

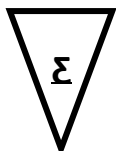
User's Manual

Canine / Feline Parvo Virus Antigen One-Step

*For the detection of Parvo Virus antigen in
faeces samples*



D1001-AG02



24

January 2022

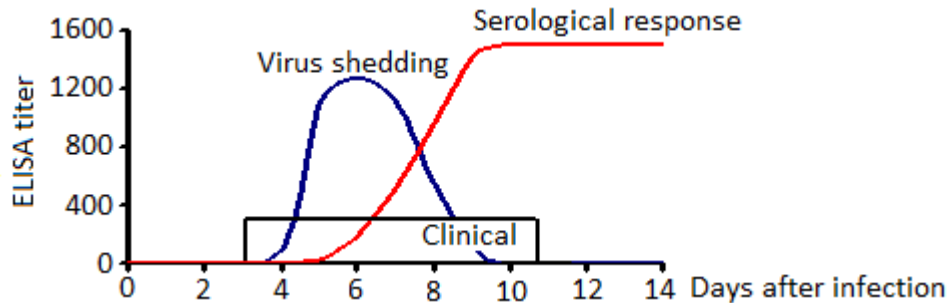
Please use only the valid version of the package insert provided with the kit.

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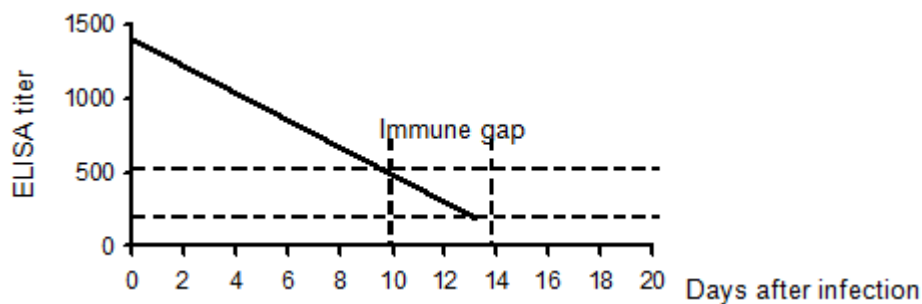
2. Introduction

Canine Parvo virus was first described in 1978 as cause of enteritis in dogs. Dogs are infected through the oropharynx. After the onset of clinical signs the virus is excreted in the faeces for several days.



Virus shedding and serological response in relation to clinical symptoms

Kennels can harbour the virus permanently in the rooms, outside pens or exercise areas. In spite of vaccination these kennels will always be a risk for puppies aged between 6-14 weeks (immune gap). Given these circumstances there is a need for a rapid, reproducible and simple diagnostic test. The Parvo One-Step is ideally suited for this purpose. In addition, this test can also be used for the diagnosis of Parvo virus infection in cats and mink. (Panleukopenia virus for cats and enteritis for mink). Following early diagnosis of Parvo virus, immediate implementation of hygiene measures and isolation of positive animals can keep further transmission to a minimum. Vaccination of in-contact healthy animals is advised.



Decrease of maternal antibodies in pups

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 Parvo virus antigen by use of a rapid immunochromatic assay.



4. Principle of the test kit

The Parvo antigen One-Step test is based on a chromatographic principle in which a monoclonal antibody reacts with epitopes of the Parvo virus. A monoclonal antibody is conjugated to colloidal gold particles and a monoclonal antibody is immobilized on the test strip in the test zone "T". Parvo virus in the faeces sample that is applied to the test strip at the sample zone "S", will bind to the colloidal 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

- 24 x Pouches, each containing 1 test strip, 1 pipette and 1 cotton swab
- 24 x Buffer vials
- 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 unopened 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

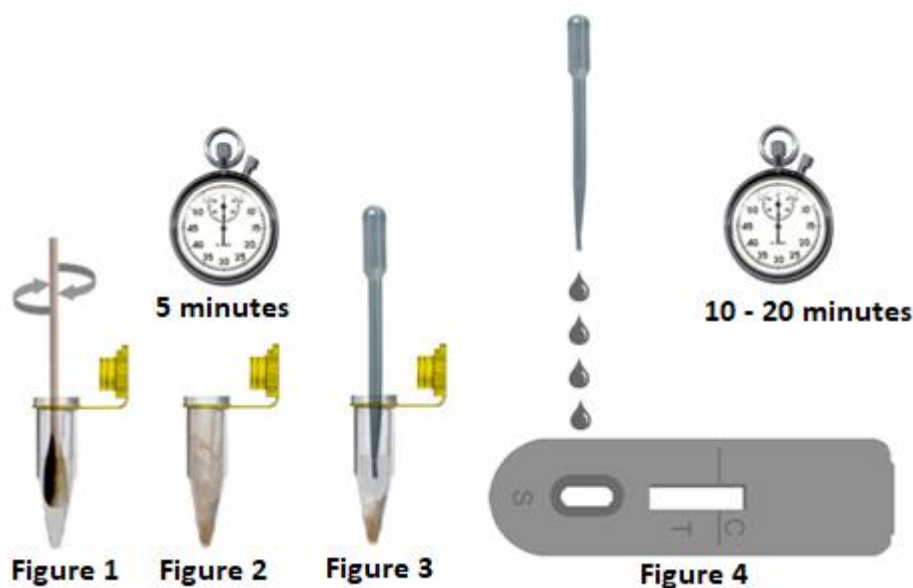
It is advised to test faeces or rectal swab medium. It is advised to test samples as concentrated as possible.

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 test strip, swab and pipette. Only open the amount of pouches to be used. An opened package should be used immediately.
2. Take an individual faecal sample using the included swab.
3. The swab should be washed in the buffer vial containing the buffer (Figure 1).
4. Squeeze the swab to the wall of the buffer vial to leave much liquid as possible.
5. Let particles sink to the bottom for 5 minutes (Figure 2). After 5 minutes 2 layers should be visible. If necessary centrifuge the sample.
6. Add **4 drops** of the supernatant (upper liquid) of the buffer vial containing the sample, with the included pipette **slowly** to the sample zone "S" (Figure 4).
7. Read the result after 10 – 20 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 zone "C" (Figure A). The sample contains Parvo virus antigen. 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 Parvo virus antigen.

Negative:

Only one line is visible in zone "C" (Figure C). The sample does not contain Parvo virus antigen.

Not valid:

No line is visible in zone "C" (Figure D). Repeat the test procedure.

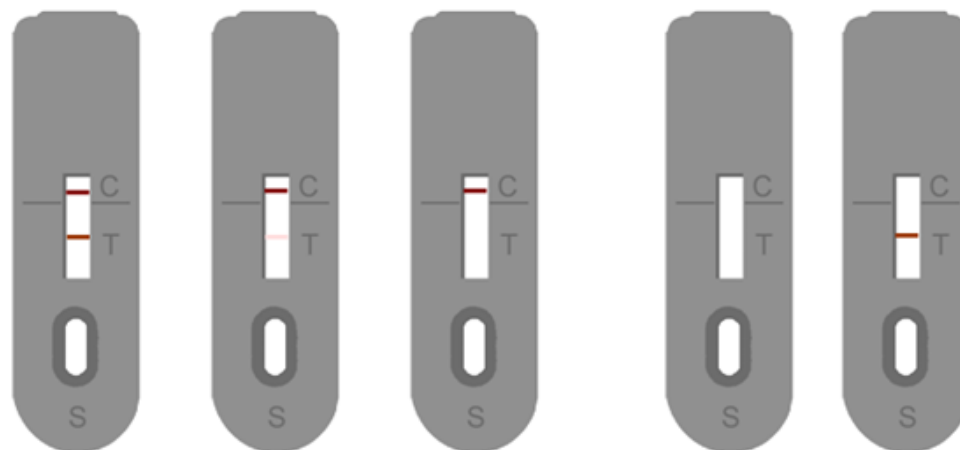


Figure A:
Positive

Figure B:
Weak positive

Figure C:
Negative

Figure D:
Not Valid

Important:

A positive result should be confirmed by PCR, haemagglutination or virus isolation for subtypes. Diseased but negative tested patients should be retested within 2-3 weeks.

In rare circumstances extreme high concentrations of E. coli bacteria might give strange precipitation in the zone "T".



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.