Version 07/2024

Click Here For More Information About

*FAST*est® FCoV Strip

ad us. vet.

***In vitro* diagnosticum**

Test-kit for the qualitative detection of Feline Coronavirus (FCoV) antigens in feces of the cat

INSTRUCTIONS FOR USE

Supplied Exclusively To The UK Veterinary Market By
Vetlab Supplies Ltd
Visit Our Website
www.vetlabsupplies.co.uk
Telephone: 01798 874567
email us: info@vetlabsupplies.co.uk

Manufacturer:
DIAGNOSTIK MEGACOR
6912 Hörbranz – AUSTRIA
www.megacor.com

1. INFORMATION ON THE TEST-KIT

TEST-KIT COMPONENTS

1 test-kit ***FAST*est® FCoV** Strip contains:
- 2 or 10 dipsticks coated with monoclonal antibodies
- 2 or 10 sample tubes with 2.0 ml buffer diluent each
- 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

TL – TEST line, **CL** – 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 100 %
Specificity 97.5 %
(Comparison Method: ELISA)

2. INTRODUCTION

Feline Coronavirus (FCoV) is a world-wide virus in domestic and wild cats occasionally causing a chronic progredient and often fatal FIP virus infection. Based on the latest scientific knowledge, a FIP infection is not transmitted from one cat to another. FIP occurs sporadic in cats infected oronasal by an apathogen variant of Feline Coronavirus (FCoV) which has mutated stress-related into a pathogen FCoV variant (FIPV).

Like FCoV antibody prevalence, also FCoV antigen shedding rates vary considerably depending on the way of housing. Multiple cat households with more than 3 cats and use of common cat litter boxes show highest prevalence. In such conditions, FCoV can be infectious up to 7 weeks. Main source of infection is FCoV infected feces.

The clinical symptoms of a FIP infection vary due to pathogenic form and manifestation of organs. The transitions between the various forms are, however, fluent. Therefore, a FIP infection could show more effusive ("wet") FIP or non-effusive ("dry") FIP. Therefore, all cats showing diffuse clinical symptoms like antibiotic resistant recurring fever, unclear different organ lesions, chronic weight loss, pleural and/or peritoneal effusions should be considered as "suspicious for FIP".

Studies proved the correlation between level of antibody titre and virus shedding rate. Although cats suffering of a manifest FIP could shed less FCoV, asymptomatic cats can shed FCoV over months via feces while other cats of the same household shed only occasionally or over weeks no virus. However, chronic shedders could shed a million times more FCoV as accidental shedders. Therefore the risk of infection and, associated therewith, the individual virus load leads to a higher FCoV mutation rate and to a higher likelihood developing a FIP infection.

FCoV infection of a breeding population could be rarely avoided with a reasonable effort. Therefore, all rehabilitation of the breeding population should concentrate on enhancing the amount of virus load and antibody status to reduce the infection risk as much as possible within this cat population.

Monitoring FCoV shedding (optimal: 5 consecutive tests at weekly intervals) using ***FAST*est® FCoV** Strip will help to detect easily and on-site asymptomatic chronic shedders and to immediately start separation and prophylaxis measures.

3. INFORMATION ON THE SPECIMEN MATERIAL

Due to the normally inhomogeneous or nest-like dissemination of antigens in the feces, the specimen material has to be mixed up homogeneously (spatula, vortex-mixer) before sampling.

For the test, the required amount of feces as described in issue 4b/Specimen collection and preparation, is needed. The amount depends on the consistency of the sample. Use the attached spoon.

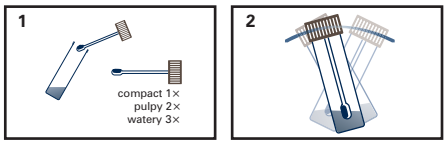
Non-cooled (**15–25 °C**), the sample should be tested within 4 hours! At **2–8 °C**, the sample can be stored up to 4 days, permanently **at minimum −20 °C**.

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. proteases, mucosa components, blood, but also viscosity, pH-value as well as grass and cat litter) **can cause interferences** (matrix effects) **that can influence the target measurement. These can lead to an impaired LF and/or unspecific reactions on the TL and CL.**

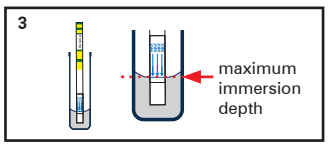
4. SPECIMEN COLLECTION AND PREPARATION

a. Open the sample tube with the buffer diluent.
b. Mix the feces sample homogeneously (applicator, vortexer). Then mix the required sample volume (**compact: 1 level spoon, pulpy: 2 level spoons, fluid-watery: 3 level spoons of feces**) steadily into the buffer diluent (fig.1).
c. Close sample tube tightly and rotate it easily to get the mixture as homogeneous as possible (fig.2).
d. For sedimentation of gross feces particles place the sample tube on a flat and horizontal surface for 1–5 minutes.



5. TEST PROCEDURE

1. Remove the dipstick from its foil pouch shortly before use.
2. Introduce the dipstick vertically and with the arrows pointing downwards into the sample tube for at least 1 minute. The liquid level (meniscus!) must not exceed the blue horizontal line below the blue arrowheads (fig.3).
3. Remove the dipstick from sample tube soonest the sample-buffer mixture (SBM) has reached the CL. If so, the pink-purple CL will appear slowly but surely (fig.4/5). If the CL will not appear after 5–10 minutes, a new SBM must be prepared and sedimented for at least 5 minutes. The dipstick must be held only in the supernatant until the LF has reached the CL (see also 7. Precautions for users*).
4. Place the dipstick on a flat and horizontal surface for incubation.



6. READING OF THE TEST RESULT

5 min

Read the test result after **5 (max. 10) minutes**. Positive test results may be observed earlier, depending on the concentration of antigen in the sample.

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 dipstick *.

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 sample tube to ensure a precise assignment.
- Use a new sample tube and a new dipstick 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.

* To avoid an application error/external influence (e.g. too much sample material, too short sedimentation time, components in the faeces that clog the pores of the suction pad), the test can be repeated. Use a new dipstick and carefully observe the sample preparation. It is advisable to only hold the dipstick in the supernatant when repeating the test until the LF has reached the CL.

8. TEST PRINCIPLE

The ***FAST*est® FCoV** Strip is based on an immunochromatographic "sandwich principle".

The FCoV antigens present in the feces sample will react in the conjugate pad with mobile monoclonal anti-FCoV antibodies (anti-FCoV mAb) which are bound to gold particles. Migrating ("lateral flow", **LF**) along the nitrocellulose membrane, these specific antigen-antibody complexes are bound by membrane-fixed monoclonal anti-FCoV mAbs producing a pink-purple TEST line (**TL**).

These mAbs guarantee a high level of specificity for the aetiologic detection of FCoV antigen only. The intensity of the TEST line or its width depends on the concentration of FCoV antigens in the tested sample.

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

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 TL and CL within the indicated incubation time or after more than 10 minutes (e.g. greyish, shadow-like lines) has to be considered as unspecific reaction and therefore as negative test result.
- TL 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.
- A single negative test result does not exclude a persisting FCoV infection, because FCoV shedding is not continuous and/or the FCoV concentration in the examined sample is below the detection limit of the test. To reliably identify chronic shedders, ideally 5 tests in weekly intervals should be done. After 3 negative tests, for the last two tests, collection samples (individual testing of at least three consecutive feces samples) should be preferred to single samples.