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FASTest® EHRLICHIA canis

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*In vitro* diagnosticum

Test-kit for the qualitative detection of antibodies against *Ehrlichia canis* in whole blood, plasma or serum of the dog

INSTRUCTIONS FOR USE



Supplied Exclusively To The UK
Veterinary Market By
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1. INFORMATION ON THE TEST-KIT

TEST-KIT COMPONENTS

1 test-kit **FASTest® EHRLICHIA** canis contains:

- 2*, 10** or 50*** test cassettes coated with specific antibodies
- 1 dropper bottle **A** with *1.0 ml, **1.5 ml or ***7.5 ml buffer diluent
- 2, 10 or 50 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 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 94.3%

Specificity 93.3%

(Comparison Method: IFAT)

2. INTRODUCTION

Canine monocytic ehrlichiosis (CME) is caused by the rickettsia *Ehrlichia canis*, which is mainly transmitted by the brown dog tick (*Rhipicephalus sanguineus*). *Ehrlichia canis* is found in many parts of the world, especially in the Mediterranean area, but also in Switzerland and partly Germany. Ehrlichiosis is common in the dog, but seldom in humans.

The concentration of specific antibodies increases sharply 2–3 weeks post infection. A fourfold titre increase of antibodies in an interval of two weeks (seroconversion) is indicative for an acute infection. In the acute stage, the dog shows apathy, anorexia, fever and lymphadenitis. In the subclinical phase, clinical symptoms are missing, but not the typical ehrlichiosis laboratory results like hyperglobulinaemia and thrombocytopenia. Chronic phase animals show slight up to life-threatening symptoms: spontaneous bleedings, neurological disorders, anaemia, severe loss of weight as well as spleno- and hepatomegaly. Indirect antibody detection is known to be an important diagnostic tool diagnosing CME beside clinical symptoms, case history (travel abroad) and direct antigen detection.

FASTest® EHRLICHIA canis is based on highly specific antibodies for a fast and reliable detection of antibodies against *Ehrlichia canis* in whole blood, plasma or serum of infected dogs.

3. INFORMATION ON THE SPECIMEN MATERIAL

Exactly 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 anticoagulant should not be used due to potential micro agglutination (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. **Plasma and/or serum 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.

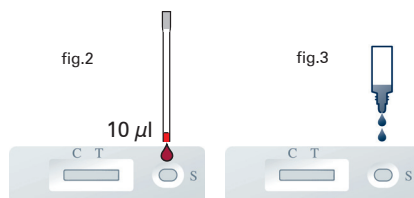
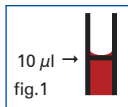
Endogeneous and exogeneous interfering substances of the sample (e.g. albumin, fibrinogen, lipids, CRP, heterophilic antibodies, especially type IgA, as well as viscosity, pH-value and excess EDTA) **as well as native blood can cause interferences** (matrix effects) **that can influence the target measurement.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

4. SPECIMEN 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. Draw sample up to the mark (**± 10 µl sample volume**) using the disposable plastic pipette. **The meniscus must be above the black line** (fig.1).
3. Place the whole sample volume (10 µl) into the sample window S of the test cassette (hold pipette vertically, fig.2).
4. Hold the buffer dropper bottle **A** vertically and express **2 drops of buffer diluent (ca. 80–100 µl)** into the sample window S of the test cassette (fig.3).
5. 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.



6. READING OF THE TEST RESULT



Read the test result **20 minutes** after the two drops of buffer diluent have been added into the sample window S.

POSITIVE TEST RESULT (fig.4)

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.5)

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.4
POSITIVE TEST RESULT



fig.5
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 **FASTest® EHRLICHIA** canis is based on an immunochromatographic “sandwich principle”.

The antibodies against *Ehrlichia canis* in the sample will react in the conjugate pad with mobile recombinant antigens, which are conjugated to colloidal gold particles. These antigen-antibody complexes are migrating along the nitrocellulose membrane (“lateral flow”, **LF**) and bind to fixed specific 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) or after more than 25 minutes has to be considered as unspecific reaction 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 bad to not visible.

Positive test result

- Dog had contact with *Ehrlichia canis* (antibody formation)!
- Antibodies can persist over months to years inspite of therapy (potential chronic carrier animals).

Negative test result

- With high likelihood, dog had no contact with *Ehrlichia canis*.
- Early infection stage of ehrlichiosis (< 2–3 weeks post infection!). Dog has not yet produced antibodies in a detectable concentration.

The diagnosis can only be based on anamnesis (stay in endemic areas, tick bites) and clinical signs. The detection of antibodies against *Ehrlichia canis* using **FASTest® EHRLICHIA** canis is only one but an important diagnostic tool to ensure the diagnosis CME.