

# ONE STEP® INFLUENZA TYPE A-H1N1 RAPID TEST

## NAME AND INTENDED USE

The One Step® Influenza Type A H1N1 Rapid Test is a lateral flow immunoassay for rapid, qualitative detection of Influenza A-H1N1 antigen directly from nasal swab, nasopharyngeal swab, nasal wash and/or nasal aspirate specimens. Test results are available in 10-30 minutes. The test is intended for use and aid in the diagnosis of influenza A H1N1 Flu (Swine Flu) Infection.

## SUMMARY

The influenza infection is an acute feverish virus infection, which principally leads to an illness of the respiratory tract and appears as an epidemic or pandemic. The infection mostly results from a droplet infection. The virus spreads from the mucous membrane of the upper respiratory to the whole bronchial tract. There the virus and its toxin can lead to a serious inflammation of the bronchial mucosa and damage of the vessels. After an incubation period of 1 to 3 days, the symptoms appear suddenly, followed by a fast increase of temperature, often accompanied by shivering, the catarrhal leading symptom appears, which contributes to the clinical course, beside painful dry cough, tracheitis, laryngitis and frequently a rhinitis and conjunctivitis. The Influenza viruses form a virus group with principally similar morphological, chemical and biological features. The types A, B and C were defined, from which many other variants are known. The distinction of the types will be possible by the different antigenicity of their nucleoproteins, which are coated by a matrix protein with type-specific antigenicity. However, both internal antigens are of less importance for the immunity. The essential antigens are the Hemagglutinin and the Neuraminidase. Both are surface antigens and subject to a permanent change of their antigenicity, which is called drift or shift. The appearance of DAI Code #82 permanent new Influenza epidemics and pandemics are particularly facilitated by an antigen variability because the new drift or shift variants infect a population which is only partly immune or, in an extreme case, completely susceptible to the disease. The determination of the Influenza type (A, B and C) gives both the clinician and epidemiologist important indications for further actions. Thus Influenza B often leads to a serious clinical course and an epidemic spread of the virus. Similarly, during an Influenza A epidemic, the epidemiological importance and derived measures for the protection of the individual and population primarily stand in the foreground, together with the severity of the clinical symptoms.

## PRINCIPLE OF THE TEST

The One Step® Influenza Type A H1N1 Rapid Test utilizes a sandwich immunoassay system and the immunochromatographic detection assay, to be performed in one assay.

Prior to testing, sample is obtained directly from the nasal swab, nasopharyngeal swab; nasal wash and/or nasal aspirate specimens. The nasal swab sample is obtained and placed into a tube containing Extraction solution; after 1 minute, mix well; then the test strip is inserted into the Sample tube.

If Influenza A H1N1 antigen is present in the sample in concentrations above the detection level ( $1 \times 10^7$  virus/ml), a labeled specific antibody-dye conjugate binds to it, forming an antigen-antibody-dye complex. This complex is migrated up, then captured by another specific antibody immobilized in the Test Zone ("T") of the membrane, producing a visible pink-rose color band on the membrane. The color intensity will depend on the concentration of H1N1 virus particles in the sample. On the other hand, a color band will always appear at the Control Zone ("C").

## MATERIALS PROVIDED (Fig. 1)

1. Test Strip
2. Extraction vial containing extraction reagent
3. Sterile Swab\*

\*In order to deliver proper sensitivity only the swab supplied with this kit should be utilized.



Figure 1

## MATERIALS REQUIRED BUT NOT PROVIDED

- Timing Device

## **WARNINGS AND PRECAUTIONS**

1. Precautions in the collection, handling, storage and disposal of the specimens.
2. For in vitro diagnostic use: Do not use the kit beyond the expiration date printed on the outside of the kit box. Dispose of all used test devices in a proper biohazard container.
3. The use of any other swab other than the swab supplied with this kit may result in decreased sensitivity.

## **KIT STORAGE**

Store Kit at room temperature out of direct sunlight, or in the refrigerator. Do not freeze.

## **SPECIMEN COLLECTION AND STORAGE**

The quality of the specimen obtained is of extreme importance. The swab should be inserted into the nasal cavity to at least 1 inch of distance. The sample must be tested within eight hours and stored under refrigeration, if not used immediately.

## **SAMPLE COLLECTION METHOD: Nasal Swab (a Nasopharyngeal (NP) Swab)**

The NP swab is collected by having the patient tip their head back, then the swab is gently inserted into one of the nostrils until resistance is met (about 1 to 2 inches in), then rotated several times and withdrawn. The procedure is not painful, but it may tickle a bit and cause eyes to tear. Doctors usually use NP swabs on adults, but may choose to do a nasal wash or aspirator on a child. In some circumstances, a doctor may use a throat swab, but this contains fewer viruses.

## **QUALITY CONTROL**

Although the Kit contains an internal quality control function (pink/rose color band in the Control region), good laboratory practice recommends the daily use of an outside control to ensure proper kit performance.

Quality control samples should be tested according to the requirements established by your laboratory.

## **PROCEDURE**

Prior to use, bring all test components and patient samples to room temperature.

### **Extraction Procedure:**

1. Insert the nasal swab into one of the nostrils until resistance is met (about 1 to 2 inches in), then rotate several times and withdraw;
2. Remove plastic cap from extraction;
3. Remove the swab containing sample from the nostril and insert into the extraction vial, twirling for 1 minute;
4. Express the liquid from the nasal swab by compressing the swab. Remove swab from tube and discard.

### **Test Procedure:**

Remove the "Test Strip" from the foil wrapper by tearing along the "splice", and place it on a clean level surface. Discard the desiccant.

*Note: A piece of adhesive foam is included to provide a stable platform for the extraction vial. This is to minimize the possibility of the vial spilling during the test procedure.*

1. Peel the cover from the adhesive foam and affix the bottom of the vial to the center of the exposed adhesive. Place the vial and base on a level surface.

2. Insert the test strip into the Extraction vial, as shown in *Fig. 2*



*Figure 2*

3. Hold the strip in a vertical position and put into the vial containing the sample. Do not let the level of liquid surpass the "maximum" level labeled on the strip.
4. Remove the strip from the vial after seeing the pink to purple liquid wetting the membrane of the strip and lay the strip on the table. (*Fig. 3*)

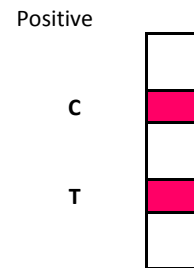


*Figure 3*

3. Read the results within 15 minutes.  
**Note: Results may show up to 30 minutes**

## **INTERPRETATION OF RESULTS**

### **Positive Test**



**Illustration 1**

1. If there are two pink-to-purple lines, one in the Control region "C", and the other in the Test region "T", then the test is POSITIVE and indicates that the specimen contains Influenza A H1N1 antigen.

## Negative Test

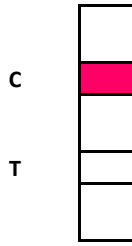


Illustration 2

- If the test has only one line in the Control region "C", and there is no line in the Test region "T", then a **NEGATIVE** test result indicates that the specimen is a presumptive negative for the presence of Influenza A H1N1 antigen.

## Invalid Test

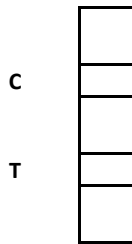


Illustration 3

- Invalid.** If no Control band appears within five minutes, the result is invalid and should be ignored. A visible Control band is needed in all cases to confirm proper test operation. If no Control band exists, this indicates the test procedure was not followed correctly or the test reagents failed.

## Sensitivity and Specificity

Preliminary—

Sensitivity for virus particles  $6 \times 10^6$  virus/ml.

Sensitivity : >94%

Specificity : >90% (*\*see note under Limitations of the Test, below*)

## Material – Lot Specific

See individual Certificate of Analysis for lot accuracy.

## LIMITATIONS OF THE TEST

- The test is for in vitro diagnostic use only. Pending FDA clearance. This test is NOT available for sale in the USA.
- Detection of Influenza A-H1N1 is dependent on the number of organisms present in the specimen. This may be affected by specimen collection.
- The One Step® Influenza Type A H1N1 Rapid Test may also cross react with Influenza A H3N2 virus.
- The procedure and patient's factors, such as age, history of viral infections, presence of symptoms, etc.
- As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the results of a single test, but should only be made by a physician after all clinical and laboratory findings have been evaluated.

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