

Revised 29 July 2010 rm (Vers. 1.1)**For Veterinary Use Only**

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

Introduction

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/feces), 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 figure). 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 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 transmitted 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

Intended use

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 FIV ab and FeLV ag by use of a Rapid Immunochromatic Assay.

Contents

- x pouches, each containing 1 x FIV test strip and 1 pipette
- 3 x pouches, each containing 1 x FeLV test strip and 1 pipette
- 1 x dropper bottle containing 3 ml buffer
- 1 x protocol

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Handling and storage of specimens

The One-Step should be stored at room temperature (+/- 21 °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 degradation of the test. Samples may be used fresh or may be kept frozen below -20°C before use.

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 serial 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.

Sample material

It is advised to test serum or plasma samples, tissue culture samples can also be tested. Do not use hemolytic or lipaemic serum.

Test protocol

Unpack the test strip and pipette. Only open the amount of pouches to be used. An opened package should be used immediately.

Add **2 drops** of serum/ plasma to the sample zone using the pipette (fig 1).

Add **2 drops** of buffer from the dropper bottle to the sample zone (fig 2).

Read the results after 5 - 20 minutes (* see 8; Validation of the test and 10; Interpretation of the test)

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Figure 1



Figure 2

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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.

Interpretation of test results

Positive:

Two bands are visible, zone “T” and zone “C” (fig. A). The cat is infected. Positive results may vary in optical density due to variations in viral or antibody concentrations in the sample.

Weak Positive:

Two bands are visible; a weak band in zone “T” and a band in zone “C” (fig. B). The sample contains low viral or antibody concentrations in the sample. Positive results may vary in optical density due to variations in antibody concentrations in the sample.

Negative:

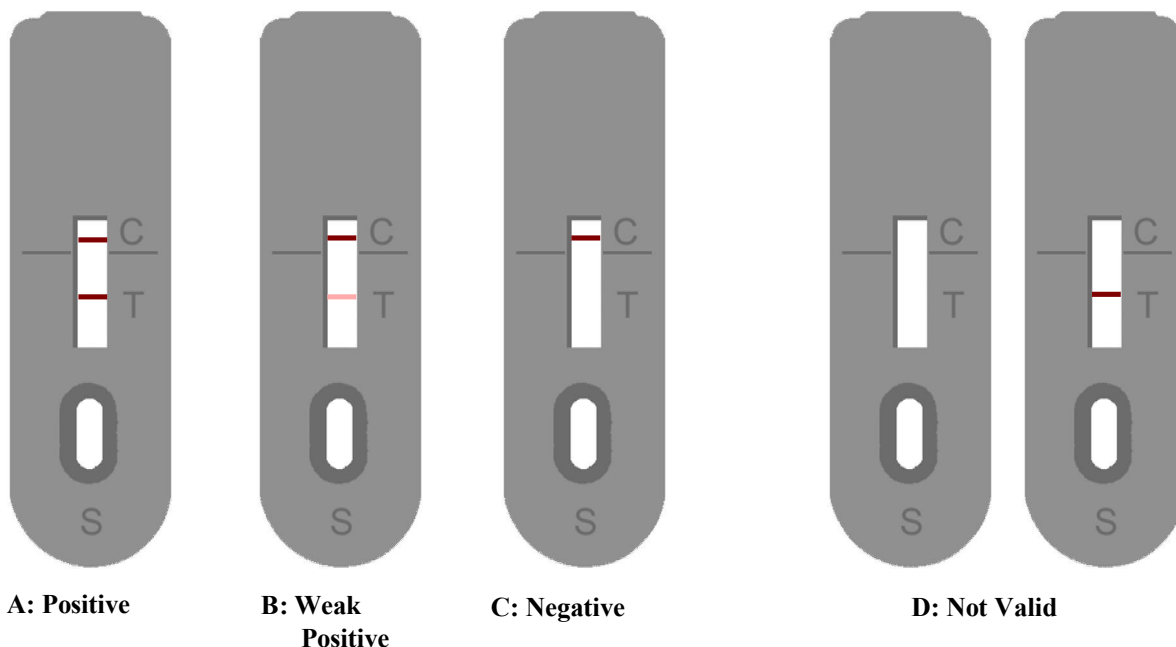
Only one band is visible in zone “C” (fig. C). The cat is not infected.

Not valid:

No band is visible in zone “C” (fig. D). Repeat the test procedure.

Important

A positive result should be confirmed by PCR or Virus Isolation. Diseased, but negative tested patients should be retested within 2-3 weeks.





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The purchaser assumes the entire risk as to the performance of these products. DRG shall not be liable for indirect, special or consequential damage of any kind resulting from use of these products.