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*FAST*est® TOXOPLASMA g

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***In vitro* diagnosticum**

Test-kit for the qualitative detection of antibodies against *Toxoplasma gondii* in whole blood, plasma or serum of the cat and dog

INSTRUCTIONS FOR USE

Manufacturer:
DIAGNOSTIK MEGACOR
6912 Hörbranz – AUSTRIA
www.megacor.com

1. INFORMATION ON THE TEST-KIT

TEST-KIT COMPONENTS

1 test-kit ***FAST*est® TOXOPLASMA** g contains:
- 2 or 10 test cassettes, coated with recombinant *T. gondii* antigens
- 1 dropper bottle **A** with 1.0 ml or 3.0 ml buffer diluent
- 2 or 10 disposable plastic pipettes
- 1 instructions for use

STABILITY AND STORAGE

Store at 15–25 °C

Expiry date – see label

APPLICATION AND ABBREVIATIONS

For veterinary use only

LOT Lot number

In vitro diagnosticum

! Do not use test-kit components from different kits, lot numbers or beyond stated expiry date.

Follow instructions for use precisely

T – TEST line, **C** – CONTROL line, **LF** – Lateral flow

LIABILITY

The entire risk due to the performance of this product is assumed by the purchaser. The manufacturer shall not be liable for indirect, special or consequential damages of any kind resulting from the use of this product.

ACCURACY

Sensitivity 98 %
Specificity 97 %
(Comparison Method: ELISA)

2. INTRODUCTION

Toxoplasmosis is caused by the protozoon *Toxoplasma gondii*. It plays an important epidemiologic role especially in the cat, but also in the dog. Other mammals, humans (zoonosis) and birds can be infected as intermediate hosts with *T. gondii* oocysts world-wide.

Definite hosts (gamogony and oocyst production) are only cats and other felids (especially lynx, ozelot, puma). The infection takes place perorally by ingestion of infectious tissue cysts (formation in the infected intermediate host) in raw meat (e. g. mouse, birds) or by sporulated oocysts (e.g. snails, worms, coprophagous arthropods a. s. o.). Due to infection intensity and uptake of the *T. gondii* stage, the patent period is only few days (oocysts 21–24 d / tissue cysts 3–5 d). Dogs are only intermediate hosts and do not egest oocysts.

Approximately 2 weeks post infection, the antibody (ab) titre increases (seroconversion) with maximum IgG titres between 2–4 weeks (optimal time point of testing). Thereafter, the titre decreases onto an "infestation titre" (< 1:50) and can persist. The prevalence for seropositivity increases with advanced age. In Germany, the prevalences for cats are indicated between 55–60 %.

Clinical symptoms are not pathognomonic in dog and cat and depend on age and immune status of the animal. Seriously acute courses with encephalitis, enteritis, hepatitis, myositis and cell lysis during protozoan propagation mostly lead to death, especially in puppies. In adults, toxoplasmosis mostly is inapparent. In older animals with chronic progression, anorexy, lethargy, fever as well as damage of myocard, liver and CNS are main issues.

Especially kittens egest up to 600 $\times 10^8$ oocysts with the feces 1–20 days long (Ø 7 days) after first infection (patent period). By reinfection with oocysts, normally a protective immunity is generated that can last up to 2 years. Therefore, with increasing reinfection the oocyst egestion can fall to zero. Actual data show that in Germany 0.6–1.4 % of cat feces samples do contain oocysts. Latent infections can be clinically activated by e.g. FeLV and / or FIV infection. In addition, tissue cysts can be a source of new antigen shedding and reactivation of infection. These tissue cysts do stimulate the ab production life-long, but do not protect from shedding.

Because a combination of coprologic and serologic testing (2× at an interval of 14 days) allows direct conclusions on the infection potential of the cat, the veterinarian using ***FAST*est® TOXOPLASMA** g is able to identify fast, simple and on-site the *T. gondii* status of the suspicious animal. This allows to immediately start further diagnostic and therapeutic as well as prophylactic measures.

3. INFORMATION ON THE SPECIMEN MATERIAL

10 µl (1 drop of attached plastic pipette) 15–25 °C warm whole blood (WB, with anticoagulant**), plasma (P) or serum (S)** are needed. **Native blood without any anticoagulant must be avoided due to the potential risk of microclots** (e. g. migration delay on the membrane, unspecific reaction!).

Mix the sample material well before use!

Non-cooled (**15–25 °C**), WB, P and S should be tested within 4 hours! At **2–8 °C**, WB, P and S can be stored up to 4 days. **Serum and / or plasma samples** can be permanently stored **at minimum −20 °C**.

Keep in mind that the sample material, as well as all used test-kit components, should have reached **room temperature** at the time of application.

Endogeneous and exogeneous interfering substances of the sample (e. g. albumin, fibrinogen, lipids, CRP, heterophilic antibodies, especially type IgA, as well as viscosity, pH-value and excess EDTA) **as well as native blood can cause interferences** (matrix effects) **that can influence the target measurement. These can lead to an impaired LF and / or unspecific reactions on T and C.**

4. SPECIMEN PREPARATION

- No specimen preparation necessary.
- **ATTENTION**: Partially filled and / or insufficient mixed EDTA, Citrate or Heparin tubes could create invisible microclots resulting in lateral flow delay and / or unspecific reactions (e. g. greyish shadow like lines).

5. TEST PROCEDURE

1. Remove the test cassette from its foil pouch shortly before use. Place it on a flat surface.
2. Draw sample **up to the mark (≙ 10 µl sample volume)** using the disposable plastic pipette. Place the **whole sample volume (10 µl) into the sample window S** of the test cassette (hold pipette vertically, fig.1).
3. Hold the dropper bottle **A** vertically and place **2 drops of the buffer diluent (ca. 80–100 µl)** into the sample window S of the test cassette (fig.2).
4. Add 1 additional drop of buffer diluent into the sample window S if there is no beginning LF visible within 1 minute after adding the buffer diluent.

fig.1

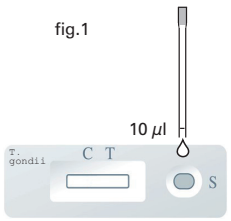
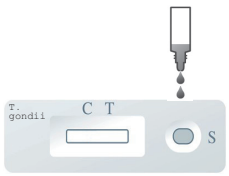


fig.2



6. READING OF THE TEST RESULT

Read the test result **15 minutes** after the buffer solution has been added into the sample window S.

POSITIVE TEST RESULT (fig.3)
A pink-purple TEST line of **any intensity** (varying from weak to strongly intensive) and a pink-purple CONTROL line appear.

NEGATIVE TEST RESULT (fig.4)
Only a pink-purple CONTROL line appears. This line indicates, irrespective of its intensity, that the test has been performed properly.

INVALID TEST RESULT
No CONTROL line visible. The test should be repeated using a new test cassette.

fig.3
POSITIVE TEST RESULT

fig.4
NEGATIVE TEST RESULT

7. PRECAUTIONS FOR USERS

- The guidelines for working in medical laboratories must be observed. It is recommended to wear disposable gloves and other personal protective equipment (protective clothing, possibly a face mask). Wash and disinfect hands after completing the test.
- Label sample material and associated test cassette to ensure a precise assignment.
- Use a new pipette and a new test cassette for each sample.
- The buffer diluent contains low concentrations of toxic sodium azide as a preservative, therefore avoid skin / eye contact and / or ingestion.
- The sample material must be seen as potentially infectious and disposed of accordingly, together with the used test-kit components.

8. TEST PRINCIPLE

The ***FAST*est® TOXOPLASMA** g is based on an immunochromatographic "sandwich principle".

The antibodies against *Toxoplasma gondii* in the sample will react in the conjugate pad with mobile monoclonal antibodies, which are conjugated to colloidal gold particles. These antigen-antibody-complexes are migrating along the nitrocellulose membrane ("lateral flow", **LF**) and bind to fixed antibodies, forming a pink-purple TEST line (**T**).

A correct test procedure will be indicated by a second pink-purple CONTROL line (**C**).

9. INFORMATION FOR THE INTERPRETATION

- The interpretation of the test result should always be based on anamnestic and clinical data as well as the therapy and prophylaxis possibilities.
- Any non-described colour or contour variation of T and C (e. g. greyish, shadow-like lines) has to be considered as unspecific reactions and therefore as negative test result.
- Due to anticoagulated whole blood and / or red hemoglobin background of the test membrane, caused by hemolytic blood samples, the visibility of T, especially in case of weak positive samples, could be from worse to not visible.
- The proof of anti-*T. gondii* ab, together wirh anamnesis and clinic shows with a high likelihood that *T. gondii* can be considered as cause of the acute disease.
- The decision starting an antibiotic therapy should be based on indirect immunofluorescence test (coupled serum test in an interval of 2–3 weeks / seroconversion) combined with clinical symptoms.
- Asymptomatic, but *T. gondii* ab positive animals have been infected with *T. gondii* at a particular time. Therefore, they are potential carriers of *T. gondii*. Subclinical animals could develop clinical symptoms at some indefinite future date, especially in case of co-infection with immune system weakening diseases like FIV, FeLV etc.
- Animals can be seronegative at the point of acute disease (no ab formation yet) and therefore show a negative test result.