



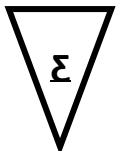
User's Manual

Bovine Corona Virus Antigen One-Step

*For the detection of Corona Virus antigen in
bovine faeces samples*



B1006-AG01



24

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

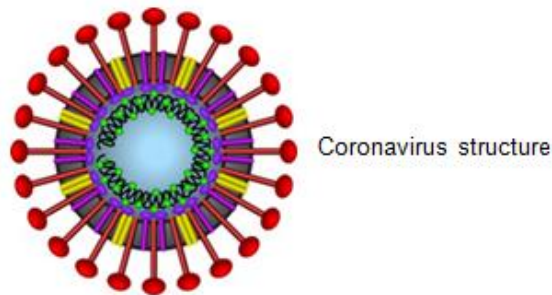
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2. Introduction

Bovine Corona Virus (BCV) was first associated with diarrhoea in new-born calves and later with winter dysentery in adult cattle. It is now considered an important pathogen causing enteric disease, often in combination with respiratory clinical signs. Fatal respiratory disease caused by BCV has been reported in young stock. BCV infections often result in high morbidity but usually in low mortality. The same virus strain can cause disease in both calves and adults, and the animal often sheds virus in both nasal secretion and faeces. The typical syndrome in calves from a few days to a few weeks of age is usually associated with infections such as Rota virus (34%), Corona virus (23%) and Cryptosporidium (18%).

Bovine Corona virus is a group 2 member of the genus Corona virus in the family Corona viridae. The Bovine Corona virus virion is enveloped and spherical in shape. The genome is a single-stranded, positive-sense RNA molecule of 27 to 32kb.



Infected animals exceed enormous number of viridal particles, and therefore contaminating the environment. In combination with the EVL Rota One-Step test the veterinarian is now able to detect the cause of diarrhoea in about 60% of all cases.

This rapid, sensitive and easy to perform diagnostic test will enable hygienic, therapeutic and prophylactic measures to be put in place to protect the other calves in the herd in order to keep the number of infected animals as low as possible.

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 Bovine Corona virus antigen by use of a rapid immunochromatic assay.

4. Principle of the test kit

The Bovine Corona antigen One-Step test is based on a chromatographic principle which a monoclonal antibody reacts with epitopes of the Corona virus. A monoclonal antibody is conjugated to colloidal gold particles and a monoclonal antibody is immobilized on the test strip in the zone "T". Bovine Corona 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 immobilized on the test strip in 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 vial
- 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

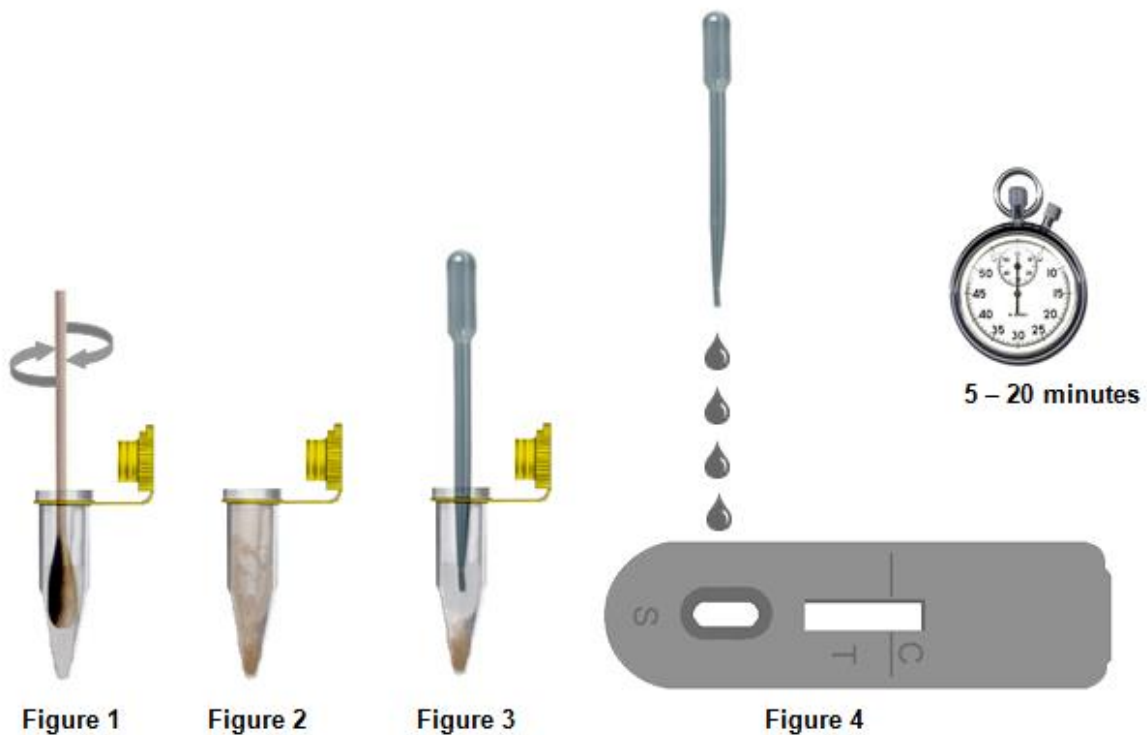
It is advised to test fresh faecal or rectal swab samples. It is advised to test samples as concentrated is possible (see test protocol chapter 9)

8. Precautions

- Handle all biologicals 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 sample using the included swab.
3. The swab should be washed in the buffer vial (see Figure 1).
4. Squeeze the swab to the wall of the tube to leave as much liquid as possible.
5. Let the particles sink to the bottom for 5 minutes (see 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 5 - 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 in zone “C” (Figure A). The sample contains Bovine Corona 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 Bovine Corona virus antigen.

Negative:

Only one line is visible in zone “C” (Figure C). The sample does not contain Bovine Corona virus antigen.

Not valid:

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

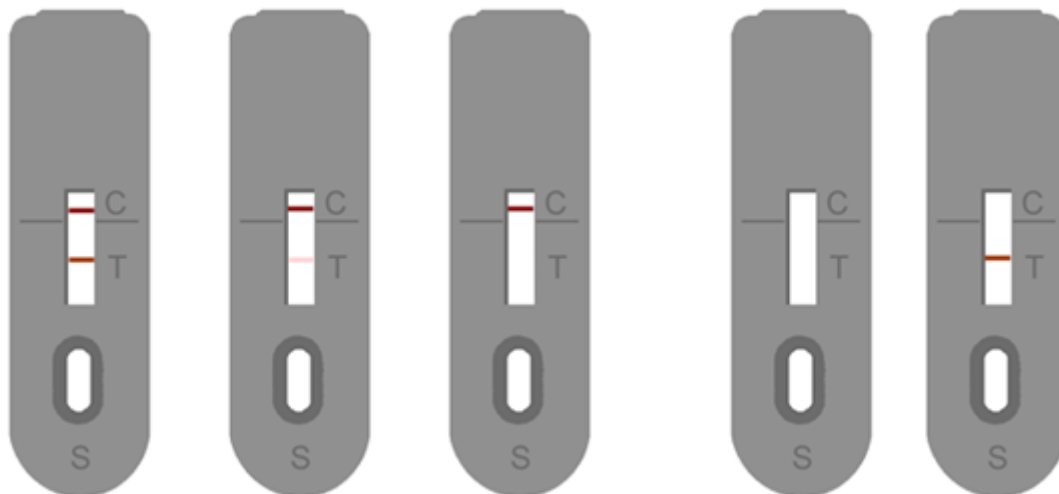


Figure A:
Positive

Figure B:
Weak positive

Figure C:
Negative

Figure D:
Not Valid

Note:

A positive result should be confirmed by PCR or virus isolation. Diseased but negative tested patients should be re-tested within 2-3 weeks.



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.