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*FAST*est® NEOSPORA caninum

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***In vitro* diagnosticum**

Test-kit for the qualitative detection of antibodies against *Neospora caninum* in whole blood, plasma or serum of the dog, cattle and deer

INSTRUCTIONS FOR USE

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1. INFORMATION ON THE TEST-KIT

TEST-KIT COMPONENTS

1 test-kit ***FAST*est® NEOSPORA** caninum contains:
- 2 or 10 test cassettes coated with recombinant *Neospora caninum* 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

B – 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 96.2 %
Specificity 100 %
(Comparison Method: IFAT)

2. INTRODUCTION

Neospora caninum plays an important epidemiological role in dogs and cattle. The dog (esp. watch dogs, stray dogs) is a definitive host (intestinal neosporosis) and excretes infectious oocysts with the feces. The intermediate host, especially cattle, but also goats, sheep and horse, gets infected via grazing land and/or water contaminated with oocysts (horizontal infection) and/or intrauterine via already infected mothers (vertical infection).

N. caninum plays an important role in abortion in cattle worldwide. Characteristics are accumulating abortions in all states of gestation, dead births and weak calves.

The dog can act as an intermediate host as well and therefore can fall sick with neosporosis (systemic neosporosis). In dogs, the symptoms are especially focused on neurological disorders: paresis/paralysis of the hind-limbs, later also of the fore-limbs, as well as polymyelitis, radiculitis and encephalomyelitis. Also, muscular atrophy, hyperextension, hyperaesthesia and dysphagia can occur. Additionally, hepatitis, pneumonitis, myocarditis and ulcerative dermatitis can appear. In older dogs *Neospora* infection usually is asymptomatic! Puppies become clinically conspicuous at the age from 3 to 9 weeks up to one year. Early diagnostics and therefore specific therapy are essential for the prognosis. Due to recent studies, there seems to be a predisposition of male dogs to *N. caninum*.

Dog: Due to the short excretion period and the low amount of oocysts in dog feces, the detection of antibodies using ***FAST*est® NEOSPORA** caninum becomes very important for the diagnosis of a neosporosis.

Cattle: Due to horizontal, but particularly to the economically more important vertical placental transmission of infection onto the offspring, with ***FAST*est® NEOSPORA** caninum suspicious stocks should be tested for *N. caninum* antibodies.

3. INFORMATION ON THE SPECIMEN MATERIAL

Approximately **50 µl (2 drops of attached plastic pipette) 15–25 °C warm whole blood (WB**, with anticoagulant) or **25 µl (1 drop of attached plastic pipette) 15–25 °C warm 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 (15–25 °C)** 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 B and C.**

4. SPECIMEN COLLECTION AND 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. Add **2 drops of anticoagulated whole blood (ca. 50 µl)** or **1 drop of plasma/serum (ca. 25 µl)** with the attached plastic pipette into the sample window A of the test cassette (hold the pipette vertically, fig.1).
3. Hold the dropper bottle **A** vertically and express **4 (four) drops (160–200 µl) of buffer diluent** into the sample window A of the test cassette (fig.2).
4. Add 1 additional drop of buffer diluent into the sample window A if there is no beginning LF visible within 1 minute after adding the buffer diluent.

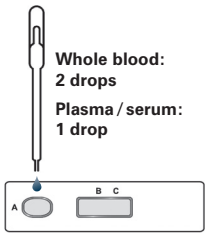


fig.1

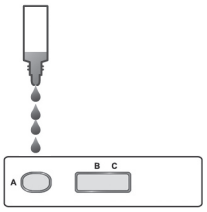


fig.2

6. READING OF THE TEST RESULT

Read the test result **15 minutes** after the four drops have beed added into the sample window A.

POSITIVE TEST RESULT (fig.3)
A pink-purple TEST line of **any intensity** (varying from very 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

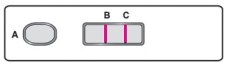
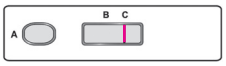


fig.4
NEGATIVE TEST RESULT



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® NEOSPORA** caninum is based on an immunochromatographic "sandwich principle" technique detecting specific antibodies against *Neospora caninum* in the whole blood, plasma or serum of the dog or cattle.

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

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 outline variation of B 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 B, especially in case of weak positive samples, could be from worse to not visible.
- The proof of anti-*Neospora caninum* antibodies, together with anamnesis and clinic shows with a high likelihood that *N. caninum* can be considered as cause of the acute disease.
- In asymptomatic animals and antibody positive animals, one should assume that they could have been infected with *N. caninum* and, as potential carriers, can transmit *N. caninum* vertically on their offspring.
- Additionally, the titre amount or the titre increase (within two tests in an interval of 2–3 weeks) can be defined via indirect immunofluorescence. A proof of the pathogen can be done by PCR in foetal fluids or tissue samples of deceased whelps or in the liquor/muscle biopsies of living animals.
- For humans, there is no zoonotic risk at all.