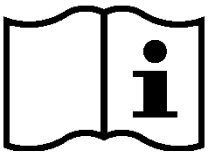
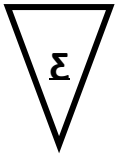


Useŕs Manual

Eimeria tenella Antigen One-Step

For the detection of Eimeria tenella antigen in faeces samples of poultry

REF AS1016-AG01



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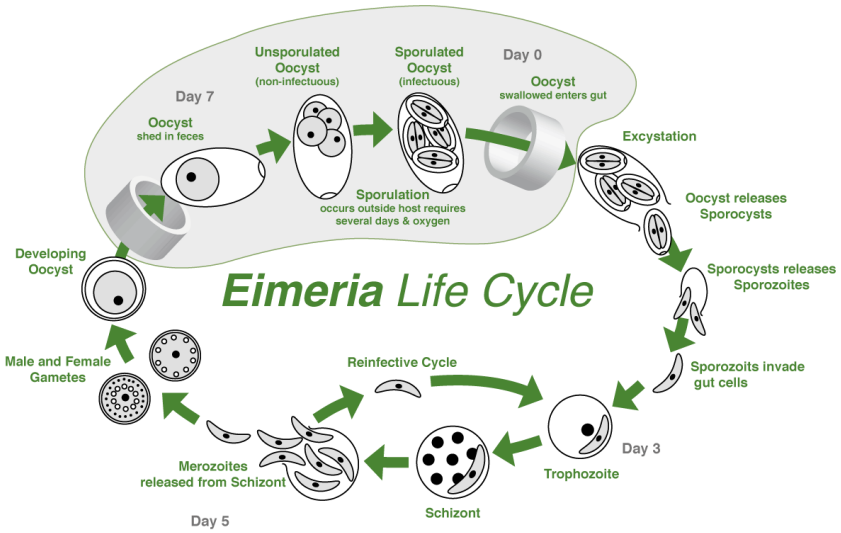
January 2022

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

1. Table of Contents

2. Introduction

This One-Step is intended to use as practical/routine screening test that can be done in a short time. This test kit is designed to detect Eimeria Tenella heat stabile antigen by use of a Rapid Immunochomatic Assay.



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 Eimeria Tenella antigen by use of a rapid immunochromatic assay.

4. Principle of the test kit

The Eimeria Tenella antigen One-Step is based on a chromatographic principle in which a monoclonal antibody reacts with epitopes of the Eimeria Tenella. A monoclonal antibody is conjugated to colloidal gold particles and a monoclonal antibody is immobilized on the test strip to the test zone “T”. Eimeria 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

- 6 x Pouches, each containing 1 test strip and 1 pipette
- 6 x Buffer vial
- 6 x Cotton swab
- 1 x Protocol
- Needed but not supplied: heating system (EVL catalogue nr.: Dry heat 219-002)

6. 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.

7. Sample material

It is advised to test faeces containing ceca material, embryonated egg culture samples can also be tested. It is advised to test samples as fresh and 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. Mix the sample well.
2. Take 1 gram of the individual sample using the included swab.
3. The swab should be washed in the buffer vial.
4. Squeeze the swab to the wall of the buffer vial to leave as much liquid as possible.
5. Place the buffer vial including the sample in the heating system at 97,5°C for 55-90 minutes.
6. Take the buffer vial including the sample out of the heating system and let it cool down for 15 minutes (spin down at 4000rpm if possible).
7. Unpack the test strip and pipette. Only take the amount of tests to be used. Close the pouch as soon as possible.
8. Place the test strip directly into the buffer vial including the sample (Figure 1).
9. Wait for 6 minutes.
10. Take the test strip out of the buffer vial including the sample and place the test strip into a second buffer vial (Figure 3).
11. Read the result after 13 – 30 minutes (for the interpretation of the test result see chapter 10 and chapter 11).

Figure 1

Figure 2

Figure 3

Figure 4

Figure 5

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 Eimeria Tenella antigen (Figure A).
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 Eimeria Tenella antigen (Figure B).

Negative:
Only one line is visible in zone “C” (Figure C). The sample does not contain Eimeria Tenella (Figure C).

Not valid:
No line is visible in zone “C” (fig. D). Repeat the test procedure with a new test cassette.

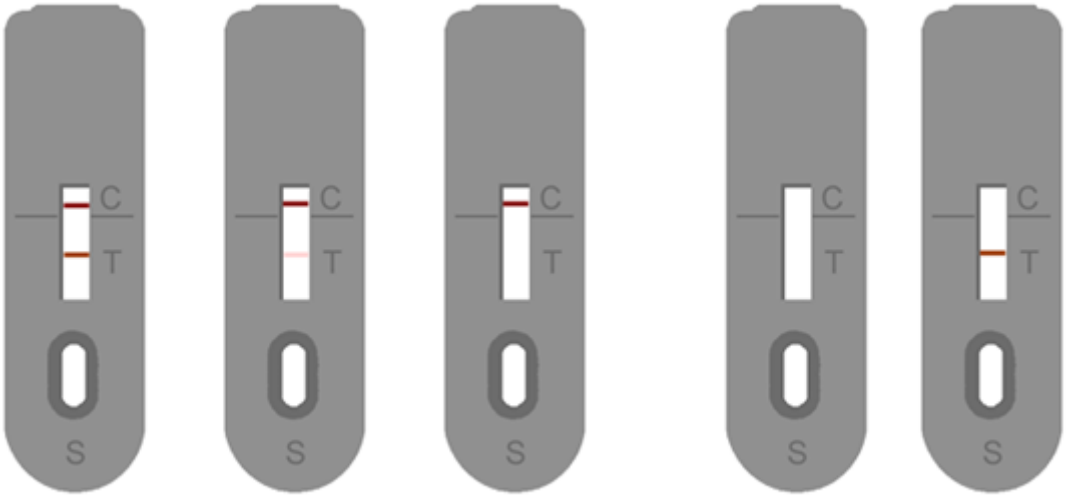


Figure A: Positive

Figure B: Weak positive

Figure C: Negative

Figure D: Not Valid

BV European Veterinary Laboratory
Postbus 198
3440 AD Woerden
The Netherlands

Tel: +31 (0)348-412549
Web: www.evlonline.org
@: info@evlonline.eu

12. Symbols used with EVL ASSAYS

Symbol	English
	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.

BV European Veterinary Laboratory
Postbus 198
3440 AD Woerden
The Netherlands

Tel: +31 (0)348-412549
Web: www.evlonline.org
@: info@evlonline.eu