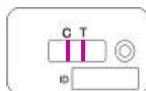


8. INTERPRETATION OF TEST RESULTS

Colour intensity of the test line will increase during incubation time and is directly proportional to CRP concentration in the sample



Positive Test result: 2 lines visible: “C” + “T”

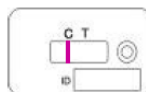
If a weak to strong and clearly signed pink/purple TEST line (T) and a clearly signed pink/purple CONTROL line (C) is shown, the test indicates the presence of CRP level > 5 mg/L.

⇒ **High likelihood for a positive inflammatory status**

Negative Test result: “1 line visible: C”

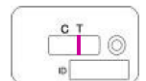
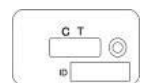
If only a weak to strong and clearly signed pink/purple CONTROL line (C) is shown, the test indicates the presence of CRP level < 5 mg/L.

⇒ **High likelihood for a negative inflammatory status**



Inconclusive Test result: “only T line” or “no line visible”

In case of only one weak to strong and clearly signed pink/purple line in the TEST zone (T) or no pink/purple line neither in the TEST zone (T) nor in the CONTROL zone (C) the test is not valid signifying that the test must be repeated using a new test cassette.



IMPORTANT INFORMATION:

- Wrong handling or wrong Interpretation of the test could have a negative effect of the significance of the test and/or make the results inconclusive.
- To avoid false results the test results should be read at **5 minutes exactly!**
- All test results should be interpreted in the context of all available case history and clinical information for the dog being tested.

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.

FASTest[®] CRP canine ad us.vet.

IN VITRO DIAGNOSTICUM

Test-Kit for the detection of C-Reactive-Protein (CRP)
in Dog's anticoagulated Whole Blood, Serum or Plasma

INSTRUCTIONS FOR USE

DIAGNOSTIK
MEGACOR

A-6912 Hörbranz
www.megacor.com

1.INTRODUCTION

FASTest[®] CRP canine is a rapid test based on rapid immunochromatography technique (“lateral flow”) for the detection of C-Reactive-Protein (CRP) in **dog's anticoagulated whole blood, serum or plasma** using high specific monoclonal antibodies. Based on a fast, simple and reliable test procedure showing the test results after 5 minutes at the latest, the **FASTest[®] CRP canine** is a very reliable screening test to differentiate between normal and pathologic increased CRP levels under in-clinic conditions.

Several studies identify canine serum C-Reactive-Protein (CRP), produced in the hepatocytes, as one of the major acute phase proteins in dogs involved especially in acute inflammatory processes. The CRP level in dogs with inflammation resp. infection (e.g. pyometra, systemic leishmaniosis, septic pneumonia etc.) are significantly higher than dogs with various other diseases (e.g. neoplastic disease, endocrine/metabolic disorders, miscellaneous like e.g. heart insufficiency etc.) and in clinically healthy dogs. During an acute phase response CRP could raise within 4 hours following onset of the initial stimulus to detectable concentrations, with highest levels 24 hours later. In untreated animals or animals developing a secondary stimulus the raised CRP level could be raised up for longer. Therefore the measurement of CRP at dogs seems to reflect the severity of the underlying disease activity, which together with dynamic changes (fast increase after stimuli, decrease after ended inflammatory stimuli) can make CRP determination a useful diagnostic tool in differentiating dogs suffering from infectious, from dogs suffering from infections (neoplastic disease, endocrine/metabolic disorders) and healthy dogs.

2. TEST PRINCIPLE

In case of presence of significant amounts of CRP in the anticoagulated whole blood, serum/plasma, CRP molecules will bind to a high specific anti-CRP monoclonal antibodies bonded to colloidal gold particles. As this complex migrates along the TEST zone (T) it will be captured by the second immobilised antibody forming a more or less (depending on the CRP concentration) pink/purple coloured band. Besides this other complexes migrates further on to the CONTROL zone (C) where they will be captured too by the second monoclonal antibody forming also a pink/purple coloured line. This indicates a proper performance of the test.

Colour intensity of the test line will increase during incubation time and is directly proportional to CRP concentration in the sample:

Negative: < 5 mg/l <- Cut-off -> Positive: ≥ 5 mg/l

3. TEST KIT COMPONENTS

1 Testkit **FASTest®** CRP canine contains:

- 1 x 2/10/25 **FASTest®** CRP cassettes coated with specific CRP binding protein
- 1 x 2/10/25 disposable inoculating loops (5 µl)
- 1 x 1 dropper bottle **A** containing 1,5/3,0 ml buffer diluent
- 1 x Instructions for use

4. STORAGE AND SHELF LIFE

- Store test kit at room temperature (15-25°C)
- When stored correctly the product can be kept up to expiry date.
- Avoid excessive heat or cold: **DO NOT FREEZE!**

5. INFORMATION ON TEST SAMPLE MATERIAL

- All test components / samples has to be allowed to warm to room temperature (15 to 25°C)
- Take required sample volume (**5µl for Sera/Plasma** or **10µl for antianticoagulated whole blood**) only with the enclosed inoculating tube or with a calibrated laboratory pipette.
- **Incomplete filled and/or insufficient mixed EDTA, citrate, heparin tubes** could raise not visible **micro blood-clots** resulting as well in **lateral flow delay** and/or **unspecific reactions** (e.g. greyish shadow like lines in the TEST zone).
- **Not cooled samples (15-25°C)** could be stored up to 4 hours prior to testing! Short term storage up to 24 hours at **2-8°C**, long term storage (plasma/serum) at min. **-20°C** for an undefined time

6. SPECIAL INFORMATION

• **FOR VETERINARY USE ONLY.**

- The **FASTest® CRP** canine can be used for dogs only.
- Do not remove any test components (room temperature!) from their individually sealed pouches until immediately before their use.
- Do not use test-kit components from different kits, lot numbers or beyond the stated expiration date.
- The buffer diluent contains low concentration of toxic sodium azide as a preservative, therefore avoid skin contact and/or ingestion.
- Follow instructions for use precisely.

7. TEST PROCEDURE

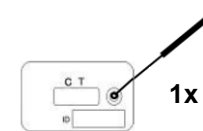
7.1 Remove the Test cassette from the foil pouch, label it with a patient name or ID number and make sure that the Test cassette is on a level surface.

7.2 Mix the sample well and dip the round end of the disposable inoculating loop.

7.2.1 Sera or Plasma: 5 µl volume

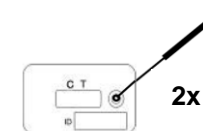
Dip the loop completely for one time and excerpt it. If handling is correct, there has to be a liquid film in the loop (volume 5µl). Press the loop into the **SAMPLE** window in a plain and soft way.

The liquid film will be absorbed of the suction membrane and the loop will be blank.

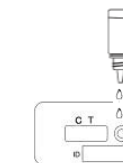


7.2.2 EDTA-/HEPARIN-Whole blood: 10µl volume

For getting a sample volume of 10µl repeat step **7.2.1** twice!



7.3 Hold the Dropper bottle vertically and express **2 drops (approx. 80 µl) of buffer diluent** into the **round SAMPLE window** of the **cassette**



7.4 The result has to be read within **5 minutes EXACTLY!** Use of a **timekeeper** is suggested! Any coloured line, which is seen after 5 minutes, has no diagnostically relevance.

