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In vitro diagnosticum

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

INSTRUCTIONS FOR USE



tion)!

at minimum -20°C.

ture at the time of application.

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:



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 reac-

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

Keep in mind that the sample material, as well as all used

test-kit components, should have reached room tempera-

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

4. SPECIMEN COLLECTION AND PREPARATION

ATTENTION: Partially filled and/or insufficient mixed

EDTA, Citrate or Heparin tubes could create invisible microclots resulting in lateral flow delay and/or unspecific

Mix the sample material well before use!

and/or unspecific reactions on T and C.

· No specimen preparation necessary.

reactions (e.g. greyish shadow like lines).

1. INFORMATION ON THE TEST-KIT

TEST-KIT COMPONENTS

1 test-kit FASTest® FeLV contains:

- 2*, 10**, 25*** or 50**** test cassettes, coated with monoclonal antibodies
- 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, 10, 25 or 50 disposable plastic pipettes
- 1 instructions for use

STABILITY AND STORAGE Store at Expiry date 15-25°C - see label APPLICATION AND ABBREVIATIONS For veterinary use only LOT Lot number Do not use test-kit In vitro diagnosticum components from different kits, lot num-Follow instructions for bers or beyond stated i use precisely expiry date

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

Sensitivity 95 %

(Comparison Method: Electron microscopy, ELISA)

T - TEST line, C - CONTROL line, LF - Lateral flow

kind resulting from the use of this product.

1. Remove the test cassette from its foil pouch shortly be-

into the sample window S of the FeLV test cassette (hold

(ca. 80-100 µl) of the buffer diluent into the sample win-

ple window S if there is no beginning LF visible within

4. Hold the dropper bottle A vertically and place 2 drops

5. Add 1 additional drop of buffer diluent into the sam-

ACCURACY

Specificity 99 %

5. TEST PROCEDURE

fore use. Place it on a flat surface.

above the black line (fig.1).

dow S of the test cassette (fig.3).

pipette vertically, fig.2).

2. Draw sample up to the mark (≙ 20 µl

sample volume) using the disposable

plastic pipette. The meniscus must be

Place the whole sample volume (20 μ I)

1 minute after adding the buffer diluent.

6. READING OF THE TEST RESULT

ence the test result of the FASTest® FeLV.



diagnostics.

2. INTRODUCTION

plastic diseases in cats world-wide

anaemia and panleukopenia-like disease.

Feline Leukaemia Virus (FeLV) is a highly contagious onco-

genic RNA virus that causes both neoplastic and non-neo-

The infection with Feline Leukaemia Viruses is transmitted

most of all by secretions (e.g. saliva), excretions (e.g. feces, urine) as well as intrauterine by blood transfusion and via

colostrum. As Feline Leukaemia Viruses can survive in the

environment only for minutes, successful contamination only can happen during close contact to infected cats.

The course of an FeLV infection essentially depends on im-

mune status, age as well as infection dose and virulence of

the virus. Diseases caused by FeLV include lymphosarcoma,

myelogenous leukaemia, thymic atrophy, non-regenerative

Because FeLV is immunosuppressive, it predisposes infect-

ed cats to a variety of secondary diseases. FeLV infected,

viraemic cats normally show high concentrations of extra-

cellular (free) p27 antigen 3 weeks post infection. p27 an-

tigen detection is proved as the method of choice in FeLV

Based on highly specific monoclonal antibodies against p27

antigen, FASTest® FeLV is an important diagnostic tool for the evaluation of clinical suspicious cats (separation of FeLV

Neither maternal antibodies nor a FeLV vaccination influ-

carrier cats) and for FeLV check prior to vaccination.

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

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.

20 ul -



20 μl

fig.1

fia.4 POSITIVE TEST RESULT

fia.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 FASTest® FeLV is based on an immunochromatograph-"sandwich principle" technique for the detection of p27 FeLV antigen in the whole blood, plasma or serum of the cat.

Extracellular FeLV antigens (p27) in the whole blood, plasma or serum of the cat will build up specific antigen-antibody complexes at the conjugate pad zone. Migrating ("lateral flow", LF) along the nitrocellulose membrane, these complexes will be bound to fixed monoclonal p27 antibodies conjugated with gold particles, forming a pink-purple TEST line (T).

A correct test procedure will be indicated by a second, pinkpurple 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. grevish, shadow-like lines) has to be considered as unspecific reaction and therefore as negative test result.
- 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.

FASTest® FeLV = NEGATIVE → no viraemia

- non-infected cat (approx. 95 %)
- latent infected cat (no antigen detectable)
- test in the first 4 weeks post infection

FASTest® FeLV = first time POSITIVE → suspicion of viraemia

transiently or persistently infected cat

ADVICE: test repetition after 4-8 weeks. Isolation of the cat during this time is recommended (FeLV shedding!).

FASTest® 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 associated diseases.
- cat becomes negative → suspicion of transient viraemia
- "regressor cat" (complete virus elimination, healthy)
- → latent infection (integrated provirus in the bone mar-
- row)