

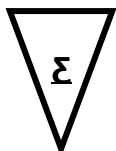
User's Manual

Newcastle Disease Virus Antibody One-Step

*For the detection of Newcastle disease virus
antibodies in serum or plasma samples*



AS1004-AB01



24

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

1. Table of Contents

1.	Table of Contents	2
2.	Introduction.....	3
3.	Intended use of the test kit	3
4.	Principle of the test kit	3
5.	Contents	3
6.	Handling and storage of specimens	4
7.	Sample material.....	4
8.	Precautions.....	4
9.	Test protocol	5
10.	Validation of the test.....	5
11.	Interpretation of the test results.....	6
12.	Symbols used with EVL ASSAYS	7

2. Introduction

Newcastle disease is caused by a paramyxovirus. It is an infection of domestic poultry and other bird species with virulent NCD.

It is a worldwide problem that presents primarily as an acute respiratory disease, but depression, nervous manifestation, or diarrhoea may be the predominant clinical form. The virus can be spread by inhalation of the virus or by ingesting of contaminated water or food. The virus may also be present in eggs laid during clinical disease and in all parts of the carcass during acute NCD infections.

The incubation period is 4 – 7 days. In general signs can include ocular and/or nasal discharge, dyspnoea and blood diarrhoea. Central nervous system signs can also occur including depression or the opposite hyperexcitability; vestibular or balance problems; tremors, especially of the head and neck; weakness and partial or total paralysis.

The onset of signs may be semi-acute to sudden death. Signs vary depending on the strain of virus and the species of bird.

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 NCD virus antibodies by use of a Rapid Immunochromatic Assay.

4. Principle of the test kit

The NCD antibody One-Step test is based on a chromatographic test strip, a monoclonal antigen reacts with epitopes of the NCD virus antibodies. A monoclonal antibody is conjugated to colloidal gold particles and the monoclonal antigen is immobilized on the strip in the test zone "T". NCD virus 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 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 and 1 pipette
- 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 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

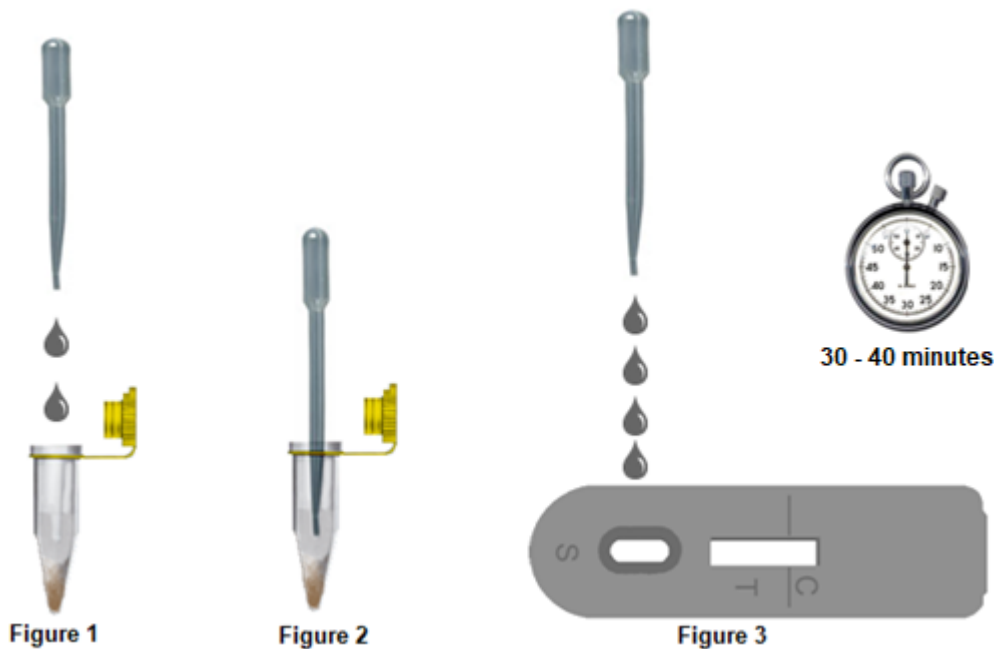
It is advised to test fresh serum or plasma samples. Do not use haemolytic or lipemic serum.

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. Add **2 drops** of the sample to the buffer vial by using the pipette (Figure 1).
3. Mix well using the pipette (Figure 2).
4. Add **4 drops** of buffer vial containing the sample, with the included pipette **slowly** to the sample zone "S" (Figure 3).
5. Read the result after 30 - 40 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 NCD virus antibodies.

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 of NCD virus antibodies.

Negative:

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

Not valid:

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

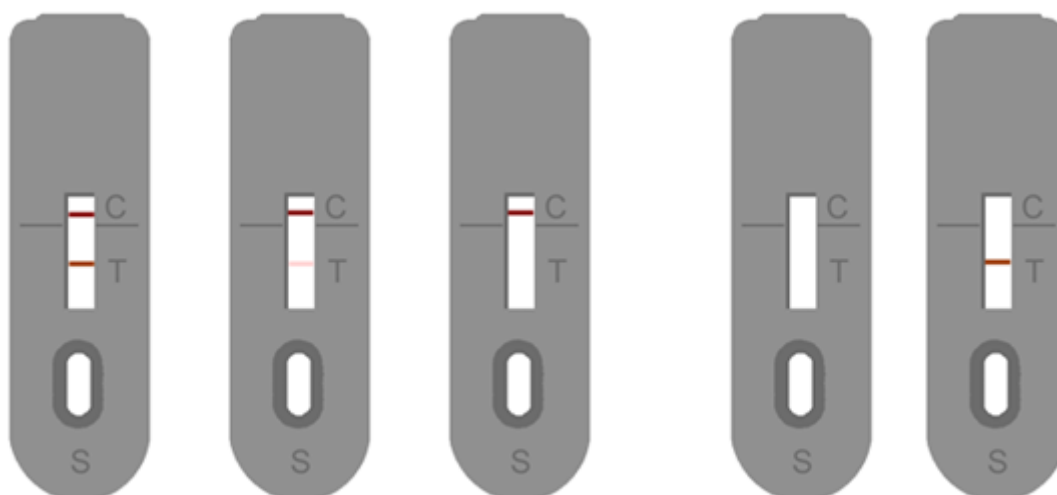


Figure A:
Positive











Figure B:
Weak positive

Figure C:
Negative

Figure D:
Not Valid



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.