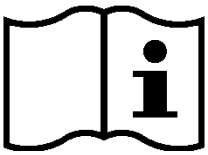
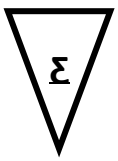


Useŕs Manual

Influenza Virus Antigen One-Step

For the detection of Influenza Virus type A antigen in faeces, throat swab material or tissue-culture material

REF AS1001-AG01



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January 2022

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

1. Table of Contents

2. Introduction

Influenza viruses are the causative agents of outbreaks of acute respiratory diseases, called "flu". The virus was isolated for the first time in 1933 and belong to the group of Orthomyxoviridae. This group can be split up in 2 groups, one containing influenza A+B and the other Influenza C. These influenza viruses can be distinguished on the basis of antigenic differences on their Nuclear Proteins (NPs), and also on matrix protein M.
Influenza A can be further divided into subtypes based on antigenic differences in their surface proteins H (= haemaglutinine) and N (= neuramidase). Up to 16 different H (H1-16) and 9 different N (N1-9) types have been identified.

The Influenza virus has a spherical shape and a size of 80-120nm. On the envelop it carriers two major proteins H and N, rod and mushroom shaped proteins respectively.
The virus is covered with approximately 500 H spikes and approx 100 N spikes per particle.
Influenza A Virus infects a wide range of animal species, including humans, pigs, dogs, cats and aquatic birds (ducks, swans, geese, etc.)

Up to now only H1, H2, H3 and incidentally H5 and H9 have found in humans, H1 and H3 have been found in pigs and H3 and H7 in horses. In contrast, all known H subtypes are found in aquatic birds especially in ducks, which are considered to be the natural reservoir of Influenza A. This means that Influenza A virus crosses species barriers and can be transmitted from one species to another either directly or indirectly through an intermediate host.

The ongoing spread of avian Influenza A viruses of the H5N1 subtype in Asia, Western Europe and Africa is of great concern and therefore rapid and reliable diagnostic is needed. This One-Step detects Influenza virus type A antigen in throat swab material or tissue-culture samples. For diagnosis of Influenza virus (IV) type A the demonstration of circulating Influenza virus antigen is the most commonly used method. Possible false-negative results, caused by natural occurring variants of the virus, have been minimized in this assay, since two monoclonal antibodies directed against two different, well conserved, epitopes of NP (Nucleoprotein) were used in this assay. In a very few cases an extreme growth of E. coli in faecal samples can cause false positive results.

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 Influenza virus type A antigen by use of a rapid immunochromatic assay.

4. Principle of the test kit

The Influenza antigen One-Step is based on a chromatographic principle in which two monoclonal antibodies react with two different, well conserved, epitopes of Influenza virus type A nuclear protein (NP).
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”. Influenza virus type A 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 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 (±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 faeces, throat swab or tissue-culture material 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 using the included swab. Tissue culture samples should be diluted 1:1 in the buffer.
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. 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 3).
7. Read the result after 5 - 20 minutes (for the interpretation of the test result see chapter 10 and chapter 11).

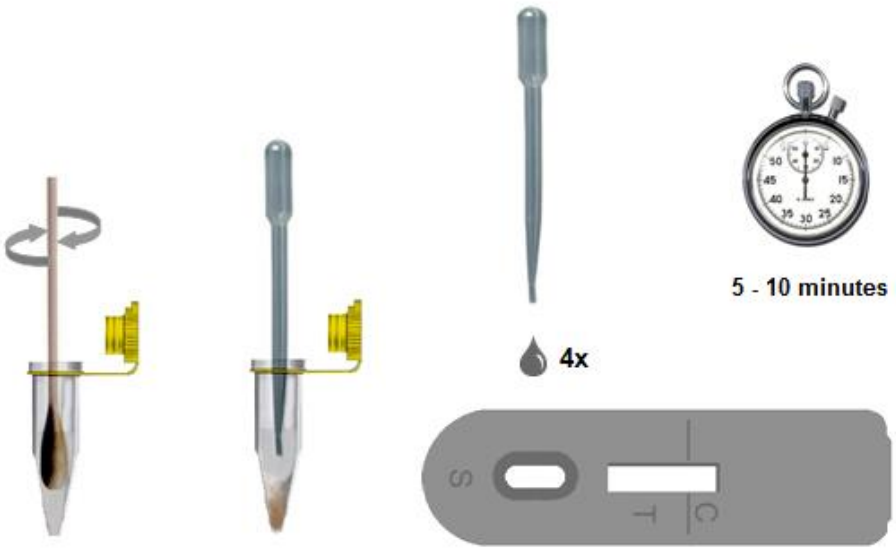

Figure 1 Figure 2 Figure 3

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:
Two lines are visible in zone “T” and in zone “C” (Figure A). The sample contains Influenza virus type A 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 Influenza virus type A antigen.

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

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

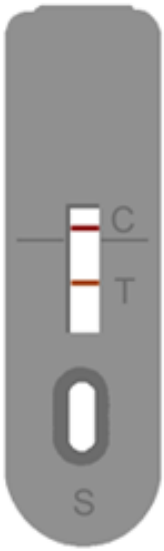

Figure A:
Positive

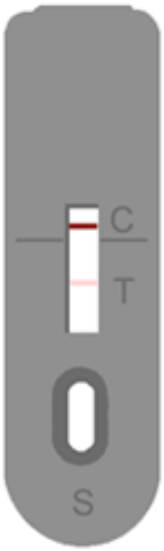

Figure B:
Weak positive

Figure C:
Negative

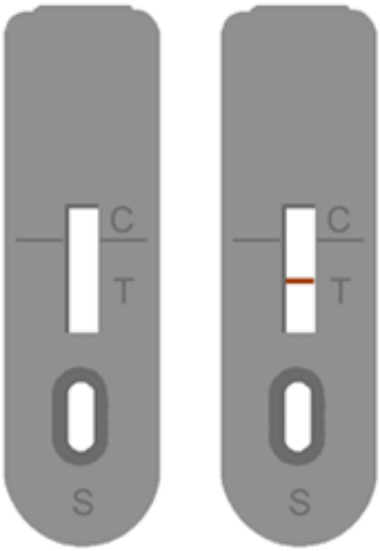

Figure D:
Not Valid

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12. Symbols used with EVL ASSAYS

Symbol	English
	Consult instructions for use
	European Conformity
IVD	In vitro diagnostic device
RUO	For research use only
REF	Catalogue number
LOT	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.