Human Influenza A (Swine Flu) Rapid test

Cat.No: DTSXY-Z9
Lot. No. (See product label)

Size

20T

Intended use

The Influenza A (Swine Flu) test is a rapid chromatographic immunoassay for the qualitative detection of type A Influenza antigens in human nasopharyngeal specimens (swab, nasopharyngeal wash and aspirate) and in pig specimens (nasal, lung tissue or feces), to aid in the diagnosis of swine flu infection in humans and in pigs, respectively. Only for laboratory use.

General Description

Influenza A virus, of the family Orthomyxoviridae, carries an RNA genome. This genome encodes one or two non-structural proteins and nine structural proteins, which, together with a host cell–derived lipid envelope, comprise the influenza virus particle. Influenza virus causes widespread morbidity and mortality among human populations worldwide. Swine influenza is known to be caused by influenza A subtypes H1N1, H1N2, H3N1, H3N2, and H2N3. In pigs, three influenza A virus subtypes (H1N1, H3N2, and H1N2) are the most common strains worldwide. The symptoms of swine flu are cough, fever, sore throat, fatigue, decreased appetite, less commonly vomiting and diarrhoea.

Principle Of The Test

The Influenza A (Swine Flu) Rapid test is a qualitative lateral flow immunoassay for the detection of type A Influenza antigen in human and pig nasopharyngeal samples and pig stool and lung-tissue samples. The membrane is pre-coated with monoclonal antibodies against Influenza type A antigens on the test line region. During testing, the sample reacts with the particle coated with anti-Influenza antibodies which was pre-dried on the test strip. The mixture moves upward on the membrane by capillary action. In the case of a positive result the specific antibodies present on the membrane will react with the mixture conjugate and generate one coloured lines. A green coloured band always appears in the control line and serves as verification that sufficient volume was added, that proper flow was obtained and as an internal control for the reagents.

Reagents And Materials Provided

1. Card tests contained plastic pipettes
2. Instructions for use
3. Testing tubes or vials
4. Diluent B (REAG)
5. Tissue/stool collection vial with buffer
6. Sterile swabs
7. Certificate of package control

Materials Required But Not Supplied

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1. Sterile collection container
2. Disposable gloves
3. Timer

Specimen Collection And Preparation

Human specimen collection:
1. Nasopharyngeal swab method: Insert swab through nostril to posterior nasopharynx
2. Nasopharyngeal aspirate method/nasal washing: Instill several drops of solution saline into each nostril and collect the liquid.
Pig specimen collection:
1. Nasal swab method: insert swab through nostril to posterior nasopharynx.
2. Nasopharyngeal washing was performed by instilling saline solution into the nostrils and allowing it to drain onto a sterile container.
3. Lung tissue from killed animal: extract a little portion of the affected lung tissue and triturate/homogenized in PBS, centrifuged, and collect the supernatant.
4. Stool collection: Stool samples should be collected in clean and dry containers (no preservatives or transport media). Send specimen to lab immediately (testing sensitivity decrease over time). Cool nasal specimen to 2-4°C (36-40°F) during storage and transport.

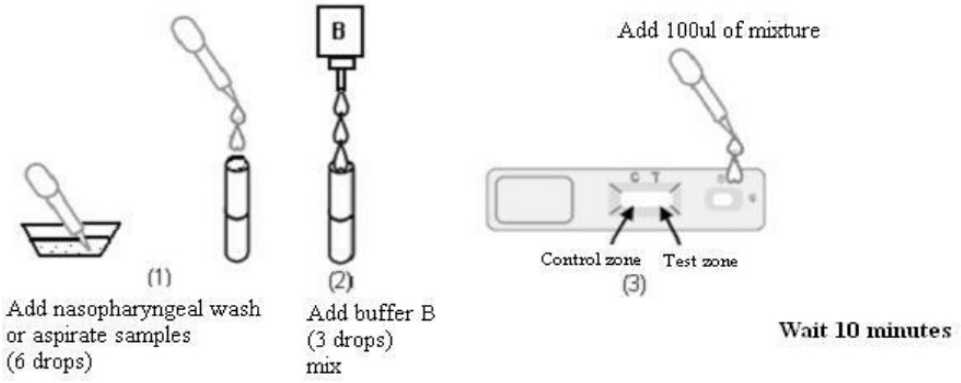
Reconstitution And Storage

Store as packaged in the sealed pouch either at refrigerated or room temperature (2-30°C /36-86°F). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. Do not freeze.

Assay Procedure

Allow the tests, samples and diluents to reach to room temperature (15-30°C/59-86°F) prior to testing. Do not open pouches until ready to perform the assay.To process the collected nasopharyngeal wash or aspirate samples:
Use a separate pipette and testing tube for each sample.

1. Add the nasopharyngeal wash or aspirate sample (6 drops or 300uL) in a testing tube or vial (1). 2. Add the diluent B (3 drops or 150uL) and mix (2). Unpack the Rapid test and use it as soon as possible. Use a new card for each sample.
3. Add 100 uL of the mixture into the window marked with S (3). Start the timer.
4. Read the result after 10 minutes.



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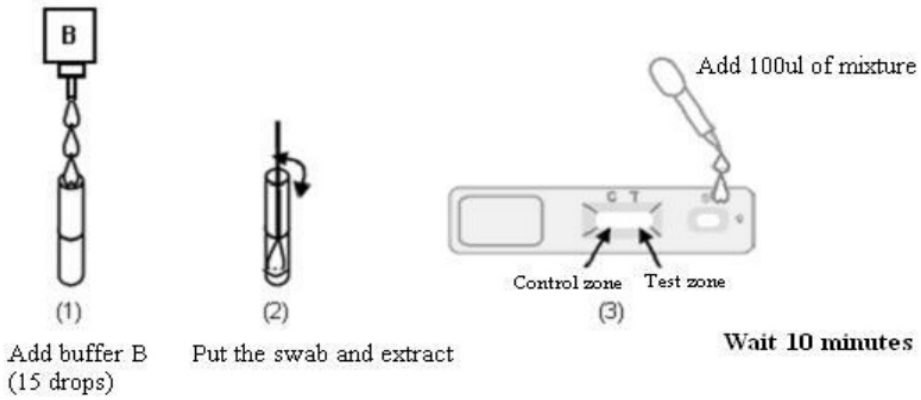
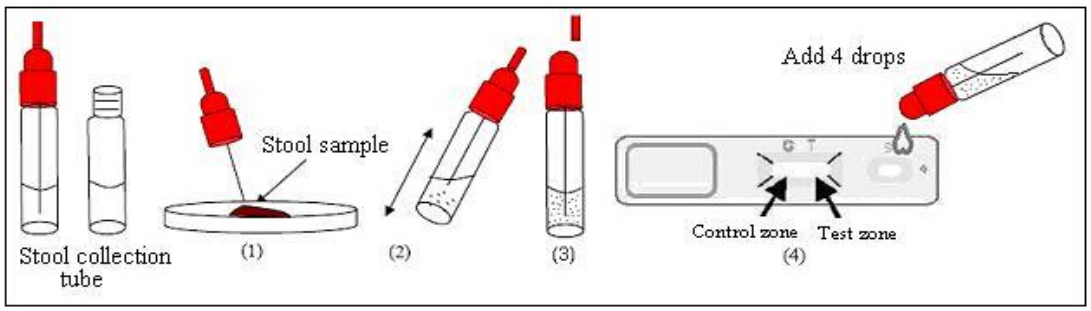
To process the collected nasopharyngeal swab:
Use a separate testing tube or vial for each sample (swab).

1. Add the diluent B (15 drops or 500 uL) into the testing tube or vial (1).
2. Put the nasopharyngeal swab, mix and extract as much liquid possible from the swab (2). Discard the swab. Unpack the Rapid test and use it as soon as possible. Use a new card for each sample.
Add 100 uL of the mixture into the window marked with S (3). Start the timer. Read the result after 10 minutes.



To process the tissue (supernatant)/stool collection sample:
Use a separate specimen collection vial for each sample. Unscrew the cap of the vial:
1. Fecal sample: introduce the stick two times into the fecal specimen to pick up a little sample (100mg) (1). Close the vial with the buffer and stool sample. Shake the vial. For liquid stool samples and lung supernatant, aspirate the specimen with a pipette and add 100μL into the specimen collection vial with buffer.
2. Unpack the Rapid test and use it as soon as possible. Vortex the vial with the sample.
3. Remove the cap of the vial. Use a new card for each sample.
4. Apply exactly 4 drops of the mixture into the window marked with S (4). Start the timer. Read the result after 10 minutes



Quality Control

Internal procedural controls are included in the test:
A green line appearing in the control line region (C). It confirms sufficient specimen volume and correct procedural technique.

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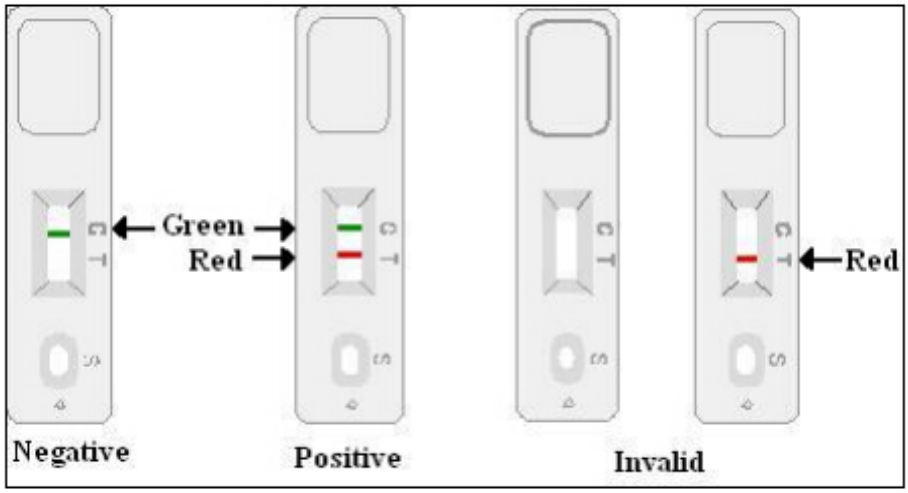
Interpretation Of Results



POSITIVE: Two lines appears across the central window in the result line region (**red** test line marked with the letter T) and in the control line region (**green** control line marked with the letter C).
NEGATIVE: Only one green band appears across the control line region marked with the letter C (control line).
INVALID: A total absence of the green control coloured band regardless the appearance or not of the red test line. Note: Insufficient specimen volume, incorrect procedural techniques or deterioration of the reagents are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit and contact your local distributor.

NOTES ON THE INTERPRETATION OF RESULTS:
The intensity of the red coloured band in the result line region (T) will vary depending on the concentration of antigens in the specimen. However, neither the quantitative value, nor the rate of increase in antigens can be determined by this qualitative test.

Performance Characteristics

Sensitivity and specificity
Different virus extract dilutions were tested directly in the sample diluent or spiked in a negative nasal specimen in accordance with the kit instructions. The detection of Influenza A showed >99% of sensitivity compared with another commercial rapid test and showed >99% of specificity compared with the commercial rapid test.

Cross-Reactivity
It was performed an evaluation to determine the cross reactivity of the Rapid test. There is not cross reactivity with common respiratory pathogens, other organisms and substances occasionally present in nasopharyngeal samples: RSV (Respiratory Syncytial Virus), Adenovirus.

Precautions

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1. Do not use after expiration date.
2. The test should remain in the sealed pouch until use.
3. Do not use the test if pouch is damaged.
4. Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, do not eat, drink or smoke in the area.
5. All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
6. The test should be discarded in a proper biohazard container after testing.
7. The test must be carried out within 2 hours of opening the sealed bag.

Limitations

1. The Rapid test will only indicate the presence of Influenza A in the specimen (qualitative detection). Neither the quantitative value nor the rate of increase in Influenza A antigens concentration can be determined by this test.
2. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of swine flu infection.
3. This test provides a presumptive diagnosis of swine flu. All results must be interpreted together with other clinical information and laboratory findings available to the physician/veterinarian.

References

1. BARENFANGER et al., "Clinical and Financial Benefits of Rapid Detection of Respiratory Viruses: an Outcomes Study". Journal of Clinical Microbiology. August 2000, Vol 38 No 8, p. 2824-2828.
2. LOWEN, A. et al., "The guinea pig as a transmission model for human influenza viruses". PNAS, June 2006, Vol 103, No 26, 9988-9992.

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