DRG® FIV Ab Rapid Test (RAP-4801 / RAP-4821)

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

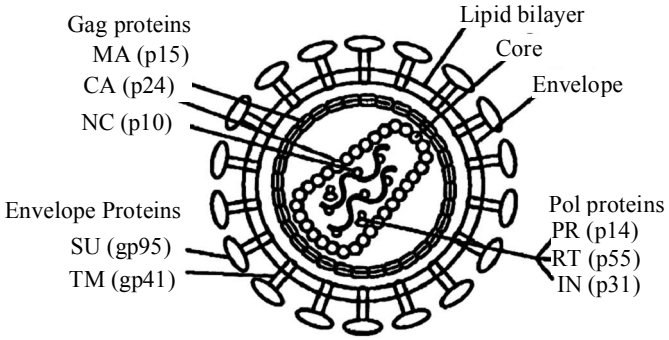
For Veterinary use only!

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.

The structure of the virus particle:



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 anti-p24 antibodies by use of a Rapid Immunochromatic Assay.

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PRINCIPLE

The FIV One- Step ab 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 color change in zone "T" indicates a positive test. FIV antibody 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 x pouches [24 x pouches], each containing 1 test strip and 1 pipette
- 1 dropper bottle containing 2 ml buffer [1 dropper bottle containing 4 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).

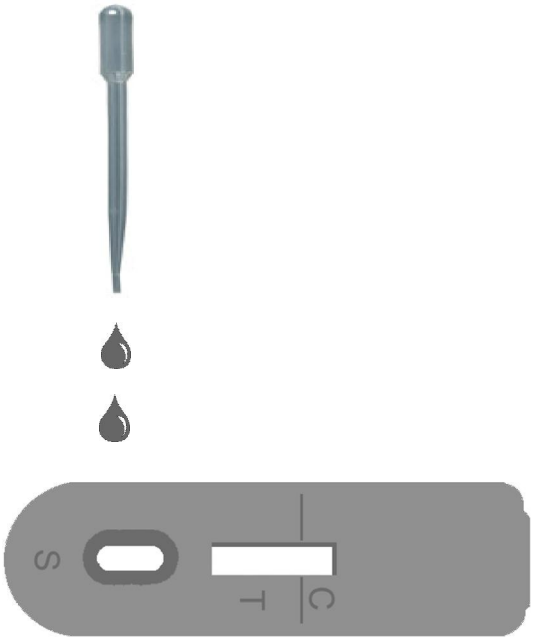

Figure 1

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 FIV anti-p24 antibodies.

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 FIV anti-p24 antibodies.

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 anti-p24 antibodies.

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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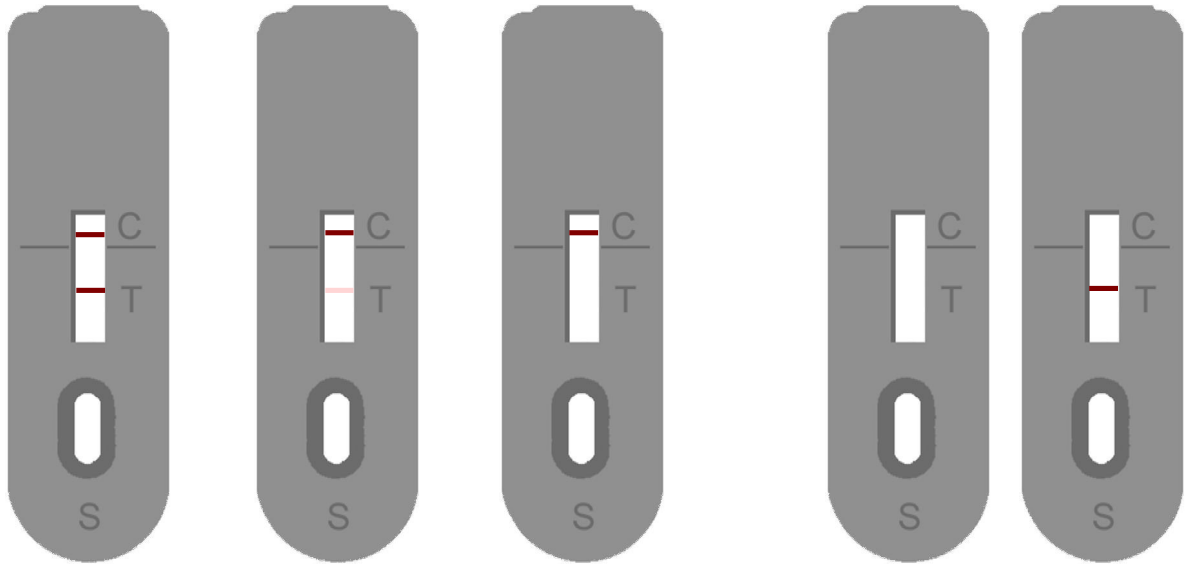

A: Positive **B: Weak Positive** **C: Negative** **D: Not Valid**

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.