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*FAST*est® CRP canine

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***In vitro* diagnosticum**

Test-kit for the qualitative detection of C-reactive protein (CRP) 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® CRP** canine contains:
- 2, 10 or 25 test cassettes coated with monoclonal antibodies
- 2, 10 or 25 dropper bottles **A** with 2.0 ml buffer diluent each
- 2, 10 or 25 disposable plastic pipettes (5 µl)
- 2, 10 or 25 disposable plastic pipettes (10 µl)
- 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 96 % – Specificity 81 % (Plasma/serum)
Sensitivity 95 % – Specificity 94 % (Whole blood)
(Comparison Method: ELISA)

2. INTRODUCTION

As response to tissue injury and inflammation, the body produces, among others, so-called acute-phase proteins (APP) in the liver. The C-reactive protein (CRP) is the most sensitive and fastest acute-phase protein of the dog, with low serum concentrations during normal homeostasis and a quick answer during and after inflammation. The function of CRP is, among others, stimulation of the unspecific immune defence by activation of scavenger cells and the complement cascade.

The measurement of CRP in dogs is useful for the diagnostics and follow-up of inflammatory diseases. In healthy dogs, there is a low CRP level below 10 mg/l. A drastic increase in the CRP level occurs on inflammatory processes within few hours (Ø 24–28 h by a factor of 10 to 100) due to infections, immune disorders, neoplasia and traumata. As soon as the inflammation subsides through a successful therapy, the CRP level decreases rapidly within Ø 24–28 h. Therefore CRP can be regarded as a real-time marker. Indicating inflammations, CRP is more sensitive than the determination of rectal temperature or leucocyte differential diagnostics. Another advantage of CRP determination is its independence to endogeneous or iatrogenic disturbing factors (e. g. glucocorticoids, stress).

***FAST*est® CRP** canine is a lateral flow immunoassay using highly specific monoclonal antibodies against dog CRP. It can be used with whole blood, plasma or serum of dogs for in-clinic and/or laboratory testing.

With the help of ***FAST*est® CRP** canine, the veterinarian is enabled to prove (positive ***FAST*est® CRP** canine: CRP ≥ 10 mg/l) or rule out (negative ***FAST*est® CRP** canine: CRP < 10 mg/l) the suspicion of an inflammatory event on-site and without technical equipment.

3. INFORMATION ON THE SPECIMEN MATERIAL

Exactly 10 µl (of attached plastic pipette) 15–25 °C warm whole blood (WB, with anticoagulant) or **exactly 5 µl 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 48 hours. **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, 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. **Adjust the stop watch to an incubation time of 5 minutes.**

2a. **EDTA/heparin whole blood**:
10 µl sample volume / short plastic pipette (fig.1a)

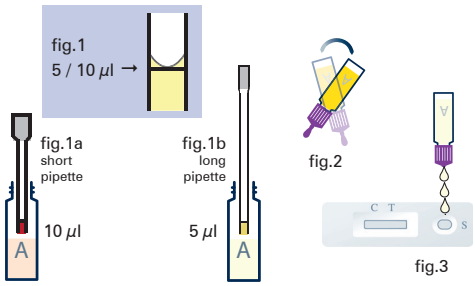
2b. **Plasma or serum**:
5 µl sample volume / long plastic pipette (fig.1b)

2c. Draw sample **up to the mark** using the respective disposable plastic pipette. **The meniscus must be above the black line (fig.1).** Place the **whole sample volume into the dropper bottle A** (hold pipette vertically, fig.1a/b).

2d. Mix the sample-buffer mixture (SBM) thoroughly (fig.2).

3. Break the tip of the dropper bottle **A**, hold the dropper bottle **A** vertically, discard the first drop and add **3 drops (100 µl) SBM** into the sample window S of the test cassette (fig.3).

4. Start the stopwatch that is adjusted to 5 minutes.



6. READING OF THE TEST RESULT

Read the test result after an incubation time of **EXACTLY 5 minutes**. After this time, the test result can no longer be interpreted.

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 plastic pipette, a new dropper bottle **A** and a new test cassette for each sample.
- Take the required sample volume (**10 µl anticoagulated whole blood** or **5 µl plasma or serum**) only with the attached plastic pipettes or with a calibrated laboratory pipette.
- 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® CRP** canine is based on an immunochromatographic "sandwich principle".

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

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

The intensity of the TEST line will increase during incubation time and is directly proportional to the CRP concentration of the sample.

9. INFORMATION FOR THE INTERPRETATION

- **Negative: < 10 mg/l** ← Cut-off → **Positive: ≥ 10 mg/l**
- **The incubation time or reading time of exactly 5 minutes is essential.**
- 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 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 worse to not visible.
- Wrong handling or wrong interpretation of the test could have a negative effect on the significance of the test and/or make the results inconclusive.