

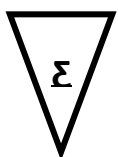
User's Manual

FeLV Virus Antigen & FIV Virus Antibody One-Step

For the detection of viral p27 antigen and FIV anti-p24 antibodies in serum or plasma samples of cats and other felids (e.g. cheetah, lion)



Fcombi 3+3



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January 2022

Please use only the valid version of the package insert provided with the kit.

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2. Introduction

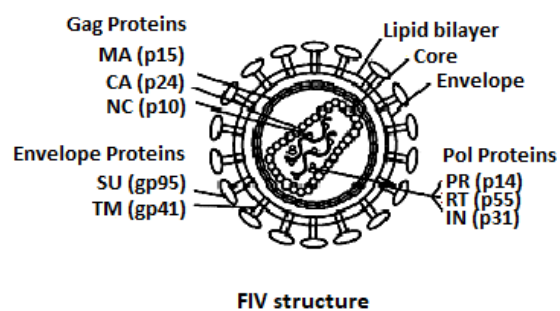
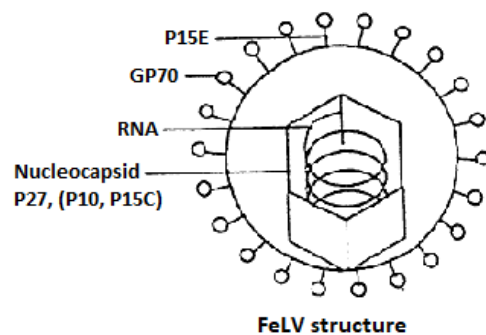
FeLV ag One-Step

FeLV is a retrovirus (oncogenic RNA virus) which causes persistent infection of domestic cats and other felids. Persistently infected cats shed the virus and invariably develop fatal diseases including Leukemia, Lymphosarcoma, Anaemia, Immuno-deficiency and Enteritis. Most cases of disease are found in cats aged 2-4 years old.

FeLV is shed in all body secretions (saliva/urine/tears/milk/faeces), but the virus is transmitted mainly by biting, mating, through the milk and in utero. Kittens under 3 months are very susceptible to infection, however susceptibility declines after 4 months of age. During the incubation period between infection and development of disease, persistently infected cats are healthy but are viraemic and therefore a source of infection for other cats. In Europe, approximately 1-5% of healthy cats are FeLV positive. With sick cats this proportion rises to around 20%.

The blood of FeLV infected cats contain high levels of FeLV p27, the major core protein of the virus (see diagram). The FeLV One-Step test rapidly and specifically detects the p27 antigen in the serum or plasma.

For this reason, the test is suitable for the detection of viraemic cats, both for the confirmation of diagnosis of disease and for the prevention of the spread of FeLV infection in households of cats.



FIV ab One-Step

FIV is a lentivirus that was discovered in 1986 by Dr. Nels Pedersen at the University of California. The virus has a world-wide distribution with a prevalence of around 5% in healthy cats. FIV is transmitting mainly by biting. It can also be transmitted from mother to kitten during the prenatal period.

The virus establishes a persistent infection from which cats usually recover. There follows an asymptomatic phase lasting several years in which the cat is clinically healthy. However, over time the immune function in the cat deteriorates and opportunistic infections (especially of the respiratory and gastrointestinal tracts, lymphomas or neurological disorders) arise.

Almost all cats infected with FIV have antibodies to viral structural proteins, particularly the envelope proteins (SU/TM) and the core proteins (p24/p17). Antibodies are first detected in serum 3-6 weeks after infection. Occasionally cats show an antibody response against a single envelope or core protein.

At the moment all attempts to develop a vaccine (until now, without success) are based on envelope proteins, in this way the detection of p24 antibodies is the only possibility to distinguish vaccinated cats from non-vaccinated cats in the future. Recent articles written indicate that the p24 response is significantly higher in clinical (reasonable) healthy cats (but FIV infected) which could mean that it can be monitored as illness progression protein.

3. Intended use of the test kit

This One-Step test is intended to use as practical/routine screening test that can be done in a few minutes. This test kit is designed to detect FeLV p27 antigen and FIV antibodies by use of a Rapid Immunochromatographic Assay.

4. Principle of the test kit

FeLV ag One-Step

The FeLV One-Step test is based on a chromatographic test strip, a monoclonal antibody and a polyclonal antibody which react with different epitopes of the FeLV p27 antigen. The polyclonal antibodies are conjugated to colloidal gold particles and the monoclonal antibody is immobilized on the strip in the test zone "T". FeLV p27 antigen in a sample that is applied to the strip at the sample zone "S" will bind to the gold particles which then migrate to zone "T". A colour change in zone "T" indicates a positive test.

Labelled colloidal gold particles are also immobilized on the test strip in the control zone "C", to indicate that the test is working properly.

FIV ab One-Step

The FIV One-Step test is based on the detection of anti-p24 antibodies since the p24 protein is essentially identical in all known strains of FIV.

P24 protein is conjugated to colloidal gold particles and the monoclonal antibody is immobilized on the strip in the test zone "T". FIV anti-p24 antibodies in a sample that is applied to the strip at the sample zone "S" will bind to the gold particles which then migrate to zone "T". A colour change in zone "T" indicates a positive test.

Labelled colloidal gold particles are also immobilized on the test strip in the control zone "C", to indicate that the test is working properly.

5. Contents

- 3 x Pouches, each containing 1 green FeLV test strip and 1 pipette
- 3 x Pouches, each containing 1 white FIV test strip and 1 pipette
- 2 x Dropper bottle containing buffer
- 1 x Protocol

6. Handling and storage of specimens

The One-Step should be stored at room temperature ($\pm 21^{\circ}\text{C}$). An unopened package can be used until the expiry date. An opened package must be used immediately. If the conditions are no longer fulfilled the test can no longer be used. Avoid freezing and heating as this will contribute to destruction of the test. Samples may be used fresh or may be kept frozen below -20°C before use.

7. Sample material

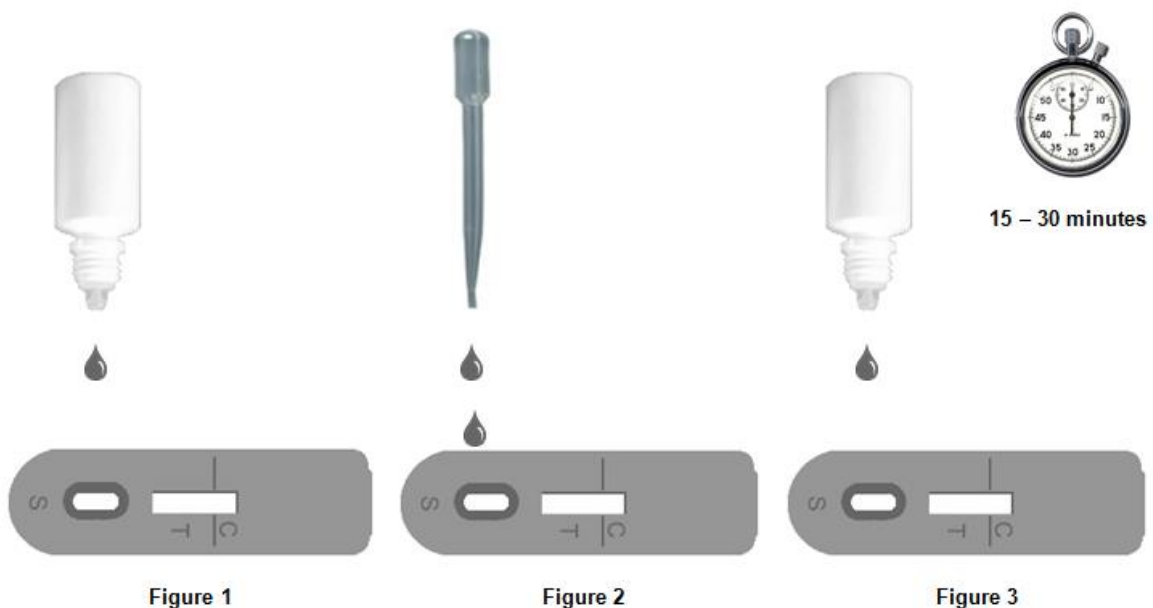
It is advised to test fresh serum or plasma samples. Do not use haemolytic or lipemic serum.

8. Precautions

- Handle all biological materials as though capable of transmitting infectious diseases.
- Do not pipette by mouth
- Do not eat, drink, smoke, prepare foods or apply cosmetics within the designated work area.
- Do not use components which passed the expiry date and do not mix components from different serials lots together.
- Optimal results will be obtained by strict adherence to this protocol. Careful pipetting and sampling throughout this procedure are necessary to maintain precision and accuracy.
- Each test strip is ultimately used as an optical reference. Therefore, do not touch the surface of the test strip and protect it from damage and dirt.

9. Test protocol

1. Unpack the FeLV and/or FIV test strip, swab and pipette. Only open the amount of pouches to be used. An opened package should be used immediately.
2. Add **1 drop** of buffer from the dropper bottle to the sample zone (Figure 1).
3. Add **2 drops** of the sample to the sample zone by using the pipette (Figure 2).
4. Add **1 drop** of buffer from the dropper bottle to the sample zone (Figure 3).
5. Read the result after 15-30 minutes (for the interpretation of the test result see chapter 10 and chapter 11).



10. Validation of the test

To validate an EVL One-Step a control line should always be visible at control zone “C”. If no control line is visible the test should be considered invalid.

Results should be read in the given time. Results read after the given time should be considered invalid. Invalid tests should be repeated with a new test.

11. Interpretation of the test results

Positive:

Two lines are visible in zone “T” and in zone “C” (Figure A). The sample contains FeLV p27 antigen / FIV anti-p24 antibodies.

Positive results may vary in optical density due to variations in viral concentrations in the sample.

Weak positive:

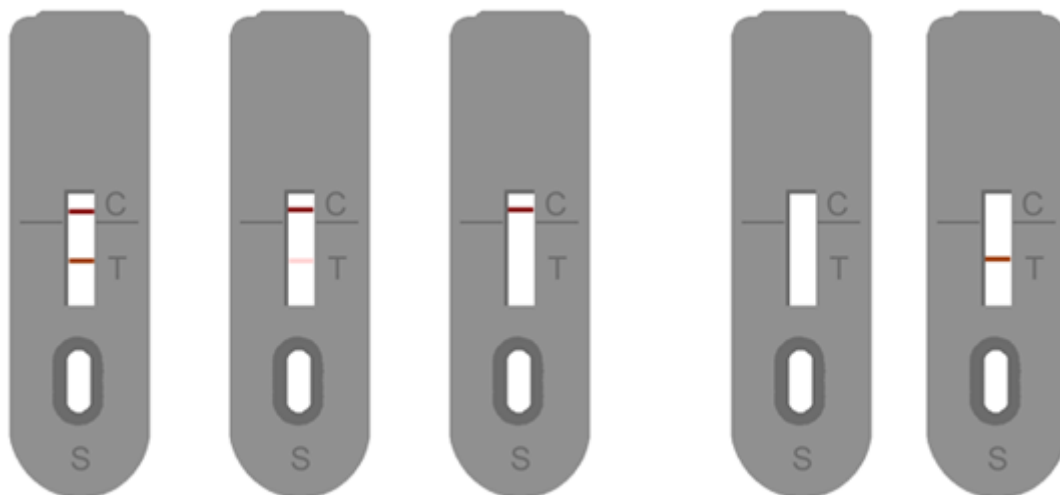
Two lines are visible, a weak line in zone “T” and a line in zone “C” (Figure B). The sample contains low concentrations of FeLV p27 antigen / FIV anti-p24 antibodies.

Negative:

Only one line is visible in zone “C” (Figure C). The sample does not contain FeLV p27 antigen / FIV anti-p24 antibodies.

Not valid:

No line is visible in zone “C” (fig. D). Repeat the test procedure with a new test cassette.



**Figure A:
Positive**











**Figure B:
Weak positive**

**Figure C:
Negative**

**Figure D:
Not Valid**



12. Symbols used with EVL ASSAYS

<u>Symbol</u>	<u>English</u>
	Consult instructions for use
	European Conformity
	In vitro diagnostic device
	For research use only
	Catalogue number
	Lot/ No. / Batch code
	Contains sufficient for <n> tests
	Storage Temperature
	Expiration Date
	Legal Manufacturer
Distributed by	Distributor
Content	Content
Volume/No.	Volume / No.

The entire risk as to the performance of these products is assumed by the purchaser. EVL shall not be liable for indirect, special or consequential damages of any kind resulting from use of the products. In case of problems or questions contact EVL.