



REF 6109

June 20, 2009

Influenza Antigen Quick

- 25 determinations -



IVD *In vitro* diagnostic device

Rapid immunochromatographic test for the detection of Influenza virus type A and type B antigen in nasal and nasopharyngeal specimens (swab, wash and aspirate)

REF	Catalogue number	LOT	Batch code
	Consult accompanying documents		Manufactured by
	Temperature limitation		Use by
	Consult operating instruction		Biological risk



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INTENDED USE

Influenza Antigen Quick is used for the qualitative determination of influenza virus type A and type B antigens in human nasal and nasopharyngeal specimens.

Influenza is caused by a virus that attacks mainly the upper respiratory tract – the nose, throat and bronchi and rarely also the lungs. The infection usually lasts for about a week. It is characterized by sudden onset of high fever, myalgia, headache and severe malaise, non-productive cough, sore throat, and rhinitis. Most people recover within one to two weeks without requiring any medical treatment. In the very young, the elderly and people suffering from medical conditions such as lung diseases, diabetes, cancer, kidney or heart problems, influenza poses a serious risk. In these people, the infection may lead to severe complications of underlying diseases, pneumonia and death.

Influenza viruses are defined by 2 different protein components, known as antigens, on the surface of the virus. They are spike-like features called haemagglutinin (H) and neuraminidase (N) components. The currently circulating influenza viruses that cause human disease are divided into two groups; A and B. Influenza A has 2 subtypes which are important for humans: A (H3N2) and A (H1N1), of which the former is currently associated with most deaths.

Noyola DE et al.: Comparison of a New Neuraminidase Detection Assay with an Enzyme Immunoassay, Immunofluorescence, and Culture for Rapid Detection of Influenza A and B Viruses in Nasal Wash Specimens. *J Clin Microbiol*, 2000, 38, 1161-1165

Weinberg A, Walker ML: Evaluation of Three Immunoassay Kits for Rapid Detection of Influenza Virus A and B. *Clin Diagn Lab Immunol*, 2005, 12, 367-370

Cazacu AC, Demmler GJ, et al.: Comparison of a New Lateral-Flow Chromatographic Membrane Immunoassay to Viral Culture for Rapid Detection and Differentiation of Influenza A and B Viruses in Respiratory Specimens. *J Clin Microbiol*, 2004, 42, 3661-3664

Irmen KE, Kelleher JJ: Use of Monoclonal Antibodies for Rapid Diagnosis of Respiratory Viruses in a Community Hospital. *Clin Diagn Lab Immunol*, 2000, 7, 396-403

PRINCIPLE OF THE TEST

Influenza Antigen Quick is a fast one-step immunochromatographic assay for the detection of Influenza virus type A and type B antigens in specimens taken from upper respiratory tract.

The membrane is pre-coated with monoclonal antibodies to Influenza virus type A and type B antigens. During testing, the antigen in the sample is allowed to react with the colored conjugates (anti-Influenza virus type A antibodies - red microspheres; anti-Influenza virus type B antibodies - blue microspheres) which were pre-dried on the test. The complex formed of virus antigen and respective conjugate then migrates upward on the membrane by capillarity. In case of a positive result the specific antibodies present on the membrane will capture the colored conjugate forming a RED or BLUE band.

The access conjugate mixture continues to migrate across the membrane to the immobilized antibodies placed in the control band region forming a green colored band. The presence of this GREEN band serves as 1) verification that sufficient volume is added, 2) that proper flow is obtained and 3) as an internal control for the reagents.

TEST COMPONENTS for 25 determinations

A	Test strips	1	
Ab	25	25 test strips containing mouse monoclonal antibodies to Influenza virus type A and type B	1 container sealed with desiccant
B	Sample diluent	2x 7.0 ml	
DIL		ready for use	dropper bottle

Materials required but not provided

- sterile swabs (Dacron, Rayon)
- sterile saline solution
- micropipettes, disposable pipettes
- tubes or vials
- disposable gloves
- timer

Size and storage

Influenza Antigen Quick has been designed for 25 determinations.

Store as packaged in the sealed pack either refrigerated or at room temperature (2-30°C).

The test is stable through the expiration date printed on the sealed pack. The test must remain in the sealed pack until use. Do not freeze.

PATIENT SAMPLES

Specimen collection and preparation

Nasal swab specimens:

- Collect specimen with a sterile swab from one nostril.
- Insert the swab approximately 3 cm into the nostril rotating against the nasal wall.
- For an optimal sample, repeat procedure using other nostril.

Nasopharyngeal swab method:

- Bend shaft of a sterile swab to follow curve of nasopharynx.
- Insert swab through nostril to posterior nasopharynx.
- Rotate swab a few times to obtain infected cells.
- For an optimal sample, repeat procedure using other nostril.

Nasal Wash or Aspirate specimens:

- Place the irrigator up to the nose.
- Let the sterile saline water run into the nose (2.5 ml), it will run out the opposite side.
- Tilt and twist the irrigator side to side and up and down directing the water flow into all portions of the nasal cavity.
- Collect the wash in a clean specimen container, tilt the head forward and allow the water with mucus to run out of the nostril into the specimen container.
- Repeat the mucus collection for the other nostril and collect it into the same container.

Nasopharyngeal aspirate method (suction apparatus, sterile suction catheter):

- Instil several drops of saline solution into each nostril.
- Place catheter through nostril to posterior nasopharynx.
- Apply gentle suction. Using rotating motion, slowly withdraw catheter.
- For an optimal sample, repeat procedure using other nostril.

Transportation of specimens

Samples should be processed as soon as possible after collection. If immediate testing of the sample is not possible, insert a swab sample into a tube that contains sterile saline solution (quantity appr. 0.5 ml). During transportation, the sample should be kept between 2-4°C. When the sample is to be tested, just squeeze as much solution as possible from the swab by pressing the swab against the walls of the tube.

Insert the test strip in the sample vertically taking care of not surpassing the limit of immersion indicated with the arrows (Note: Please note that in case of transported sample there is no need to use the sample diluent B since the sample is already diluted and the virus is extracted in the saline solution that had been used to transport the swab).

In the case of the wash and aspirate specimens, the sample is already collected using sterile saline solution. No further processing is needed. When transporting such samples, keep them in the same container that had been used to collect the sample (after covering it with a cap) and keep it refrigerated at 2-4°C during the transportation.

When testing the sample, use the same procedure mentioned in the package insert.

The samples can be stored in the refrigerator (2-4 °C) for up to 8 hours prior to testing.

ASSAY PROCEDURE

Allow the tests components and samples to reach room temperature (15-30°C) prior to testing. Do not open the package until ready to perform the assay.

Take care to agitate samples gently in order to ensure homogeneity. Shake the test tube with a vortex if necessary in order to assure good sample dispersion.

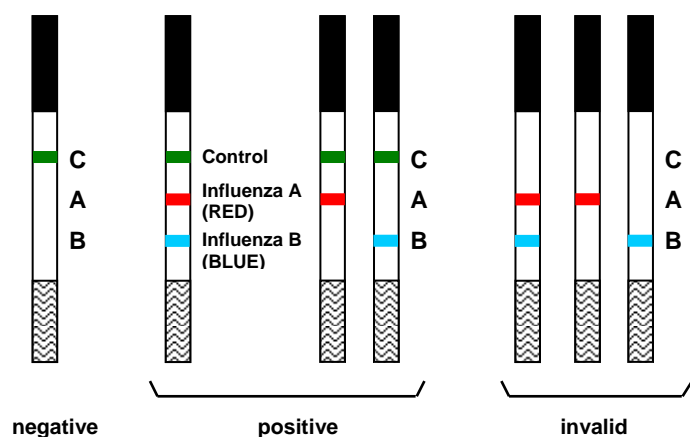
Nasal or Nasopharyngeal Swab specimens:

1. Put 10 drops or 500 µl of Sample diluent (B) into a clean tube
2. Add the swab to tube.
3. Mix and extract as much sample material as possible from the swab.
4. Dispense 150 µl in a new testing tube.
5. Remove a Test strip (A) from the container and use it as soon as possible.
6. Insert the test strip in the sample vertically taking care of not surpassing the limit of immersion indicated with the arrows.
7. Read the result at 10 minutes after dispensing the sample

Nasal or Nasopharyngeal Wash or Aspirate specimens:

1. Add the nasopharyngeal wash or aspirate sample (6 drops or 300 µl) in a testing tube or vial.
2. Add 3 drops or 150 µl of the Sample diluent (B) and mix.
3. Extract some of the liquid and dispense 150 µl in a new testing tube.
4. Remove a Test strip (A) from the container and use it as soon as possible.
5. Insert the test strip in the sample vertically taking care of not surpassing the limit of immersion indicated with the arrows.
6. Read the result at 10 minutes after dispensing the sample.

EVALUATION OF RESULTS



NEGATIVE: Only one GREEN band (control line) appears in the white central zone of the test (control region).

POSITIVE: In addition to the GREEN control band, a distinguishable RED band (Influenza A virus positive), a BLUE band (Influenza B virus positive) or both RED and BLUE band (Influenza A and B virus positive) also appear in the white central zone of the test (result region).

INVALID: A total absence of the control band (GREEN) regardless of the appearance or not of the result lines (RED or BLUE). 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 performance using a new test. If the problem persists please contact your local distributor.

Test validity

Internal procedural controls are included in the test. A green line appearing in the control region is an internal control. It confirms sufficient specimen volume and correct procedural technique.

Limitations of the method

The test must be carried out within 2 hours after removing the strips from the container.

This test provides a presumptive diagnosis for Influenza A + B infections. A confirmed infection diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

Influenza Antigen Quick should be used only with nasal swabs, nasal wash and nasal aspirate samples. The use of swab specimens taken from other sites or the use of other samples such as saliva, sputum or urine has not been established. The quality of the test depends on the quality of the sample; proper nasal specimens must be obtained.

A negative result may be obtained if the specimen is inadequate or antigen concentration is below the sensitivity of the test. 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 Influenza infection.

The intensity of the result bands (RED or BLUE) varies depending on the concentration of antigens present in the specimen. However, neither the quantitative value, nor the rate of increase in antigens can be determined by this qualitative test.

Any clinical diagnosis should not be based on the results of in vitro diagnostic methods alone. Physicians are supposed to consider all clinical and laboratory findings possible to state a diagnosis.

ANALYTICAL PERFORMANCE

Analytical Sensitivity

The minimum detectable unit of Influenza virus A and B is about 10 ng/ml each.

Diagnostic Sensitivity

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 type A and/or type B with Influenza Antigen Quick showed > 99% of sensitivity compared with another commercial rapid test.

Diagnostic Specificity

The use of mouse monoclonal antibodies in the elaboration of Influenza Antigen Quick assures high degree of specificity for the detection of Influenza type A and type B antigens.

The detection of Influenza type A and type B virus with Influenza Antigen Quick showed >99% of specificity compared with another commercial rapid test.

Cross Reactivity

An evaluation was performed to determine the cross reactivity of the Influenza Antigen Quick. There was no cross reactivity found with common respiratory pathogens occasionally present in nasopharyngeal samples like:

- Respiratory syncytial virus
- Adenovirus
- Parainfluenza virus

SAFETY PRECAUTIONS

- **This kit is for in vitro use only.** Follow the working instructions carefully. GA GENERIC ASSAYS GmbH and its authorized distributors shall not be liable for damages indirectly or consequentially brought about by changing or modifying the procedure indicated. The kit should be performed by trained technical staff only.
- The expiration dates stated on the respective labels are to be observed.
- Do not use or mix reagents from different lots. Do not use reagents from other manufacturers.
- All reagents should be kept at 2 - 8 °C before use in the original shipping container.
- Some of the reagents contain small amounts of Sodium azide (0.095%) as preservative. They must not be swallowed or allowed to come into contact with skin or mucosa.
- Sample materials must be handled as infectious material. Wear disposable gloves while handling clinical specimens. Dispose clinical specimens in accordance with local legislation.
- Since the kit contains potentially hazardous materials, the following precautions should be observed:
 - Do not smoke, eat or drink while handling kit material,
 - Always use protective gloves,
 - Never pipette material by mouth,
 - Wipe up spills promptly, washing the affected surface thoroughly with a decontaminant.
- In any case GLP should be applied with all general and individual regulations to the use of this kit.