DRG® FeLV Ag Rapid Test (RAP-4816 / RAP-2740)

Revised 28 July 2010 rm (Vers. 2.1) **For Veterinary Use Only**

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

INTRODUCTION

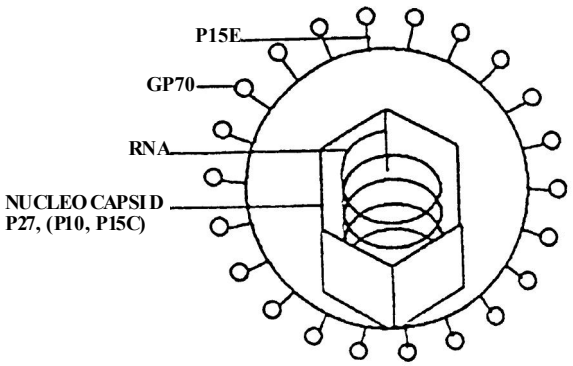
For Veterinary use only!

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.



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 FeLV p27 antigen by use of a Rapid Immunochromatic Assay.

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PRINCIPLE

This 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 color change in zone "T" indicates a positive test. FeLV antigen is also immobilized on the strip in the control zone "C", which binds the gold conjugate to indicate that the test is working properly.

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 destruction of the test.

Samples may be used fresh or may be kept frozen below -20˚C before use.

CONTENTS

- 6 [24] x pouches, each containing 1 test strip and 1 pipette
- 1 [4] x dropper bottle containing 2 ml buffer
- 1 x protocol

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.

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TEST PROTOCOL

1. Unpack the test strip and pipette. Only open the amount of pouches to be used. An opened package should be used immediately.
2. Add **2 drops** of serum/ plasma to the sample zone using the pipette (fig 1).
3. Add **2 drops** of buffer from the dropper bottle to the sample zone (fig 2).
4. Read the results after 5 - 20 minutes (* see 9; Validation of the test and 10; Interpretation of test results).

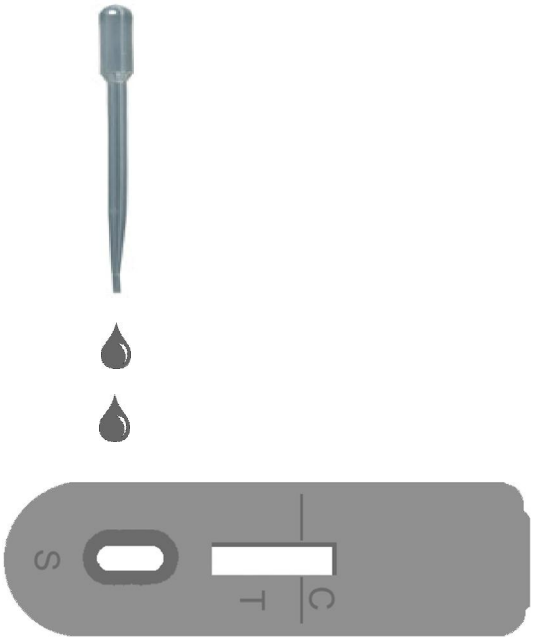

Figure 1

Figure 2

5 – 20 minutes

VALIDATION OF THE TEST

To validate this One-Step Test 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 sample contains FeLV p27 antigen.

Positive results may vary in optical density due to variations in 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 concentrations FeLV p27 antigen.

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 sample does not contain FeLV p27 antigen.

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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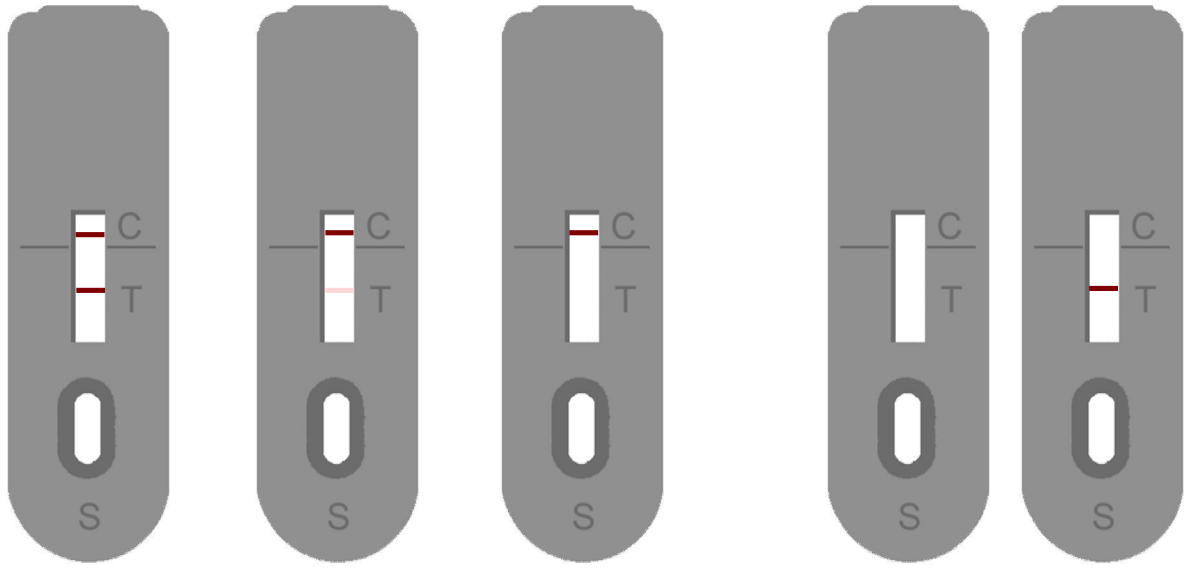

A: Positive **B: Weak Positive** **C: Negative** **D: Not Valid**

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.