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*FAST*est® LYME

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***In vitro* diagnosticum**

Test-kit for the qualitative detection of antibodies against *Borrelia burgdorferi* sensu lato 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 ***FAST*est® LYME** contains:
- 2 or 10 test cassettes, coated with *Borrelia b.* s.l. 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 90 %
Specificity 98.6 %
(Comparison Method: IFAT)

2. INTRODUCTION

Borreliosis caused by the borrelia species *Borrelia burgdorferi* sensu lato (*B. b.* s.l., genospecies *B. b.* sensu stricto, *B. garinii*, *B. afzelii*) is a world-wide spread infectious disease in dogs, other animals and in humans. Borrelia transmitting ticks (*Ixodes ricinus*, castor bean tick) are infected up to 30 % with borrelia. In dogs from endemic areas, the antibody prevalence (up to 95 %) correlates with dog ownership, dog's outdoor time and sucking time of the ticks.

The definitive in-clinic diagnosis "Lyme borreliosis" is often complex and can only be done by an analytical view combining many details like case history, clinical symptoms (e.g. lethargy, exhaustion, fever, swollen lymph glands, switching lameness, arthritis and neurological disorders) and especially by laboratory diagnostics. A successful therapy is based on an early detection of symptoms (first signs 2 to 5 months after tick exposition). Antibody detection (IgM before IgG) succeeds earliest in week 4 to 6 after tick exposition, after 3 months the antibody level is highest. A titre increase (seroconversion) is always seen before clinical signs of lameness and fever. Therefore, a negative test in an animal with clinical symptoms can rule out an acute borreliosis.

For the detection of antibodies, a two-step diagnostics is known to be golden standard. First step starts with an in-clinic antibody screening test like ***FAST*est® LYME**. Due to the fact that dogs from endemic areas show antibodies against *B. b.* s.l. on principle, a positive ***FAST*est® LYME** only means contact with borrelia in the past, not always implying an active lyme borreliosis. A determination whether the antibody titre is caused by antibodies due to vaccination or due to a natural infection is only possible by repeatedly running Western Blot tests (second diagnostic step). Based on highly specific, recombinant *B. b.* s.l. antigens, the early detection of *Borrelia burgdorferi* sensu lato IgG antibodies via ***FAST*est® LYME** is an additional important diagnostic tool to assure the diagnosis "borreliosis".

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) 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. **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 (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 insufficiently 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. Take the disposable plastic pipette and express **2 drops of anticoagulated whole blood (ca. 50 µl)** or **1 drop of plasma or serum (ca. 25 µl)** 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 drops (ca. 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.

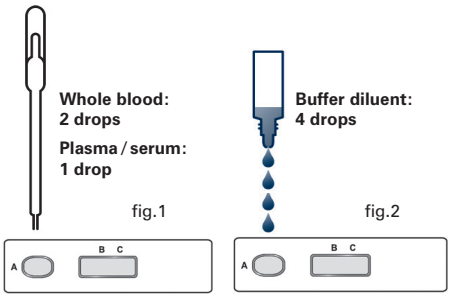


fig.1 fig.2

6. READING OF THE TEST RESULT

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

POSITIVE TEST RESULT (fig.4)
A pink-purple TEST line **of any intensity** (varying from very weak to stronly 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.3
POSITIVE TEST RESULT

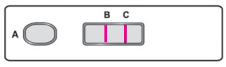
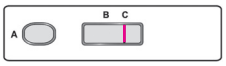


fig.4
NEGATIVE TEST RESULT



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® LYME** is based on an immunochromatographic "sandwich principle".

The antibodies against Borrelia of the sample bind to mobile antibodies conjugated with gold particles. Migrating along the nitrocellose membrane ("lateral flow", **LF**), these antigen-antibody complexes bind to fixed recombinant Borrelia 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 contour variation of B and C (e.g. greyish, shadow-like lines) 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 B, especially in case of weak positive samples, could be from worse to not visible.

Positive test result:

- The dog had contact with *Borrelia burgdorferi* sensu lato. To rule out whether the antibody reaction is based on an acute or chronic borreliosis, two serum samples at intervals of 2–4 weeks should be taken for testing with IFAT and/or Western Blot. A definite titre increase in the IFAT or a Borrelia-specific band pattern in the Blot are indicative for an ongoing borreliosis.
- An acute borreliosis is possible at dogs from endemic areas.
- Dog is vaccinated against Borrelia. Antibodies based on vaccination can be detectable from months to years post vaccination.

Negative test result:

- Dog had no contact with *Borrelia burgdorferi* sensu lato.
- Early borreliosis infection stage (< 4–6 weeks post infection). Dog has not yet produced antibodies in a detectable concentration.