

DRG[®] Influenza Ag Rapid Test (RAP-4804 / RAP-4805)

Revised 6 Dec. 2011 cc (Vers. 2.1)

For Veterinary Use Only**THIS KIT IS INTENDED FOR RESEARCH USE ONLY.****NOT FOR USE IN DIAGNOSTIC PROCEDURES.***Please use only the valid version of the package insert provided with the kit***INTRODUCTION****For research use only!**

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 (=haemagglutinine) an 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 80-120 nm. 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 been 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 an other 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. Possible false positive results can be caused by E. coli in faecal matter and is therefore not recommended to be used in this assay.

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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.

PRINCIPLE

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 zone "T" indicates a positive test. Influenza Virus type A antigen is also immobilized on the test strip in the control zone "C", which binds the colloidal gold particles to indicate that the test is working properly.

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.

CONTENTS

- 6 / 24 x pouches, each containing 1 test strip, 1 pipette and 1 cotton swab
- 6 x Micro tube
- 2 / 8 x Dropper bottle
- 1 x protocol

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 serial 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.



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SAMPLE MATERIAL

It is advised to test swab material from nose and throat, Tissue culture samples can also be tested.

It is advised to test samples as concentrated as possible (see Test protocol; 8).

It is recommended not to use faecal matter due to possible false positive reactions induced by E. coli contamination.

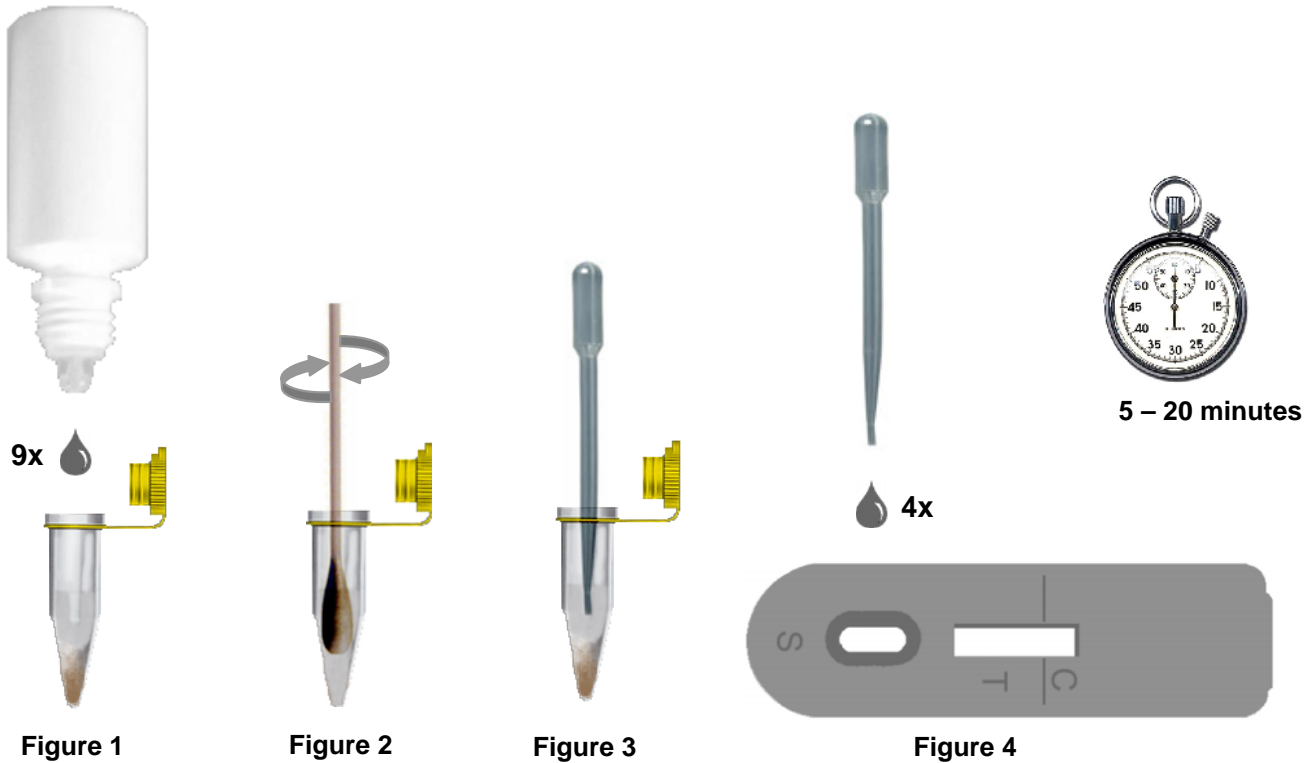
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TEST PROTOCOL

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. Add 9 drops ($\pm 300 \mu\text{L}$) from the dropper bottle to a micro tube (fig. 1).
3. Take a sample using the included swab.
Tissue culture samples should be diluted 1:1 in the buffer.
4. Vigorously wash the swab in the buffer vial (fig. 2).
5. Let particles, if present, sink to the bottom. If necessary centrifuge the sample.
6. Add 4 drops of the supernatant or tissue culture mixture (fig. 3), with the included pipette to the sample zone "S" (fig. 4).
7. Read the results after 5 - 20 minutes (* see 9; Validation of the test and 10; Interpretation of test results).



(or tissue culture sample, diluted 1:1 in buffer)

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To validate this One-Step Test 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.

A very weak background staining (gray/purple) line may occur on the test zone. This should not be considered positive. In case of doubt of a negative sample the buffer should be ran as control. Also positive or negative samples can be ordered separately.

INTERPRETATION OF TEST RESULTS***Positive:***

Two bands are visible, zone “T” and zone “C” (fig. 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 bands are visible; a weak band in zone “T” and a band in zone “C” (fig. B). The sample contains low concentrations Influenza virus type A antigen.

Positive results may vary in optical density due to variations in antibody concentrations in the sample.

Negative:

Only one band is visible in zone “C” (fig. C). The sample does not contain Influenza virus type A antigen.

Not valid:

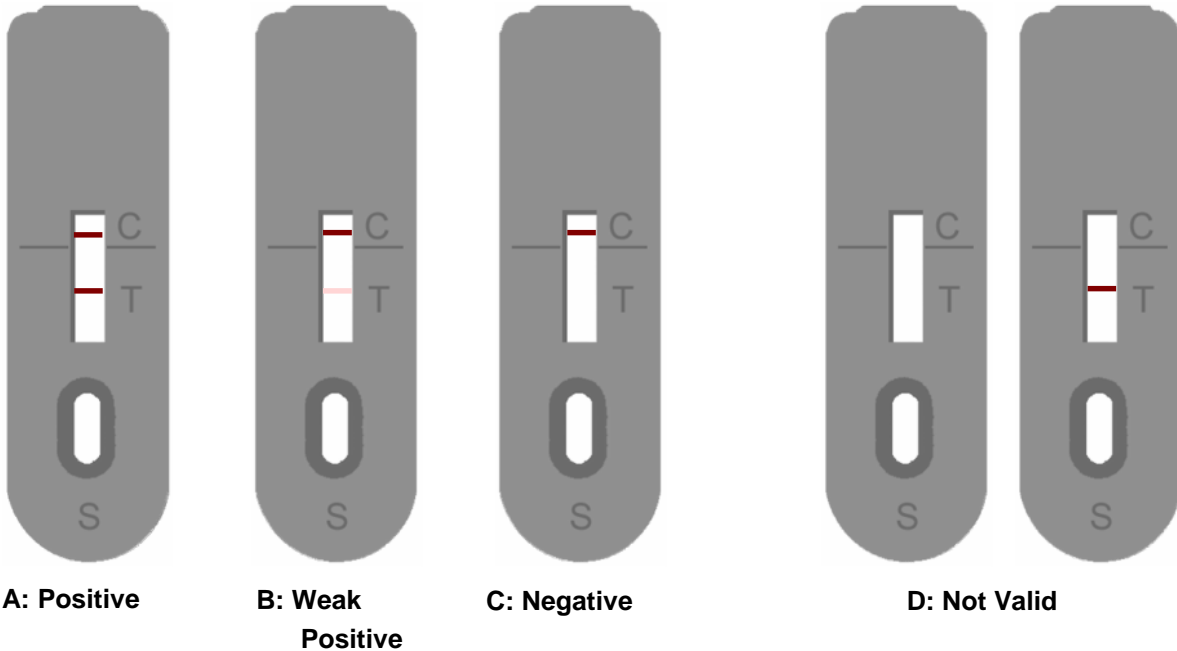
No band is visible in zone “C” (fig. D). Repeat the test procedure.

Important

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

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The purchaser assumes the entire risk as to the performance of these products. DRG shall not be liable for indirect, special or consequential damage of any kind resulting from use of these products.