

Influenza A- H1N1 Virus

One-Step Test Kit

Cat. No. I-075

INTENDED USE

The QikTech Influenza A H1N1 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 5 minutes or less. The test is intended for use as an aid in the diagnosis of Influenza A H1N1 (Swine Flu) infection.

SUMMARY AND EXPLANATION

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 a damage of the vessels. After an incubation time 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 contribute 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, too. 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 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 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 PROCEDURE

The QikTech Influenza A H1N1 test utilizes a sandwich immunoassay system and the immunochromatographic detection assay, to be performed in one assay. Prior to the test, the nasal swab sample is obtained and placed into an Extraction tube with the Solution buffer. If Influenza A H1N1 antigen is present in the sample in concentrations above the detection level (1×10^5 virus/ml), a labeled specific antibody-dye conjugate binds to it forming an antigen-antibody-dye complex. This complex is migrated up, and 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 Influenza A H1N1 antigen in the sample. On the other hand, a color band will always appear at the Control zone ("C").

MATERIALS PROVIDED

1. Test Device in foil pouch
2. Extraction Tube with the dry chemical.
3. Solution Buffer (0.5ml)
4. Swab
5. Positive Control (sold separately)

MATERIALS REQUIRED BUT NOT PROVIDED

1. Timing device.

WARNINGS AND PRECAUTIONS

2. 1. Precautions in the collection, handling, storage and disposal of the specimens.
3. 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

KIT STORAGE

Store kit at room temperature and out of direct sunlight

SPECIMEN COLLECTION AND STORAGE

The quality of the specimen obtained is of extreme important. The swab should be inserted into nasal for around 1 inch of distance. The sample must be tested within eight hours.

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 quality control requirements established by your laboratory.

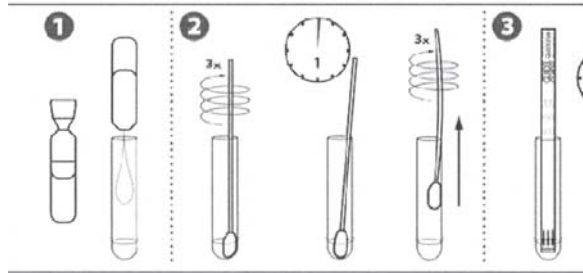
PROCEDURE

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

EXTRACTION PROCEDURE

1. Add all the contents of the Solution Buffer vial into the Extraction Tube and shake well.
2. Insert the swab into nasal with distance of 1 inch.
3. Place the swab sample into the extraction tube. Roll the swab at least 3 times while pressing the head against the bottom and the side of the extraction tube.

- Roll the swab head against the inside of the extraction tube as you remove it. Dispose of the used swab in accordance to your biohazard waste disposal protocol.

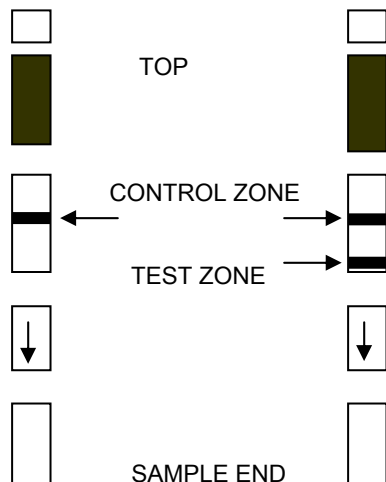


TEST PROCEDURE

- Remove the "Test Strip" from the foil wrapper.
- Place the strip into the extraction tube with the arrows on the test strip pointing down.
- Do not handle or move the test strip until the test is completed and ready for reading.

Read the results in 5 minutes.

INSERT THE TEST STRIP INTO THE EXTRACTION TUBE



NEGATIVE

POSITIVE

INTERPRETATION OF RESULTS

POSITIVE RESULT:

At 5 minutes, any shade of a pink-to-red Test Line forms and the appearance of a Control Line indicates a positive result for the presence of Influenza A H1N1 antigen



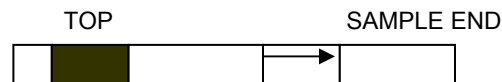
NEGATIVE RESULT:

At 5 minutes, the appearance of ONLY the Control Line indicates the sample is negative for Influenza A H1N1 antigen. A negative result should be reported as a presumptive negative for the presence of influenza antigen...



INVALID RESULT:

If a color band does not appear in the Control zone "C", the test results are invalid. The Sample may have been added to the wrong window, or the test device may have deteriorated. The specimen should be re-tested using a new test device.



SENSITIVITY AND SPECIFICITY

Sensitivity: 94%; Specificity: 90%.

LIMITATIONS OF THE TEST

- The test is for *in vitro* diagnostic use only.
- Detection of Influenza A H1N1 is dependent on the number of organisms present in the specimen. This may be affected by specimen collection, procedure and patient's factors such as age, presence of symptoms, etc.
- QikTech Influenza A H1N1 test also detects H3N2 by cross reaction.
- 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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