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*FAST*est® FIP

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***In vitro* diagnosticum**

Test-kit for the qualitative detection of antibodies against the Feline Coronavirus (FCoV) in whole blood, plasma, serum and effusion of cats

INSTRUCTIONS FOR USE

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DIAGNOSTIK MEGACOR
6912 Hörbranz – AUSTRIA
www.megacor.com

1. INFORMATION ON THE TEST-KIT

TEST-KIT COMPONENTS

1 test-kit ***FAST*est® FIP** contains:
- 2, 10 or 25 test cassettes coated with recombinant FCoV antigens
- 1 dropper bottle **A** with 1.0 ml, 3.0 ml or 7.5 ml buffer diluent
- 2, 10 or 25 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 97.4 % – Specificity 94.6 %
(Comparison Method: IFAT)

2. INTRODUCTION

Feline infectious peritonitis (FIP) is a world-wide spread chronic progressive virus infection, often with a fatal end.

To latest studies, FIP is not an infection transmitted from cat to cat. FIP occurs sporadic in domestic cats and wildcats infected oronasally with the apathogenic Feline Coronavirus (FCoV). Probably due to stress, the apathogenic FCoV mutates into the pathogenic FIP virus. FCoV antibody prevalences vary depending to the way of housing: in cat breedings with multiple cat households from 50 % up to 80 %, in private households only 15 %.

Clinically, FIP varies due to progression and manifestation in organs. Usually there is a smooth transition between the FIP forms, so FIP can be more "wet" or more "effusive". Therefore, all cats showing unclear symptoms like recurrent fever resistant of antibiotic therapy, unclear organ alterations, chronic weight loss, pleural and/or peritoneal effusion should be considered as suspicious for FIP.

Due to the fact that actually no test method exists which can differentiate between FIP virus and FCoV, FCoV antibody detection is a very important diagnostic tool. Healthy cats with a negative antibody test are most likely neither carriers nor excretors of FCoV. Therefore, ***FAST*est® FIP**, based on highly specific and recombinant FCoV antigens, is an optimal screening test for the reliable detection of FCoV antibodies in whole blood, plasma, serum and effusion of the cat.

3. INFORMATION ON THE SPECIMEN MATERIAL

Approximately **40–50 µl (1 drop of attached plastic pipette) 15–25 °C warm whole blood (WB**, with anticoagulant**), plasma (P), serum (S) or effusion material (E; pleural/peritoneal effusion)** are needed. **Native blood without anticoagulant must 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**), E should be tested immediately. If this is not possible, E should be tested within 4 hours, similarly to WB, P and S. At **2–8 °C**, WB, P and S (not E!) can be stored up to 4 days. **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, CRP, heterophilic antibodies, especially type IgA, and/or 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. Discard the first drop of the sample! Take the disposable plastic pipette (**not directly from the needle!**) and express **1 drop (ca. 40–50 µl) of the sample** 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 1–2 additional drops of buffer diluent into the sample window A if there is no beginning LF visible within 1 minute after adding the buffer diluent.

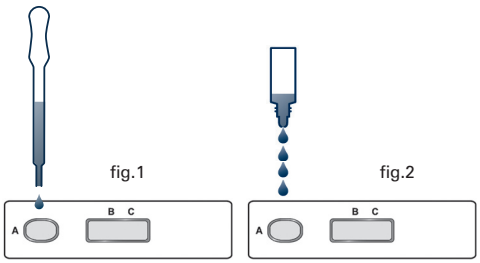


fig.1

fig.2

6. READING OF THE TEST RESULT

Read the test result after an incubation time of

Whole blood, plasma and serum

15 minutes

Effusion

30 minutes

after the four drops of buffer diluent have been added into the sample window A.

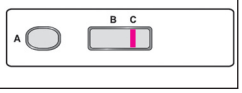
POSITIVE TEST RESULT (fig.3)
A pink-purple TEST line **of any intensity** (varying from very weak to strongly intensive) and a pink-purple CONTROL line appear.

NEGATIVE TEST RESULT (fig.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® FIP** is based on an immunochromatographic "sandwich principle" technique.

The antibodies against FCoV present in the sample will react in the conjugate pad with mobile antibodies, which are conjugated to colloidal gold particles. These antibody complexes are migrating ("lateral flow", **LF**) along the nitrocellulose membrane and bind to fixed recombinant FCoV 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) appearing within the incubation time or after more than 20 minutes (effusion: 40 minutes) has to be considered as unspecific reaction and therefore as negative test result.
- Due to concentration of FCoV antibodies, positive test results may be observed within the indicated incubation period.
- B can vary both in intensity (from weak to intense pink-purple) and width. Therefore, any pink-purple line appearing within the required incubation time is to be interpreted as a positive test result.
- Due to anticoagulated whole blood and/or red hemoglobin background of the test membrane caused by hemolysed blood samples, the visibility of B, especially in case of weak positive samples, could be from worse to not visible.
- **There is still no possibility to discriminate between the "harmless" FCoV strains and the FIP producing FIPV mutants of FCoV. A positive test result shows only that the infection has taken place (or even is still going on) with FCoV. Each seropositive cat could die of a FIP infection regardless of the detected antibody titre, but must not take place stringently.**

The diagnosis "FIP" must always be based on anamnesis and clinical signs. The detection of anti-FCoV antibodies using the *FAST*est® FIP is only one additional, but important diagnostic tool for

- **the identification of infected cats**
- **controlling the FCoV-free status in cat kennels, animal shelters**
- **controlling a single cat before its integration in an antibody-free cat group**
- **controlling the FCoV-free status before a FIP-vaccination**

A **positive *FAST*est® FIP** indicates
- a cat with a FIP infection
- a cat infected with an apathogen FCoV (eliminator)
- a cat which has been infected with FCoV, has eliminated the virus but still shows FCoV antibodies
- a cat vaccinated against FIP*

* Due to vaccine producers, cats being FIP vaccinated normally show a negative ***FAST*est® FIP** test result, because a commercial FIP vaccine normally stimulates only a local IgA response and a cellular immunity. In rare cases, the FIP vaccination could induce a low production of antibodies and therefore a positive ***FAST*est® FIP** test result.

A **negative *FAST*est® FIP** indicates
- a cat with no FIP or no present FCoV-infection
- a diseased cat, showing clinical signs of FIP or FCoV (e.g. due to final FIP stage: binding of all antibodies in antigen-antibody complexes)