Version 04/2023

Click Here For More Information About

*FAST*est® FIV

ad us. vet.

***In vitro* diagnosticum**

Test-kit for the qualitative detection of antibodies against the Feline Immunodeficiency Virus (FIV) in whole blood, plasma or serum of the cat

INSTRUCTIONS FOR USE

Vetlab Supplies
Specialists in Veterinary Laboratory Supplies

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® FIV** contains:
- 2*, 10** or 25*** test cassettes, coated with recombinant 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

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 96,4 % – Specificity 99,2 %
(Comparison Method: Westernblot)

2. INTRODUCTION

The Feline Acquired Immunodeficiency Syndrome (FAIDS), caused by the Feline Immunodeficiency Virus (FIV), is distributed world-wide in felids. Prevalences can vary in a wide range due to keeping conditions (stray cats, day release cats) from 2–3 % in Germany up to over 30 % in Italy and 44 % in Japan.

Infection with FIV containing body fluids, blood or blood components normally goes parenteral (through bite injuries, blood transfusions, mating with following neck bite) as well as by transplacental and perinatal transmission into the blood of healthy cats. Free-roaming tomcats with strong territorial behaviour are regarded as "risk animals" with significantly higher infection rates.

The initial stage of infection (enlarged lymph nodes, pyrexia, neutropenia etc.) often remains unnoticed. The following lag period usually is asymptomatic over years. Only then, first specific symptoms become apparent, predominantly caused by the diverse secondary symptoms (e. g. stomatitis, tumour diseases, anaemia and leukopenia), to a lesser extent by the virus itself (e. g. neurological symptoms, lymphomas).

Due to the more or less asymptomatic initial phase and latent period and the fact that nearly 95 % of the FIV infected cats show high FIV antibody levels 4 weeks post infection, the detection of FIV antibodies plays an important role as routine method of choice for the diagnosis of a potential FIV infection.

Based on highly specific, recombinant FIV antigens, ***FAST*est® FIV** is an important diagnostic tool for the diagnostic evaluation of clinical as well as anamnestic FIV suspicious cats.

3. INFORMATION ON THE SPECIMEN MATERIAL

Exactly 20 µl (of attached plastic pipette) 15–25 °C warm whole blood (WB, with anticoagulant**), plasma (P) or serum (S)** are needed. **Native blood without any anticoagulant must be avoided due to the potential risk of microclots** (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. **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, 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. Draw sample **up to the mark (≙ 20 µl sample volume)** using the disposable plastic pipette. **The meniscus must be above the black line** (fig.1).
3. Place the whole sample volume **(20 µl) into the sample window S** of the test cassette (hold pipette vertically, fig.2).
4. Hold the dropper bottle **A** vertically and place **2 drops (ca. 80–100 µl) of the buffer diluent** into the sample window S of the test cassette (fig.3).
5. 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.

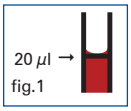

fig.1

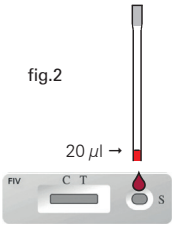

fig.2

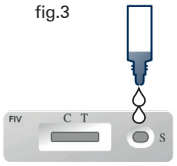

fig.3

6. READING OF THE TEST RESULT

Read the test result **10 minutes** after the two drops have been added into the sample window S. Beyond this time, test results should not 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 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® FIV** is based on an immunochromatographic "sandwich principle" technique detecting anti-FIV antibodies in the whole blood, plasma or serum of the cat.

The antibodies against FIV present in the sample will react in the conjgatd pad with mobile antigens conjugated to colloidal gold particles. These Ag-Ab-complexes are migrating ("lateral flow", **LF**) along the nitrocellulose membrane and bind to membrane-fixed recombinant FIV antigens, forming a pink-purple TEST line **T**.

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

* ***FAST*est® FIV** remains negative in the event of an FIV vaccination and corresponding vaccine-related antibody formation. ***FAST*est® FIV** can therefore differentiate between antibodies caused by infection (positive test) and antibodies caused by vaccination (negative test).

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) has to be considered as unspecific reaction and therefore as negative test result.
- Positive test results may be observed even before the end of incubation. Beyond this time, test results should not be interpreted.
- Due to anticoagulated whole blood and / or red hemoglobin background of the test membrane, caused by hemolytic blood samples, the visibility of B, especially in case of weak positive samples, could be from worse to not visible.
- B can vary both in intensity (from weak to strong pink-purple) and in width. Therefore, any pink-purple line which appears within the required incubation time has to be interpreted as a positive test result.

***FAST*est® FIV = NEGATIVE**
➔ lack of FIV antibodies
– non-infected cat
– infected cat in initial phase of infection (absent titre increase Ø up to 4 weeks (ca. 95 %), but also up to 1 year post infection)
– cat in terminal phase (inadequate antibody production ➔ concentration below detection limit of the test).
– FIV vaccinated cat *

***FAST*est® FIV = single POSITIVE**
➔ presence of FIV antibodies
– infected, viraemic cat (> 6 months)
– kitten younger than 6 months (maternal antibodies!)