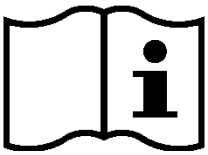
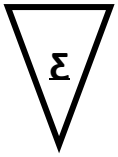


Useŕs Manual

Aujesky's Disease Virus Antibody One-Step

For the detection of Aujesky's Disease virus in porcine serum or plasma samples

REF P1005-AB01



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January 2022

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

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2. Introduction

In piglets, a variety of neurological signs are associated with the disease, but respiratory signs are often the most striking clinical feature. The disease is less pronounced in older pigs and, after recovery, i.e. in adult pigs, a lifelong latent infection is established. From such asymptotic pigs, Aujesky's disease virus (ADV) has been isolated from cranial ganglia and lymphoid tissue. The virus can be transmitted by physical contact with infected animals or through maternal infection of foetal or suckling pigs by reactivated virus in lately infected sows.
All herds in endemic regions should be monitored for the presence of infection and uninfected herds protected by control measures. Some countries practice vaccination, while some others try to control the spread by culling sero-positive pigs.
Pigs infected with ADV field strains (mostly adult lately infected pigs) or vaccinated with gE+ vaccine, produce antibodies against ADV glycoprotein gE.
This test kit is designed to detect these antibodies against the gE glycoprotein by use of a blocking Enzyme Immuno Assay (ELISA). This test kit meets the requirement of the EC-program.

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 Aujesky's disease virus antibodies by use of a rapid immunochromatic assay.

4. Principle of the test kit

The ADV antibodies One-Step test is based on a chromatographic principle in which a monoclonal antigen reacts with epitopes of the ADV virus antibodies. A monoclonal antibody is conjugated to colloidal gold particles and a monoclonal antigen is immobilized on the test strip in the test zone "T". ADV antibodies in the sera or plasma sample that is applied to the test strip at the sample zone "S", will bind to the colloidal gold particles which the migrate to zone "T". **No colour change** in zone "T" indicates a positive test. Labelled colloidal gold particles are also immobilized on the test strip in 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 vials
- 1 x Protocol

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 fresh serum or plasma samples. It is advised to test samples as concentrated as possible.

8. Precautions

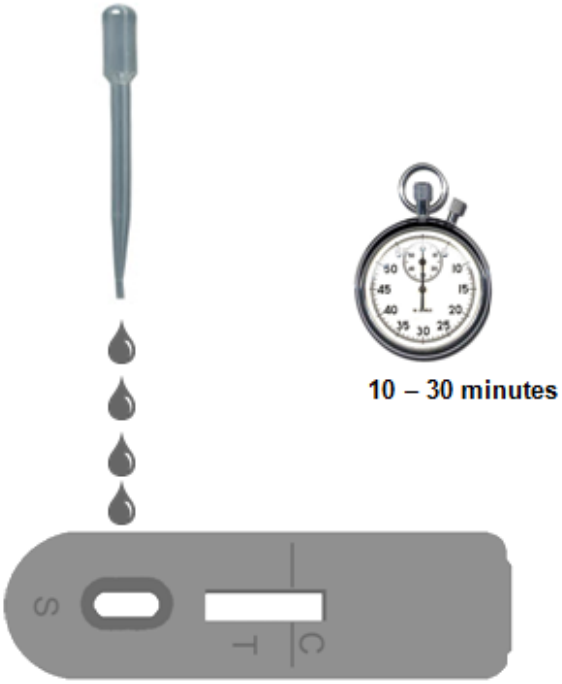
- Handle all biologicals materials as though capable of transmitting infectious diseases.
- Do not pipette by mouth
- Do not eat, drink, smoke, prepare foods or apply cosmetics within the designated work area.
- Do not use components which passed the expiry date and do not mix components from different 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 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 buffer vial using the pipette (Figure 1).
3. Mix well using the pipette (Figure 2).
4. Add **4 drops** of the buffer vial containing the sample, with the included pipette ***slowly*** to the sample zone "S" (Figure 3).
5. Read the result after 10 – 30 minutes (for the interpretation of the test result see chapter 10 and chapter 11).

Figure 1

Figure 2



10 – 30 minutes

Figure 3

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:
Only one line is visible in zone "C" (figure A). The sample contains ADV antibodies.

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 ADV virus antibodies.
Positive results may vary in optical density due to variations in viral concentrations in the sample.

Negative:
Two lines are visible, zone "T" and zone "C" (Figure C). The sample does not contain ADV virus antibodies.

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

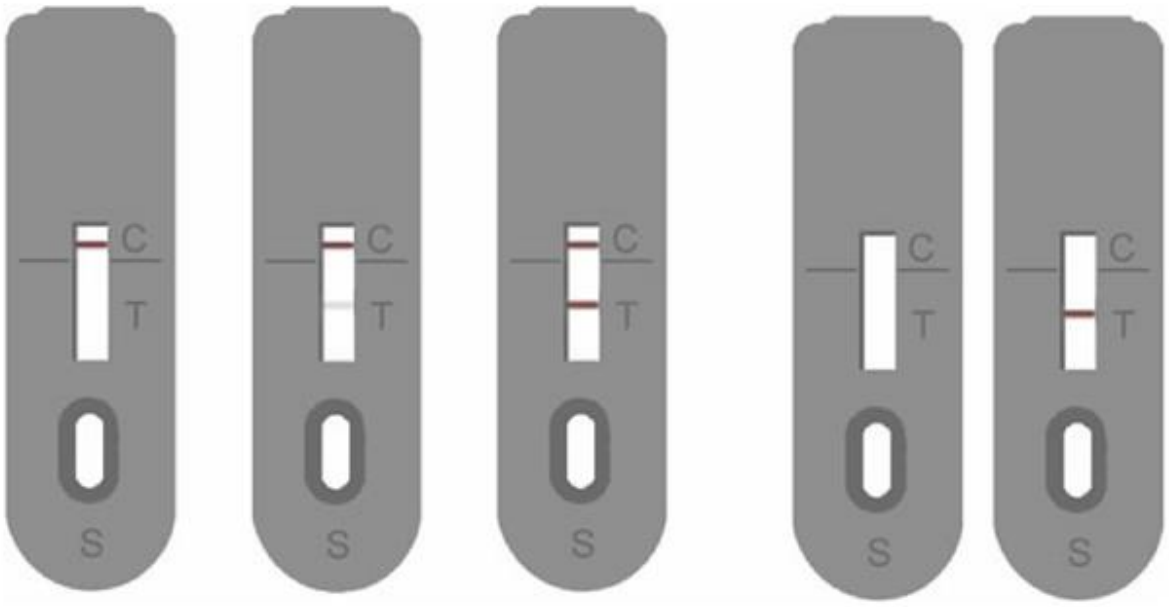


Figure A: Positive | Figure B: Weak positive | Figure C: Negative | Figure D: Not Valid

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

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.