

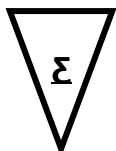
User's Manual

Human Adeno / Rota Virus Antigen One-Step

*For the detection of Adeno and Rota virus
antigen in faeces and tissue culture samples*



H1005-AG11



6

January 2022

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

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2. Introduction

Adeno virus was discovered in 1953. The Adeno virus causes pharyngitis / bronchitis / -pneumonia. 15% Of respiration diseases in children under 5 years of age are caused by Adeno Virus. 11% of the acute gastro-enteritis cases are caused by this virus. Ocular diseases (Keratoconjunctivitis) swimming pool conjunctivitis can occur at all different ages, especially in immune suppressed people (SLE, HIV etc.). The clinical spectrum of diseases associated with certain adeno viruses depends on the site of infection. For example, infection with adenovirus 7 acquired by inhalation is associated with severe lower respiratory tract disease, whereas oral transmission of the virus typically causes no or mild disease.

Epidemics of enteric Adeno have been found several times combined with Adeno virus infections. Cultivation of the Adeno virus can be very difficult, especially the enteric types; it can take sometimes 28 days before the virus can be detected in the culture.

Rota viruses are important causes of severe gastroenteritis in many new-born animals, especially in intensively reared farm animals. Rotaviral gastroenteritis may result in mortality for populations at risk such as infants, the elderly, and immunocompromised patients. In temperate climates, Rota virus infections occur mainly in the winter months.

Rota virus is one of the factors in “Neonatal disease complex”, 27% of death cases were caused by Rota virus (Animal Pharm, April 1997). Infected animals exceed enormous numbers of Rota viral particles, and usually are detectable up to 1 week after infection or for more than 30 days in immunocompromised patients, thus contaminating the environment. The risk of getting a herd outbreak of neonatal diarrhoea is particularly high during the parturition season because of rapid spread of the virus.

Rota virus is transmitted by the faecal-oral route; clinical as well as subclinical infections are common. Symptoms are diarrhoea, vomiting, dehydration and apathy. Rota virus can also cross species barriers. Human rota virus can infect animals and vice-versa, with canine and feline-like viruses found in humans.

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 kit is designed to detect Adeno and Rota virus antigen by using a Rapid Immunochromatic Assay.

4. Principle of the test kit

The Adeno / Rota One-Step is based on a chromatographic principle in which a monoclonal antibody reacts respectively epitopes of Adeno and Rota virus. A monoclonal antibody is conjugated to colloidal gold particles and a monoclonal antibody is immobilized on the test strip in test zone "T". Adeno or Rota virus antigen in the faeces sample that is applied to the test strip at the sample zone "S", will bind to the colloidal gold particles which 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 de control zone "C", to indicate that the test is working properly.

5. Contents

- 6x Pouches, each containing 1 test strip, 1 pipette and 1 cotton swab
- 6x Buffer vials
- 1x 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

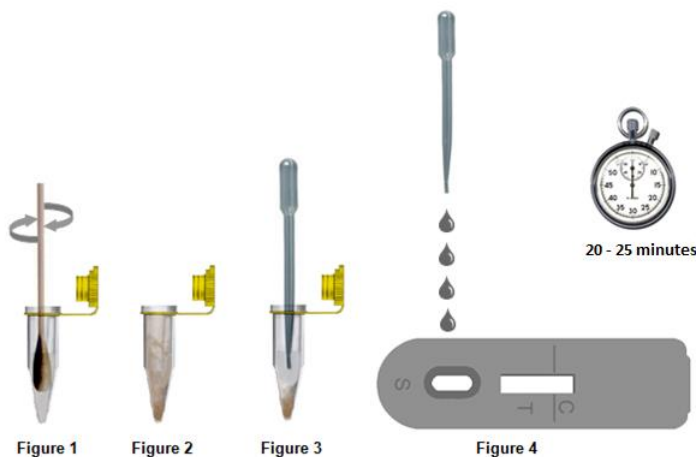
It is advised to test faeces or rectal swab samples. It is advised to test samples as fresh and concentrated as possible.

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, 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 (Figure 1).
4. Squeeze the swab to the wall of the buffer vial to leave much liquid as possible.
5. Let particles, if present, sink to the bottom. 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 results after 20-25 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. Invalid tests should be repeated with a new test.

11. Interpretation of the test results

Adeno Positive:

Two lines are visible, in the lower part of zone “T” and zone “C” (Figure A). The sample contains Adeno virus antigen. Positive results may vary in optical density due to variations in viral concentrations in the sample.

Rota Positive:

Two lines are visible, in the upper part of zone “T” and zone “C” (Figure A). The sample contains Rota virus antigen. Positive results may vary in optical density due to variations in viral concentrations in the sample.

Adeno Weak Positive:

Two lines are visible, a weak line in the lower part of zone “T” and zone “C” (Figure A). The sample contains low concentrations of Adeno virus antigen.

Rota Weak Positive:

Two lines are visible, a weak line in the upper part of zone “T” and zone “C” (Figure A). The sample contains low concentration of Rota virus antigen.

Negative:

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

Not valid:

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

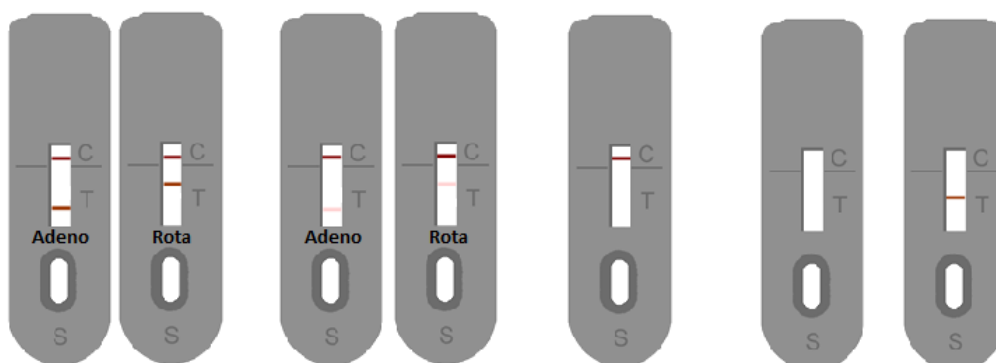


Figure A:
Positive

Figure B:
Weak positive

Figure C:
Negative

Figure D:
Not Valid



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.