



Influenza A (H1N1 / Swine Flu)

A rapid Immunochromatographic test for the qualitative detection of Influenza A (H1N1 or Swine Flu) viral antigen from nasal aspirate or nasal / throat swabs samples

Cat. No. 551-25-DN-A

For Professional In Vitro Diagnostic use only

Read Instructions before use

INTENDED USE

OnSight™ – Influenza A (H1N1) Test Kit is a rapid diagnostic kit for the detection and identification of influenza virus A (H1N1 or Swine Flu) in nasopharyngeal swab and nasal aspirate specimens, using the rapid immunochromatographic method. The identification was based on the monoclonal antibodies specific for the nucleoprotein of Influenza virus A (H1N1). It will provide information for clinical doctors to prescribe correct medications.

INTRODUCTION

The flu is a contagious respiratory illness caused by influenza viruses. It can cause mild to severe illness, and at times can lead to death. The influenza virus can be divided to three types: type A, B, and C. Influenza types A or B viruses cause epidemics of disease almost every winter. In the United States, these winter influenza epidemics can cause illness in 10% to 20% of people and are associated with an average of 36,000 deaths and 114,000 hospitalizations per year. Getting a flu shot can prevent illness from types A and B influenza. Influenza type C infections cause a mild respiratory illness and are not thought to cause epidemics. The flu shot does not protect against type C influenza. Complications of flu can include bacterial pneumonia, ear infections, sinus infections, dehydration, and worsening of chronic medical conditions, such as congestive heart failure, asthma, or diabetes.

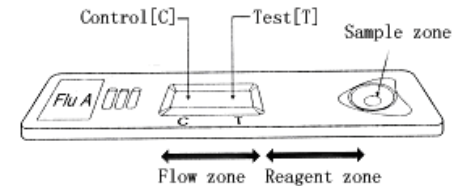
The **OnSight™ – Influenza A (H1N1)** test kit can quickly detect Swine or H1N1 Flu.

TEST PRINCIPLE

OnSight™ – Influenza A (H1N1) Test is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect influenza type A (H1N1) nucleoprotein antigens in nasopharyngeal specimens.

The test device is composed of the following three parts, namely sample pad, reagent pad and reaction membrane. The whole strip is fixed inside a plastic test device. The reagent membrane contains the colloidal-gold conjugated with the monoclonal antibodies against Influenza virus A (H1N1); the reaction membrane contains the secondary antibodies for virus A (H1N1), and the polyclonal antibodies against the mouse globulin, which are pre-immobilized on the membrane.

When the sample is added into the sample window, conjugates dried in the reagent pad are solubilized and migrate along with the sample. If influenza A (H1N1) is present in the sample, a complex formed between the anti-influenza A conjugate and the virus A (H1N1) will be caught by the specific anti-influenza A monoclonal coated on the T region. Results appear in 15 minutes in the form of a red line that develops on the strip. Whether the sample contains the virus or not, the solution continues to migrate to encounter another reagent (anti-mouse IgG antibody) that binds the remaining conjugates, thereby producing a red line on the region C.



KIT COMPOSITION

Test Device	25 test devices
Sample Extraction Buffer	2 tubes x 11 ml
Accessories	
Sterilized Swabs	25 pieces
Tube for extraction	25 pieces
Nozzle with filter	25 (additional 1)
Stand	1 piece

APPLICABLE SAMPLES

It is applicable to detect and diagnosis of the influenza virus A (H1N1) form samples of nasal swabs, nasal aspirates or throat swabs.

SAMPLE COLLECTION



1) Nasal Aspiration

Collect nasal aspirate fluids using the specific aspirator as instructed.



2) Nasal Swabbing

Completely insert the sterilized swab, which is supplied in this kit, into the nasal basin, and swab several times to collect the epidermal cells of the mucus.



3) Throat Swabbing

Insert **deeply** the sterilized swab into the throat and swab several times to collect the epidermal cells of the mucus. **Caution has to be paid to avoid the swab to be contaminated with saliva.**

TEST PROCEDURE

1) Preparation of Sample

Add 0.5 ml of the sample extraction buffer into the test tube, which is supplied in this kit, and put on the stand.

1. Nasal Aspirate

Add 0.5 ml of the nasal aspirate fluid into transfer buffer or 2 ml of the buffered saline. Add 0.5 ml of this mixture to the extraction tube which contains 0.5 ml of the extraction buffer (up to the upper memory line), and mix well by squeezing.

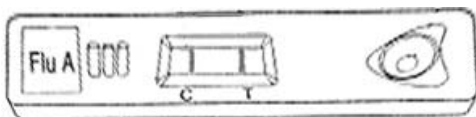
2. Nasal or Throat Swab Samples

Add the swab which has been used to collect the sample into the extraction tube, which was previously added with 0.5 ml of extraction buffer. After mixing, squeezing the tube several times with fingers from outside of the tube to immerse the swab. Remove the swab. The extracted solution will be used as test sample.

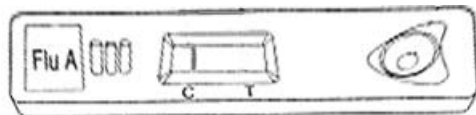
2) Procedure

1. Insert a nozzle (which has filter with it) into the sample extraction tube tightly.
2. Reverse the extraction tube, and add 3 drops (about 100 µL) by squeezing of the extracted solution on the sample window of test device.
3. Read result in 15 minutes after sample application following the criteria described below.

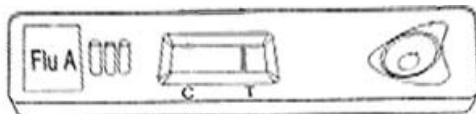
RESULT INTERPRETATION



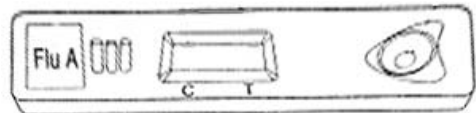
POSITIVE: One colored line appears in the control(C) region, and one colored line on the T region. The shade of color may vary, but it should be considered positive whenever there is even a faint line.



NEGATIVE: One colored line appears in the control(C) region, and no line on the T region. The negative result indicates that there is no influenza A viral particles in the sample or the number of viral particles is below the detectable range.



INVALID: When there is no colored line appears in the control(C) region. The test is invalid even if there is a line in T region. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new device. If the problem persists, discontinue using the lot immediately and contact your local distributor.



PRECAUTIONS

- For in vitro diagnostic use only.
- Do not use the kit after the expiration date.
- The test device should remain in the sealed pouch until use.
- If the **OnSight™ – Influenza A (H1N1)** Test kit was kept 4°C, let all the reagents warm up to room temperature before proceeding with the test.
- Avoid touching the nitrocellulose with your fingers.
- Wear gloves when handling the samples.
- Dispose of gloves, swabs, test tubes, and sensitized strips in accordance with GLP.
- Never use reagents from another kit.

LIMITATIONS

- The **OnSight™ – Influenza A (H1N1)** is an acute-phase screening test. Specimens that are collected after this phase may contain antigen titles below the reagent's sensitivity threshold. So a negative test result does not exclude infection with influenza A (H1N1).
- The **OnSight™ – Influenza A (H1N1)** test detects both viable and non-viable influenza A (H1N1) antigen. Test performance depends on antigen load in the specimen and may not correlate with cell culture performed on the same specimen. A positive test does not rule out the possibility that other pathogens may be present. Therefore, the results must be compared with all other available clinical and laboratory information to make an accurate diagnosis.
- Performance of the test has not been established for monitoring antiviral treatment of influenza.
- Bloody samples may not be appropriate for use in the test.

STORAGE AND STABILITY

Store the kit at room temperature (2-30°C). **OnSight™ – Influenza A (H1N1)** Test Kit and reagents are stable until the expiration dates marked on their outer packaging and containers.

QUALITY CONTROL

To use the following control to calibrate the test plate:

Positive Control (3.0~3.9×10⁵ TCID₅₀ / Test)

Weak Positive Control (3.0~3.9×10⁴ TCID₅₀ / Test)

Negative control (sample extraction buffer)

1) Detection Range

Minimal detection limit for Flu A is 3.0×10⁴ TCID₅₀ / Test.

2) Cross Reactivity Study Results

1. The following Influenza A strains were tested with the Test; **all tested positive.**

H1N1: 5 strains

H2N2: 3 strains

H3N2: 7 strains

2. **Influenza B strain**

No cross reaction with 9 Influenza B strains.

3. **Virus other than influenza:**

No cross reaction with following pathogens

Adenovirus Type 1 ~ 8,11,19,37, Coxsackie virus Type A16,B1 ~ 5, Cytomegalovirus, Echovirus Type 3,6,9,11,14,18,30, Enterovirus Type 71, HSV-1, Mumps virus, Parainfluenza virus Type 1~3, Poliovirus Type 1~3, Respiratory syncytial virus, Rhinovirus Type 1A,13,14

4. Mycoplasma etc.

No cross reaction with *Chlamydia pneumoniae*, *Chlamydia psittaci*, *Chlamydia trachomatis*, *Mycoplasma pneumonia*.

5. Bacteria

No cross reaction with following bacteria:

Acinetobacter baumannii, *Bacteroides fragilis*, *Bordetella pertussis*, *Candida albicans*, *Candida glabrata*, *Cardiobacterium hominis*, *Eikenella corrodens*, *Enterococcus gallinarum*, *Escherichia coli*, *Haemophilus phrophilus*, *aemophilus infiuenzae*, *Haemophilus parainfluenzae*, *Haemophilus paraphrophilus*, *Kingella kingae*, *Klebsiella pneumoniae*, *Listeria monocytogenes*, *Moraxella catarrhalis*, *Neisseria gonorrhoeae*, *Proteus mirabilis*, *Proteus vulgaris*, *Pseudomonas aeruginosa*, *Serratia marcescens*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Streptococcus pneumoniae*, *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Streptococcus sp. group C, G, F*, *Streptococcus mutans*

3) Clinical Test Data Summary

Nasal Aspirates		Positive	Negative	Total
Culture	Positive	52	7	59
	Negative	8	106	114
	Total	60	113	173

Sensitivity=52 / 59=88.1%

Specificity=106 / 114=93.0%

Nasal Swab		Positive	Negative	Total
Culture	Positive	18	1	19
	Negative	4	83	87
	Total	22	84	106

Sensitivity=18 /19=94.7%

Specificity=83 / 87=95.4%

Throat Swab		Positive	Negative	Total
Culture	Positive	9	4	13
	Negative	4	63	67
	Total	13	67	80

Sensitivity=9 / 13=69.2%

Specificity= 63 / 67=94.0%

REFERENCES

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2. Kunin CM: The Responsibility of the infectious disease community for the optimal use of antimicrobial agents. J. Infect Dis 1985; 151: 388-398
3. Influenza Prevention and Control, available at:
<http://www.cdc.gov/ndcidod/diseases/flu/fluivirus.htm>

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