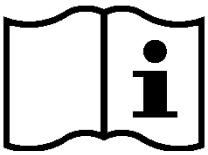
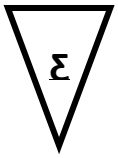


Useŕs Manual

Human Adeno Virus Antigen One-Step

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

REF H1005-AG01



6

January 2022

1. Table of Contents

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.
The virion is non-enveloped, spherical and about seventy to ninety nm in size and the genome encodes about thirty proteins. Both strands of adeno virus DNA encode genes.
There are a number of virus groups which have double-stranded DNA genomes of considerable size and complexity. Members belonging to the genus adeno viruses share common epitopes on the hexons.
Subgenus is defined by the DNA homology of more than 50% between members within a subgenus and less than 20% between members of different subgenera. The serotype is defined by quantitative neutralization with hyperimmune sera. The ratio of homologous to heterologous neutralization titre must be greater than 16.
There are 4 Adeno virus groups. Group I and group II are both from the non-enteric Adeno group. Group III (type 41) and group IV (type 40) are both enteric subtypes. The EVL Adeno One-Step test detects group specific Adeno virus antigen in samples of all kind of species (human, mice, bovine, pig, etc.).

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 virus antigen by using a Rapid Immunochromatic Assay.

4. Principle of the test kit

The Adeno One-Step is based on a chromatographic principle in which a monoclonal antibody reacts with Adeno virus antigen. A monoclonal antibody is conjugated to colloidal gold particles and a monoclonal antibody is immobilized on the test strip in test zone “T”. Adeno virus antigen in the faeces or tissue culture 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 (±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 or rectal swab samples, tissue culture samples can also be tested. 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 as much liquid as possible.
5. Let particles, if present, sink to the bottom (Figure 2). 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).

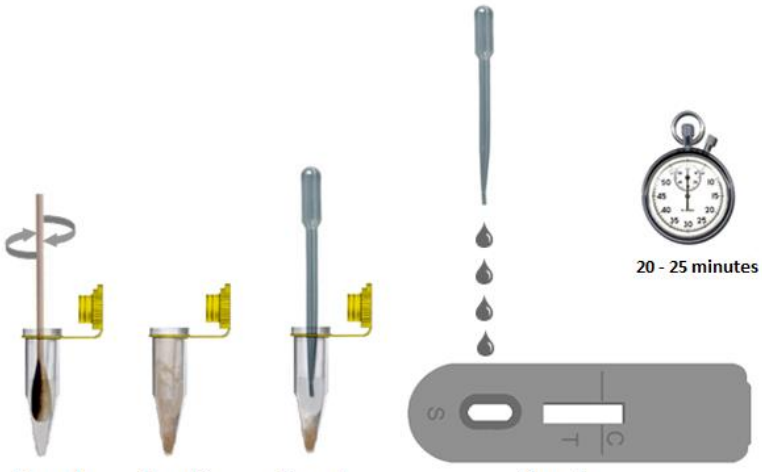


Figure 1 Figure 2 Figure 3 Figure 4

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

Positive:
Two lines are visible, in 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.

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 Adeno virus antigen.

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

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

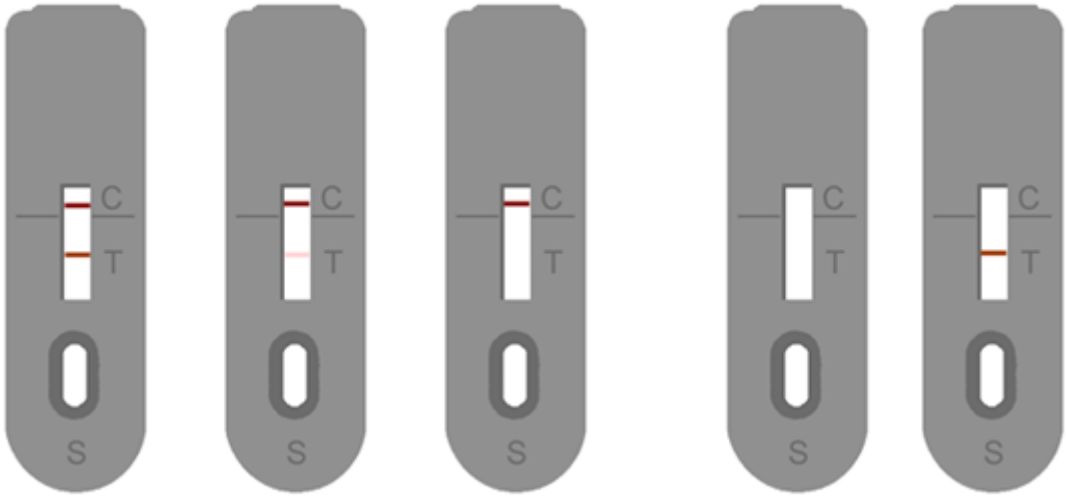


Figure A: Positive

Figure B: Weak positive

Figure C: Negative

Figure D: Not Valid

12. Symbols used with EVL ASSAYS

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