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*FAST*est® BRUCELLA canis

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***In vitro* diagnosticum**

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

INSTRUCTIONS FOR USE

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1. INFORMATION ON THE TEST-KIT

TEST-KIT COMPONENTS

1 test-kit ***FAST*est® BRUCELLA** canis contains:
- 2 or 10 test cassettes coated with recombinant *Brucella canis* antigens
- 1 dropper bottle **A** with 0.5 ml or 1.0 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 72.7 %
Specificity 90.7 %
(Comparison Method: Rose Bengal Test)

2. INTRODUCTION

Brucella canis is a gram-negative bacterium appearing worldwide and being a potential danger for dogs and humans (zoonosis).

Although the prevalences are very low or *B. canis* is partially seen rather obliterated in countries with high breeding standards, increased attention must be paid to brucellosis, especially in dog breedings. By mating with dogs from abroad (with lower breeding standards), brucellosis can be imported easily and unnoticed.

The pathogen mainly propagates via infectious abort material or vaginal fluids, by mating or vertically from bitch to puppies.

Infected animals show failure in gravidity or infertility as well as atypical symptoms (e. g. uveitis). In about 75 % of the cases, females abort after 45 to 55 days of gestation. Early embryonic death and absorption or abortion 10 to 20 days after mating is reported, too. These abortions may go unnoticed, and the female then is often presented with the preliminary report "failure to conceive".

In males, the main signs are epididymitis, testicular atrophy and a moist scrotal dermatitis, in addition to bad semen quantity (esp. with chronic brucellosis) and quality.

Besides to missing or misunderstood symptoms, antibody levels in chronic animals can drop under the limit of detection. Hence, breeding dogs should be routinely tested for antibodies with serological methods to prevent the danger of propagation via venereal transmission.

Being fast, simple and reliable, ***FAST*est® BRUCELLA** canis enables the veterinarian to have a complete on-site predication of the brucellosis status of the single animal or the complete breeding. Therapeutic and prevention measures can be applied immediately, adapted to dog and breeder needs.

3. INFORMATION ON THE SPECIMEN MATERIAL

Approximately **25 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. **Express 1 drop** (ca. 25 µl) **of whole blood, plasma or serum** into the sample window S **using the disposable plastic pipette** (fig.1).
3. Hold the buffer dropper bottle **A** vertically and express **1 drop of buffer diluent (ca. 40–50 µl)** into the sample window S (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

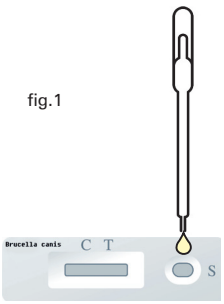
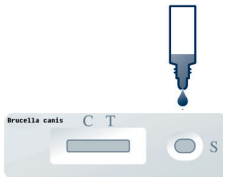


fig.2



6. READING OF THE TEST RESULT

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

POSITIVE TEST RESULT (fig.3)
A pink-purple TEST line (T) **of any intensity** (varying from very weak to strongly intensive) and a pink-purple CONTROL line (C) 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® BRUCELLA** canis is based on an immunochromatographic "sandwich principle".

The *Brucella canis* antibodies of the sample will bind to specific mobile monoclonal antibodies, which are bound to gold particles. Migrating ("lateral flow", **LF**) along the nitrocellulose membrane, these antigen-antibody complexes are bound by specific recombinant *B. canis* antigens producing 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 20 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 *Brucella canis*!
- To rule out whether the antibody reaction is based on an acute or chronic brucellosis, two serum samples at intervals of 2 to 4 weeks should be taken for testing with IFAT and / or Agar Gel Immunodiffusion (AGID) etc. A definite titre increase in the IFAT or AGID is indicative for an ongoing Brucellosis.

Negative test result
- Dog had no contact with *Brucella canis*.
- Early brucellosis infection stage (< 2–4 weeks post infection!). Dog has not yet produced antibodies in a detectable concentration.
- In chronic infected animals, antibody titres cannot always be detected by single testing. Therefore, breeding dogs should be serologically tested routinely (multiple testing) to minimize the danger of venereal propagation of the pathogen.