Toxoplasma gondii IgM micro-capture ELISA

Enzyme immunoassay for the in-vitro diagnostic qualitative determination of IgM-class antibodies against Toxoplasma gondii in human serum or plasma.

REF  RE57111

Σ  96

2-8°C

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1. INTRODUCTION

Toxoplasma gondii is a small intracellular parasite, whose life cycle has a sexual and an asexual phase. Sexual development is restricted to the intestinal cells of (probably exclusively) cats; the oocysts formed are excreted and due to their resistant cell walls they may be infectious under advantageous circumstances for at least 1 year. Animals and man are intermediate hosts for the asexual proliferation of T. gondii: the ingested parasites will proliferate explosively within the host cells lysing them eventually. They disseminate throughout the body via circulation and lymphatic system and though may infect any cell type. In muscle and brain cells cysts are formed which are spheroidal and about 5-100 µm in diameter. Cysts are virtually immortal in the intermediate host.

Toxoplasma gondii is the most common parasite in humans, but its abundance (7-80 %) is highly dependent on the geographic area, the socioeconomic status and the nutritional customs. Infection only rarely causes toxoplasmosis and usually clinical symptoms are absent, but may produce severe problems in immunosuppressed persons and fetus.

Because only a primary infection during pregnancy may be dangerous and even fatal for the unborn (the probability of congenital infection is about 50 %), the recent onset of an infection must be excluded.

In pregnant women in over 98 % of cases, the absence of IgM excludes the possibility of recent infection. In newborns the very presence of anti-toxoplasma IgM is sufficient to confirm a congenital toxoplasmosis, since maternal IgM, unlike IgG, does not cross the placental barrier. But a significant number of infected infants do not develop detectable IgM levels and thus are false negative. In immunosuppressed patients toxoplasmosis causes severe complications mostly by reactivation of an earlier latent infection.

<table>
<thead>
<tr>
<th>Species</th>
<th>Disease</th>
<th>Symptoms</th>
<th>Mechanism of Infection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxoplasma gondii</td>
<td>Toxoplasmosis</td>
<td>Acquired Toxoplasmosis: lymphadenopathy, chorioretinitis</td>
<td>Ingestion of oocysts by food, including water contaminated by feces of cats or contaminated soil</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Congenital Toxoplasmosis: hydrocephalus, microcephaly, intracranial calcifications, chronical chorioretinitis</td>
<td>Ingestion of cysts by eating raw or insufficiently cooked meat, esp. pork</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Congenital infection</td>
</tr>
</tbody>
</table>

The presence of pathogen or infection may be identified by
- PCR
- Serology: Detection of antibodies by IF, ELISA

2. INTENDED USE

The Toxoplasma gondii IgM µ-capture ELISA is intended for the qualitative determination of IgM antibodies to Toxoplasma gondii in human serum or plasma (citrate).

3. PRINCIPLE OF THE ASSAY

The qualitative immunoenzymatic determination of IgM-class antibodies to Toxoplasma gondii is based on the ELISA (Enzyme-linked Immunosorbent Assay) µ-capture technique. Microtiter strip wells are coated with anti-human IgM-class antibodies to bind corresponding antibodies of the specimen. After washing the wells to remove all unbound sample material horseradish peroxidase (HRP) labelled Toxoplasma gondii antigen is added. This antigen-conjugate binds to the captured Toxoplasma gondii specific IgM antibodies. This immune complex is visualized by adding Tetramethylbenzidine (TMB) substrate which gives a blue reaction product. The intensity of this product is proportional to the amount of Toxoplasma gondii specific IgM antibodies in the specimen. Sulphuric acid is added to stop the reaction. This produces a yellow endpoint colour. Absorbance at 450 nm is read using an ELISA microwell plate reader.
4. MATERIALS

4.1. Reagents supplied

- **Toxoplasma gondii Microtiterplate (IgM)**: 12 break apart 8-well snap-off strips coated with anti-human IgM-class antibodies; in resealable aluminium foil.

- **Sample Diluent**: 1 bottle containing 100 ml of phosphate buffer (10 mM) for sample dilution; pH 7.2 ± 0.2; coloured yellow; ready to use; white cap; < 0.1 % MIT; < 0.1 % CMIT; < 0.1 % NaN₃.

- **Stop Solution**: 1 bottle containing 15 ml sulphuric acid, 0.2 mol/l; ready to use; red cap.

- **Washing Solution (20x conc.)**: 1 bottle containing 50 ml of a 20-fold concentrated phosphate buffer (0.2 M); pH 7.2 ± 0.2, for washing the wells; white cap; < 1 % Ethanol; < 0.5 % Bromonitrodioxane.

- **Toxoplasma gondii Conjugate**: 1 bottle containing 15 ml of peroxidase labelled Toxoplasma gondii antigen; coloured red, ready to use; black cap; 0.02 % Bromonitrodioxan; 0.02 % MIT.

- **TMB Substrate Solution**: 1 bottle containing 15 ml 3,3',5,5'-tetramethylbenzidine (TMB) (< 0.04 %); ready to use; yellow cap; < 0.0001 % CMIT; < 0.0001 % MIT; < 0.01 % H₂O₂.

- **Toxoplasma gondii IgM Positive Control**: 1 vial containing 2 ml control (human serum or plasma); coloured yellow; ready to use; red cap; < 0.1 % Bromonitrodioxan; < 0.1 % MIT.

- **Toxoplasma gondii IgM Cut-off Control**: 1 vial containing 3 ml control (human serum or plasma); coloured yellow; ready to use; green cap; < 0.1 % Bromonitrodioxan; < 0.1 % MIT.

- **Toxoplasma gondii IgM Negative Control**: 1 vial containing 2 ml control (human serum or plasma); coloured yellow; ready to use; blue cap; < 0.1 % MIT; < 0.1 % CMIT; < 0.1 % NaN₃.

4.2. Materials supplied

- 1 Strip holder
- 1 Cover foil
- 1 Test protocol

4.3. Materials and Equipment needed

- ELISA microwell plate reader, equipped for the measurement of absorbance at 450/620 nm
- Incubator 37 °C
- Manual or automatic equipment for rinsing wells
- Pipettes to deliver volumes between 10 and 1000 µl
- Vortex tube mixer
- Deionised or (freshly) distilled water
- Disposable tubes

5. STABILITY AND STORAGE

The opened reagents are stable up to the expiry date stated on the label when stored at 2...8 °C.

6. REAGENT PREPARATION

It is very important to bring all reagents, samples and controls to room temperature (20...25 °C) before starting the test run!

6.1. Coated snap-off strips

The ready to use break-apart snap-off strips are coated with anti-human IgM-class antibodies. Immediately after removal of the strips, the remaining strips should be resealed in the aluminium foil along with the desiccant supplied and stored at 2...8 °C.

6.2. Washing Solution (20x conc.)

Dilute Washing Solution 1 + 19; e. g. 10 ml Washing Solution + 190 ml fresh and germ free redistilled water. The diluted buffer is stable for 5 days at room temperature. Crystals in the concentrate disappear by warming up to 37 °C in a water bath.

6.3. TMB Substrate Solution

The reagent has to be stored in the dark. The solution should be colourless or could have a slight blue tinge. If the substrate turns into blue, it may have become contaminated and should be thrown away.
7. SPECIMEN COLLECTION AND PREPARATION

Use human serum or plasma (citrate) samples with this assay. If the assay is performed within 5 days after sample collection, the specimens should be kept at 2...8 °C; otherwise they should be aliquoted and stored deep-frozen (-70…-20 °C). If samples are stored frozen, mix thawed samples well before testing. Avoid repeated freezing and thawing. Heat inactivation of samples is not recommended.

7.1. Sample Dilution

Before assaying, all samples should be diluted 1+100 with Sample Diluent. Dispense 10 µl sample and 1 ml Sample Diluent into tubes to obtain a 1+100 dilution and thoroughly mix with a Vortex.

8. ASSAY PROCEDURE

8.1. Test Preparation

Please read the test protocol carefully before performing the assay. Result reliability depends on strict adherence to the test protocol as described. If performing the test on ELISA automatic systems we recommend increasing the washing steps from three to five and the volume of Washing Solution from 300 µl to 350 µl to avoid washing effects. Pay attention to chapter 12. Prior to commencing the assay, the distribution and identification plan for all specimens and standards/controls should be carefully established on the result sheet supplied in the kit. Select the required number of microtiter strips or wells and insert them into the holder.

Please allocate at least:

1 well (e. g. A1) for the Substrate Blank,
1 well (e. g. B1) for the Negative Control,
2 wells (e. g. C1+D1) for the Cut-off Control and
1 well (e. g. E1) for the Positive Control

It is recommended to determine standards/controls and patient samples in duplicate.

Perform all assay steps in the order given and without any appreciable delays between the steps.

A clean, disposable tip should be used for dispensing each control and sample.

Adjust the incubator to 37 ± 1 °C.

1. Dispense 100 µl standards/controls and diluted samples into their respective wells. Leave well A1 for the Substrate Blank.
2. Cover wells with the foil supplied in the kit.
3. **Incubate for 1 hour ± 5 min at 37 ± 1 °C.**
4. When incubation has been completed, remove the foil, aspirate the content of the wells and wash each well three times with 300 µl of Washing Solution. Avoid overflows from the reaction wells. The soak time between each wash cycle should be > 5 sec. At the end carefully remove remaining fluid by tapping strips on tissue paper prior to the next step!

   **Note:** Washing is critical! Insufficient washing results in poor precision and falsely elevated absorbance values.

5. Dispense 100 µl Toxoplasma gondii Conjugate into all wells except for the blank well (e. g. A1). Cover with foil.
6. **Incubate for 1 hour ± 5 min at room temperature.** Do not expose to direct sunlight.
7. Repeat step 4.
8. Dispense 100 µl TMB Substrate Solution into all wells.
9. **Incubate for exactly 15 min at room temperature (20...25 °C) in the dark.**
10. Dispense 100 µl Stop Solution into all wells in the same order and at the same rate as for the TMB Substrate.
    Any blue colour developed during the incubation turns into yellow.
11. Measure the absorbance of the specimen at 450/620 nm within 30 min after addition of the Stop Solution.
8.2. Measurement
Adjust the ELISA Microwell Plate Reader to zero using the Substrate Blank in well A1.
If due to technical reasons - the ELISA reader cannot be adjusted to zero using the Substrate Blank in well A1, subtract the absorbance value of well A1 from all other absorbance values measured in order to obtain reliable results!
Measure the absorbance of all wells at 450 nm and record the absorbance values for each control and patient sample in the distribution and identification plan.
Dual wavelength reading using 620 nm as reference wavelength is recommended.
Where applicable calculate the mean absorbance values of all duplicates.

9. RESULTS

9.1. Run Validation Criteria
In order for an assay to be considered valid, the following criteria must be met:
- **Substrate Blank** in A1: Absorbance value < 0.100
- **Negative Control** in B1: Absorbance value < Cut-off
- **Cut-off Control** in C1 and D1: Absorbance value 0.150 – 1.300
- **Positive Control** in E1: Absorbance value > Cut-off
If these criteria are not met, the test is not valid and must be repeated.

9.2. Calculation of Results
The cut-off is the mean absorbance value of the Cut-off Control determinations.
Example: Absorbance value Cut-off Control 0.44 + absorbance value Cut-off control 0.42 = 0.86 / 2 = 0.43 Cut-off = 0.43

9.2.1. Results in Units
Patient (mean) absorbance value x 10 = [NovaTec Units = NTU] 
Example: 1.591 x 10 = 37 NTU (Units)

9.3. Interpretation of Results

<table>
<thead>
<tr>
<th>Cut-off</th>
<th>10 NTU</th>
<th>-</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>&gt; 11 NTU</td>
<td>Antibodies against the pathogen are present. There has been a contact with the antigen (pathogen resp. vaccine).</td>
</tr>
<tr>
<td>Equivocal</td>
<td>9 – 11 NTU</td>
<td>Antibodies against the pathogen could not be detected clearly. It is recommended to repeat the test with a fresh sample in 2 to 4 weeks. If the result is equivocal again the sample is judged as negative</td>
</tr>
<tr>
<td>Negative</td>
<td>&lt; 9 NTU</td>
<td>The sample contains no antibodies against the pathogen. A previous contact with the antigen (pathogen resp. vaccine) is unlikely</td>
</tr>
</tbody>
</table>

Diagnosis of an infectious disease should not be established on the basis of a single test result. A precise diagnosis should take into consideration clinical history, symptomatology as well as serological data. In immunocompromised patients and newborns serological data only have restricted value.
To estimate (primary or recurrent) T. gondii infections by serology it is advised to test serum pairs. The second sample can be drawn 14 to 21 days after the first one. Both samples should be tested at the same time and in the same test to allow interpretation of significant differences in antibody levels. It is advised to perform a combination of IgM, IgA and IgG testing.
In addition, it should be noted that Toxoplasma gondii IgM antibodies may persist for months or even years after an infection has resolved.

10. SPECIFIC PERFORMANCE CHARACTERISTICS

10.1. Precision

<table>
<thead>
<tr>
<th>Intraassay</th>
<th>n</th>
<th>Mean (OD)</th>
<th>CV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum #1</td>
<td>24</td>
<td>1.563</td>
<td>2.9</td>
</tr>
<tr>
<td>Serum #2</td>
<td>24</td>
<td>0.304</td>
<td>1.5</td>
</tr>
</tbody>
</table>
### 10.2. Diagnostic Specificity
The diagnostic specificity is defined as the probability of the assay of scoring negative in the absence of the specific analyte. It is > 98%.

### 10.3. Diagnostic Sensitivity
The diagnostic sensitivity is defined as the probability of the assay of scoring positive in the presence of the specific analyte. It is 95.8%.

### 10.4. Interferences
Interferences with hemolytic, lipemic or icteric sera are not observed up to a concentration of 10 mg/ml hemoglobin, 5 mg/ml triglycerides and 0.5 mg/ml bilirubin.

### 10.5. Cross Reactivity
The polyclonal B-cell activation induced by Epstein-Barr virus (EBV) may result in false-positive Toxoplasma gondii IgM antibody results.

**Note:** The results refer to the groups of samples investigated; these are not guaranteed specifications.

### 11. LIMITATIONS OF THE PROCEDURE
Bacterial contamination or repeated freeze-thaw cycles of the specimen may affect the absorbance values.

### 12. PRECAUTIONS AND WARNINGS
- In compliance with article 1 paragraph 2b European directive 98/79/EC the use of the in vitro diagnostic medical devices is intended by the manufacturer to secure suitability, performances and safety of the product. Therefore the test procedure, the information, the precautions and warnings in the instructions for use have to be strictly followed. The test procedure, the information, the precautions and warnings in the instructions for use have to be strictly followed. The use of the testkits with analyzers and similar equipment has to be validated. Any change in design, composition and test procedure as well as for any use in combination with other products not approved by the manufacturer is not authorized; the user himself is responsible for such changes. The manufacturer is not liable for false results and incidents for these reasons. The manufacturer is not liable for any results by visual analysis of the patient samples.
- Only for in-vitro diagnostic use.
- All materials should be regarded and handled as potentially infectious.
- All components of human origin used for the production of these reagents have been tested for anti-HIV antibodies, anti-HCV antibodies and HBsAg and have been found to be non-reactive.
- Do not interchange reagents or strips of different production lots.
- No reagents of other manufacturers should be used along with reagents of this test kit.
- Do not use reagents after expiry date stated on the label.
- Use only clean pipette tips, dispensers, and lab ware.
- Do not interchange screw caps of reagent vials to avoid cross-contamination.
- Close reagent vials tightly immediately after use to avoid evaporation and microbial contamination.
- After first opening and subsequent storage check conjugate and control vials for microbial contamination prior to further use.
- To avoid cross-contamination and falsely elevated results pipette patient samples and dispense conjugate without splashing accurately to the bottom of wells.
- The ELISA is only designed for qualified personnel who are familiar with good laboratory practice.
- The concentrations of the hazardous materials mentioned in point 4.1. are very low. Therefore there is hardly any toxicological risk. Nevertheless rinse with plenty of water upon contact with eyes, skin or mucous membranes and consult a doctor in case of irritations. All solutions should be handled with adequate care.

### 12.1. Disposal Considerations
Residues of chemicals and preparations are generally considered as hazardous waste. The disposal of this kind of waste is regulated through national and regional laws and regulations. Contact your local authorities or waste management companies which will give advice on how to dispose hazardous waste.
13. ORDERING INFORMATION

Prod. No.: RE57111 Toxoplasma gondii IgM micro-capture ELISA (96 Determinations)

BIBLIOGRAPHY / LITERATUR / BIBLIOGRAPHIE / BIBLIOGRAFÍA


ABBREVIATIONS / ABKÜRZUNGEN / ABRÉVIATIONS / ABBREVIAZIONI / ABREVIACIÓNES / ABREVIATURAS

| MIT  | 2-Methyl-2H-isothiazol-3-one          |
| CMIT | 5-Chloro-2-methyl-2H-isothiazol-3-one|
| NaN | Sodium azide / Natriumazid          |
| H₂O₂ | Hydrogen peroxide / Wasserstoffperoxid |
**SUMMARY OF TEST PROCEDURE / KURZANLEITUNG TESTDURCHFÜHRUNG / RÉSUMÉ DE LA PROCEDURE DE TEST / SCHEMA DELLA PROCEDURA / RESUMEN DE LA TÉCNICA / RESUMO DO PROCEDIMENTO DE TESTE**

Toxoplasma gondii IgM micro-capture ELISA

### Test Preparation

Prepare reagents and samples as described. Establish the distribution and identification plan for all specimens and controls on a result sheet. Select the required number of microtiter strips or wells and insert them into the holder.

### Assay Procedure

<table>
<thead>
<tr>
<th></th>
<th>Substrate Blank (e. g. A1)</th>
<th>Negative Control</th>
<th>Cut-off Control</th>
<th>Positive Control</th>
<th>Sample (diluted 1+100)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative Control</td>
<td>-</td>
<td>100 µl</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Cut-off Control</td>
<td>-</td>
<td>-</td>
<td>100 µl</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Positive Control</td>
<td>-</td>
<td>-</td>
<td>100 µl</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Sample (diluted 1+100)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>100 µl</td>
<td>100 µl</td>
</tr>
</tbody>
</table>

Cover wells with foil supplied in the kit

**Incubate for 1 h at 37 °C**

Wash each well three times with 300 µl of Washing Solution

<table>
<thead>
<tr>
<th></th>
<th>Conjugate</th>
<th>100 µl</th>
<th>100 µl</th>
<th>100 µl</th>
<th>100 µl</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative Control</td>
<td>100 µl</td>
<td>100 µl</td>
<td>100 µl</td>
<td>100 µl</td>
<td>100 µl</td>
</tr>
<tr>
<td>Positive Control</td>
<td>100 µl</td>
<td>100 µl</td>
<td>100 µl</td>
<td>100 µl</td>
<td>100 µl</td>
</tr>
<tr>
<td>Sample (diluted 1+100)</td>
<td>100 µl</td>
<td>100 µl</td>
<td>100 µl</td>
<td>100 µl</td>
<td>100 µl</td>
</tr>
</tbody>
</table>

Cover wells with foil supplied in the kit

**Incubate for 1 h at room temperature**

Wash each well three times with 300 µl of Washing Solution

<table>
<thead>
<tr>
<th></th>
<th>TMB Substrate</th>
<th>100 µl</th>
<th>100 µl</th>
<th>100 µl</th>
<th>100 µl</th>
<th>100 µl</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative Control</td>
<td>100 µl</td>
<td>100 µl</td>
<td>100 µl</td>
<td>100 µl</td>
<td>100 µl</td>
<td></td>
</tr>
<tr>
<td>Positive Control</td>
<td>100 µl</td>
<td>100 µl</td>
<td>100 µl</td>
<td>100 µl</td>
<td>100 µl</td>
<td></td>
</tr>
<tr>
<td>Sample (diluted 1+100)</td>
<td>100 µl</td>
<td>100 µl</td>
<td>100 µl</td>
<td>100 µl</td>
<td>100 µl</td>
<td></td>
</tr>
</tbody>
</table>

**Incubate for exactly 15 min at room temperature in the dark**

Photometric measurement at 450 nm

*(reference wavelength: 620 nm)*

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TOXM0460engl,dt,it,es-05022014-CS
<table>
<thead>
<tr>
<th>Symbols / Symbole / Symbôles / Símbolos / Σύμβολα</th>
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<tr>
<td><strong>REF</strong></td>
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<tr>
<td><strong>LOT</strong></td>
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<tr>
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<tr>
<td><strong>IVD</strong></td>
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<tr>
<td><strong>Store at:</strong> / Lagern bei: / Stocker à: / Almacene a: / Armazenar a: / Conservare a: / Αποθήκευση στους:</td>
</tr>
<tr>
<td><strong>Manufacturer:</strong> / Hersteller: / Fabricant: / Productor: / Fabricante: / Fabbricante: / Παραγωγός:</td>
</tr>
<tr>
<td><strong>Caution:</strong> / Vorsicht! / Attention! / ¡Precaución! / Cuidado! / Attenzione! / Προσοχή!</td>
</tr>
</tbody>
</table>

Symbols of the kit components see MATERIALS SUPPLIED.

Die Symbole der Komponenten sind im Kapitel KOMPONENTEN DES KITS beschrieben.

Voir MATERIEL FOURNI pour les symbôles des composants du kit.

Símbolos de los componentes del juego de reactivos, vea MATERIALES SUMINISTRADOS.

Para símbolos dos componentes do kit ver MATERIAIS FORNECIDOS.

Per i simboli dei componenti del kit si veda COMPONENTI DEL KIT.

Για τα σύμβολα των συστατικών του κιτ συμβουλευτείτε το ΠΑΡΕΧΟΜΕΝΑ ΥΛΙΚΑ.

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**IBL AFFILIATES WORLDWIDE**

<table>
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<tr>
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<th>IBL International Corp.</th>
</tr>
</thead>
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</tr>
</tbody>
</table>

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**WEB:** http://www.IBL-International.com

**LIABILITY:** Complaints will be accepted in each mode –written or vocal. Preferred is that the complaint is accompanied with the test performance and results. Any modification of the test procedure or exchange or mixing of components of different lots could negatively affect the results. These cases invalidate any claim for replacement. Regardless, in the event of any claim, the manufacturer’s liability is not to exceed the value of the test kit. Any damage caused to the kit during transportation is not subject to the liability of the manufacturer.

Symbols Version 3.5 / 2012-01-20