

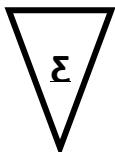
User's Manual

Rabies Virus Antigen One-Step

*For the detection of Rabies virus antigen in
EDTA blood, saliva swab material, wound
swab material, liquor or tissue-culture
material*

REF

D1006-AG01



6

January 2022

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

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2. Introduction

Rabies vaccines for use in man or animal consist of inactivated antigen suspensions of in vitro cultured rabies virus. The potency virus test for inactivated rabies vaccines as recommended by the World Health Organization is the NIH mouse protection test (NIH test, Seligmann, 1973). This NIH test suffers from several drawbacks (e.g. animal distress, time consuming, poor reproducibility), therefore the introduction of alternative testing methods is highly recommended.

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 Rabies virus antigen by use of a rapid immunochromatic assay.

4. Principle of the test kit

The Rabies virus antigen One-Step test is based on a chromatographic principle in which two monoclonal antibodies react with the different, well conserved, epitopes of Rabies virus. One monoclonal antibody is conjugated to colloidal gold particles and the other monoclonal antibody is immobilized on the test strip in the test zone "T". Rabies virus antigen in the 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, 1 pipette and 1 cotton swab
- 6 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 opened 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

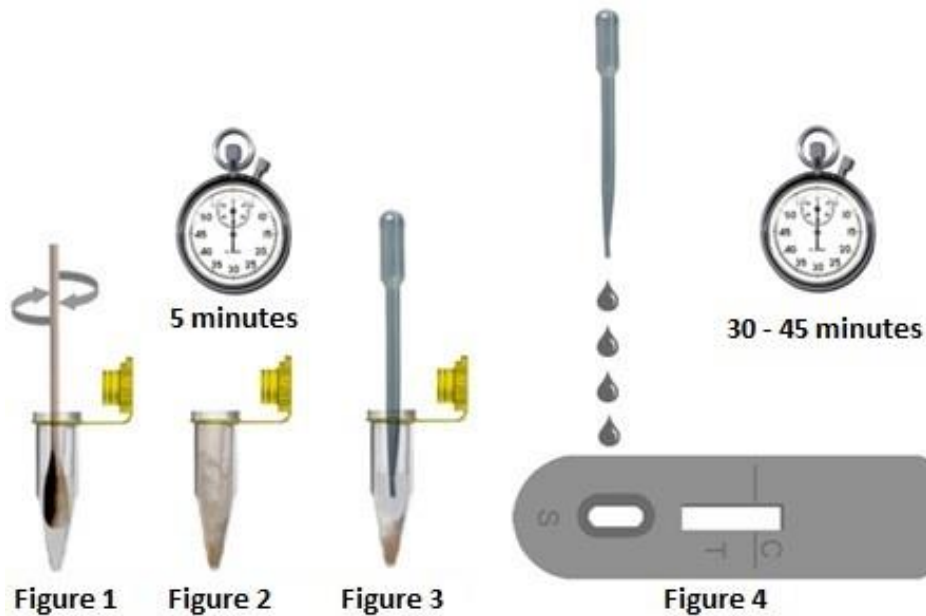
It is advised to test samples. It is advised to test samples as concentrated as possible,

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 sample by using the including swab. Tissue culture samples should be diluted 1:1 in the buffer.
3. The swab should be washed in de buffer vial (Figure 1).
4. Squeeze the swab to the wall of the tube to leave as 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 buffer vial containing the sample, with the included pipette **slowly** to the sample zone "S" (Figure 4).
7. Read the result after 30 – 45 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 Rabies 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 Rabies virus antigen.

Negative:

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

Not valid:

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

Note:

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

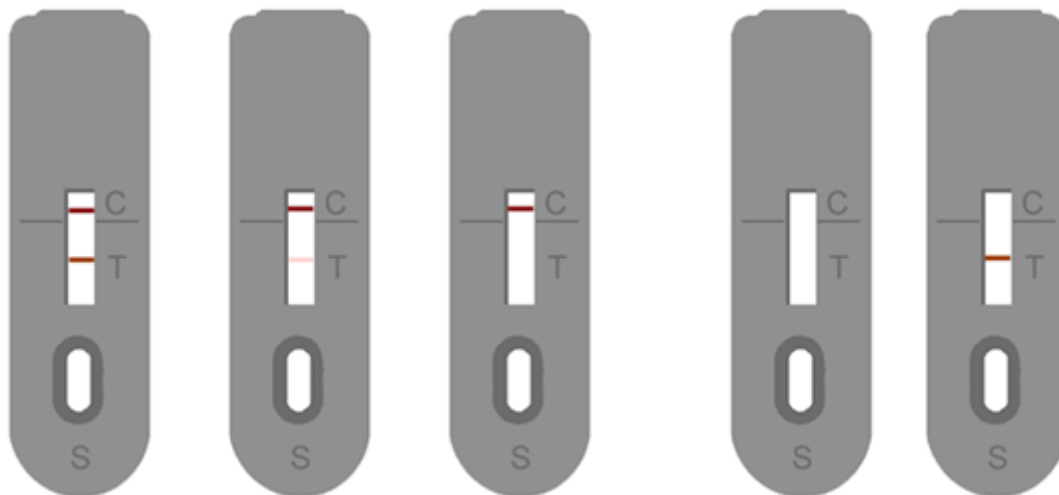


Figure A:
Positive











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.