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*FAST*est® FeLV-FIV

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***In vitro* diagnosticum**

Test-kit for the qualitative detection of Feline Leukaemia Virus (FeLV) antigens and / or Feline Immunodeficiency Virus (FIV) antibodies in whole blood, plasma or serum of the cat

INSTRUCTIONS FOR USE

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1. INFORMATION ON THE TEST-KIT

TEST-KIT COMPONENTS

1 test-kit ***FAST*est® FeLV-FIV** contains:
- 2*, 6**, 15***, 25*** or 50**** twin test cassettes, coated with monoclonal FeLV antibodies or recombinant FIV proteins
- 1 dropper bottle **A** with *1.0 ml, **3.0 ml, ***7.5 ml or ****2 dropper bottles **A** with 7.5 ml buffer diluent
- 2, 6, 15, 25 or 50 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

FeLV: Sensitivity 95,0 % – Specificity 99.0 %
FIV: Sensitivity 96.4 % – Specificity 99.2 %
(Comparison Method: Westernblot, ELISA)

2. INTRODUCTION

The Feline Leukaemia Virus (FeLV) as well as the Feline Immunodeficiency Virus (FIV) occur world-wide in felids. Prevalences in Germany range from 2 % (FeLV) to 2–3 % (FIV).

Both diseases cause similar clinical symptoms in infected cats due to their immunosuppressive effects. FeLV antigen or FIV antibody detection are proven to be the diagnostic method of choice confirming a FeLV or FIV infection, respectively.

FeLV infected, viraemic cats normally show high concentrations of extracellular (free) FeLV antigen 3 weeks post infection. About 95 % of the FIV infected cats show high FIV antibody concentrations approximately 4 weeks post infection.

Based on highly specific monoclonal FeLV antibodies and recombinant FIV proteins, respectively, ***FAST*est® FeLV-FIV** is an important diagnostic tool for the evaluation of clinically 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)** per test cassette are needed. **Native blood without any anticoagulant must not be used 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 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 twin 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 FeLV test cassette (hold pipette vertically, fig.2). **Repeat the whole procedure with the same pipette for the FIV test cassette.**
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 FeLV and the FIV 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.

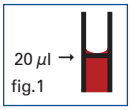
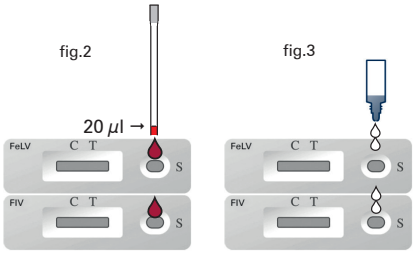


fig.1



6. READING OF THE TEST RESULT

10 min

Read the test result **10 minutes, maximum 15 minutes** after the 2 drops of buffer diluent have been added into the sample window S.

POSITIVE FeLV and / or FIV TEST RESULT (fig.4–6)
A pink-purple TEST line **of any intensity** (varying from very weak to stronly intensive) and a pink-purple CONTROL line appear.

NEGATIVE TEST RESULT (fig.5–7)
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 twin test cassette.

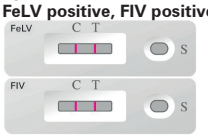


fig.4
FeLV positive, FIV positive

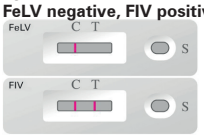


fig.5
FeLV negative, FIV positive

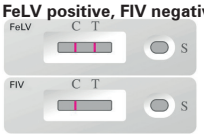


fig.6
FeLV positive, FIV negative

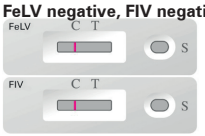


fig.7
FeLV negative, FIV negative

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 twin test cassette to ensure a precise assignment.
- Use a new pipette for each twin test cassette.
- 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® FeLV-FIV** is based on an immunochromatographic "sandwich principle" technique.

Extracellular FeLV antigens and / or antibodies against FIV present in the sample react in the conjugate pad with mobile monoclonal antibodies, which are conjugated to colloidal gold particles. These antigen-antibody complexes are migrating along the nitrocellulose membrane ("lateral flow", **LF**), and bind to fixed monoclonal antibodies against FeLV or recombinant FIV antigens, respectively, forming a pink-purple TEST line (**T**).

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 T and C (e. g. greyish, shadow-like lines) has to be considered as unspecific reactions 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 T, especially in case of weak positive samples, could be from worse to not visible.
- T 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.
- **Neither maternal antibodies nor a FeLV vaccination influence the test result of the *FAST*est® FeLV, because it is an FeLV antigen test!**
- ***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).**
- Kittens up to an age of 6 months may show a positive FIV test result due to the existence of maternal antibodies.

*FAST*est® FeLV

***FAST*est® FeLV = NEGATIVE → no viraemia**
– non-infected cat (approx. 95 %)
– latent infected cat (no antigen detectable)
– test in the first 4 weeks post infection

***FAST*est® FeLV = first time POSITIVE → suspicion of viraemia**
– transiently or persistently infected cat
ADVICE: test repetition after 4–8 weeks.

***FAST*est® FeLV = second time POSITIVE → viraemia**
→ distinction transient or persistent viraemia
→ 3rd test after 6 weeks
→ 4th test after another 10 weeks

- **cat still positive →** suspicious for **persistent** viraemia **→ "progressor cat"** with high risk developing FeLV or FIV associated diseases.
- **cat becomes negative →** suspicion of **transient** viraemia **→ "regressor cat"** (complete virus elimination, healthy) **→ latent infection** (integrated provirus in the bone marrow)

*FAST*est® FIV

***FAST*est® FIV = NEGATIVE**
→ lack of FIV antibodies
– non-infected cat
– infected cat in initial phase (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).
– FIV vaccinated cat

***FAST*est® FIV = 1st time POSITIVE**
→ presence of FIV antibodies
– infected, viraemic cat (> 6 months)
– kitten younger than 6 months (maternal antibodies!)