic* Toxoplasma gondii IgM test, 186 serum samples were analyzed in comparison to an ELISA test system from another manufacturer. Using a borderline region from 300 to 350 U/ml, a sensitivity of 97.7% and a specificity of 98.4% were determined.

| Product   | Sensitivity | Specificity |
|---|-------------|-------------|
| SERION ELISA <i>classic</i> Toxoplasma gondii IgG | 98.2 %      | 99.8 %      |
| SERION ELISA <i>classic</i> Toxoplasma gondii IgM | 97.7 %      | 98.4 %      |

## Precision

### SERION ELISA *classic* Toxoplasma gondii IgG

| Sample  | Mean value (OD) | Intraassay CV (%) (n=20) | Mean value (OD) | Interassay CV (%) (n=10) |
|---------|-----------------|--------------------------|-----------------|--------------------------|
| Serum 1 | 0.545           | 1.7                      | 0.578           | 2.7                      |
| Serum 2 | 0.863           | 2.7                      | 0.933           | 3.9                      |
| Serum 3 | 1.909           | 1.8                      | 2.016           | 2.2                      |

## SERION ELISA *classic* Toxoplasma gondii IgM

| Sample  | Mean value (OD) | Intraassay CV (%) (n=20) | Mean value (OD) | Interassay CV (%) (n=10) |
|---------|-----------------|--------------------------|-----------------|--------------------------|
| Serum 1 | 0.302           | 5.0                      | 0.202           | 9.9                      |
| Serum 2 | 0.938           | 4.8                      | 0.936           | 6.5                      |
| Serum 3 | 1.146           | 5.3                      | 1.142           | 5.8                      |

### Pathogen

*Toxoplasma gondii* is an eucaryotic protozoa of the sporozoa group. The obligatory intracellular parasite is distributed worldwide.

### Disease

Following oral uptake of the parasite, e. g. with contaminated food, the organism penetrates the gut and enters the reticuloendothelial system. Due to the following hematogenous dissemination, *Toxoplasma gondii* is able to infect many different organs and tissues. Approximately 50% of infections with *Toxoplasma gondii* proceed subclinically. The remainder demonstrate only unspecific symptoms such as low fever, exhaustion, headache as well as muscle and joint pain after an incubation period of one to three weeks. A minority of patients suffer from high fever up to 39 °C and swelling of lymph nodes. In 1% of infected children and young adults complications such as myocarditis, meningitis or pneumonia are reported. After recovery, *Toxoplasma gondii* persists in infected tissues by forming cysts.

### Diagnosis

The diagnosis of toxoplasmosis is based on clinical findings and serological investigations. ELISA tests are recommended for the demonstration of IgG and IgM antibodies. Screening for *Toxoplasma* infections during pregnancy is of significant importance in prenatal care. The transmission of *Toxoplasma gondii* via the transplacental route has been observed in all stages of pregnancy, although the risk of a prenatal transmission as well as the outcome of infection depends on the stage of pregnancy. The risk of an infection of the unborn child via transplacental transmission is limited to seronegative women who acquire a primary infection during pregnancy. IgM antibodies directed against *Toxoplasma gondii* can persist for months after infection. Therefore, the determination of the IgG antibody avidity allows for differentiation of primary from past infections.

## Highlights

- Sensitive IgM detection as an initial test for the diagnosis of acute infections, particularly during pregnancy
- Demonstration of IgG antibodies for determination of immune status with results expressed in IU/ml referenced to the international standard of the WHO
- Detection of intrathecally synthesized IgG antibodies for CSF diagnostics
- Differentiation of acute from past infections by determination of IgG antibody avidity using the corresponding avidity reagent
- Sensitive IgM detection in *Dried Blood Spots* (DBS) for demonstration of infections in neonates

| Product   | Order No. |
|---|-----------|
| SERION ELISA <i>classic</i> Toxoplasma gondii IgG     | ESR110G   |
| SERION ELISA <i>classic</i> Toxoplasma gondii IgM     | ESR110M   |
| SERION ELISA <i>avidity reagent</i> Toxoplasma gondii | B110AVID  |

### SERION ELISA control

Please visit our website for more information.

### Institut Virion\Serion GmbH

Friedrich-Bergius-Ring 19, 97076 Würzburg, Germany  
Tel. +49 931 3045 0 Fax +49 931 3045 100  
Mail [info@serion-diagnostics.de](mailto:info@serion-diagnostics.de) Web [www.serion-diagnostics.de](http://www.serion-diagnostics.de)

virion\serion