Proflow™ Influenza A

(for *In Vitro* Diagnostic use only)

PRODUCT CODE PL.3022 **20 Tests**

INTENDED USE

The Proflow™ Influenza A test is a single use rapid membrane immunoassay for the qualitative detection of influenza type A antigen, including subtypes A(H1N1) and A(H3N2), in human nasopharyngeal samples to aid in the diagnosis of influenza infection. For *In Vitro* Diagnostic Use.

SUMMARY AND EXPLANATION

Influenza is caused by viruses that predominantly attack the upper respiratory tract – the nose, throat and bronchi and rarely also the lungs. The infection usually lasts for about a week. It is characterised 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 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.

The currently circulating influenza viruses that cause human disease are divided into two groups: A and B. Influenza A has 2 subtypes which are significant to humans: A(H3N2) and A(H1N1), of which the former is currently associated with most deaths. Influenza virus subtypes are defined by 2 different protein components on the surface of the virus. They are spike-like features called haemagglutinin (H) and neuraminidase (N). Outbreaks and sporadic human infection with swine influenza or avian influenza have been occasionally reported.

PRINCIPLE OF THE TEST

The Proflow™ Influenza A test is a single use rapid membrane immunoassay for the qualitative detection of influenza A antigen in human nasopharyngeal samples.

Monoclonal antibodies to influenza A antigen are coated onto the test line region of the strip. During testing the sample migrates along the membrane by capillary action and is allowed to react with the conjugate on the test strip.

In the case of a positive result the specific antibodies present on the membrane will capture the coloured conjugate. A green line should always appear in the control line region to show that sufficient volume was added, proper flow was obtained and the reagents functioned correctly. Failure of the control line to appear, whether or not test lines are present, indicates an invalid assay.

The test is interpreted by the presence or absence of visibly detectable coloured lines in the test region at 10 minutes or less depending on the concentration of antigen present. A positive result will show a pink/red test line and a green control line, indicating that influenza A antigen is present in the sample. A negative test result, read at 10 minutes, will show only a green control line, indicating that influenza A antigen was not detectable in the sample.

MATERIALS PROVIDED

- PL.3122 Proflow™ Influenza A Test Device: 20 Devices
- PL.3222 Proflow™ Influenza A Diluent
- PL.3322 Proflow™ Influenza A Positive Control Swab
- Proflow™ test tubes: 20
- Plastic pipette: 20
- Proflow™ swabs: 20
- Package insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Sample collection container
- Timer or stopwatch
- Biohazard disposal container
- Disposable gloves

STABILITY AND STORAGE

- Store all components at 2-30ºC.
- Do not freeze or overheat.
- Do not use beyond the expiration date printed on the outer package label.
- The test kits should be kept away from direct sunlight, moisture and heat.

PRECAUTIONS

- For *In Vitro* Diagnostic Use only.
- For professional use only.
- Directions should be read and followed carefully.
- Tests are for single use only. Do not reuse.
- Reagents are provided at the necessary working strength. Do not dilute reagents.
- Do not interchange reagents between kits with different lot numbers.
- Do not use kits or reagents beyond the stated expiration dates.
- Microbial contamination of reagents may decrease the accuracy of the assay.
- Treat all materials as if they were infectious and dispose of all material in accordance with local regulation.

SAMPLE STORAGE AND COLLECTION

NASOPHARYNGEAL SWAB METHOD

- Bend shaft 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.

NASOPHARYNGEAL ASPIRATE METHOD

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

Test sample as soon as possible. Allow the tests, samples and diluent to reach room temperature 15-30ºC prior to testing. Cool sample to 2-8ºC (36-46ºF) during storage and transport for 8 hours prior to testing.

TEST PROCEDURE

NASOPHARYNGEAL SWAB METHOD (SAMPLE AND CONTROLS)

1. Remove the test from its pack just before use. Place the test on a clean flat surface.
2. Label each test with appropriate patient information.
3. Use a separate pipette and test for each sample or control.
4. Put the swab into the test tube.
5. Add 15 drops (or 500uL) of diluent and agitate to remove cells from swab.
6. Dispense 3 drops (or 100uL) of the sample mix into the circular window.
7. Read the result at 10 minutes. Do not read the results after 10 minutes as they may be inaccurate.

NASOPHARYNGEAL ASPIRATE METHOD

1. Remove the test from its pack just before use. Place the test on a clean flat surface.
2. Label each test with appropriate patient information.
3. Use a separate pipette and test for each sample or control.
4. Add 6 drops (or 200uL) of nasopharyngeal wash or aspirate sample into a test tube.
5. Add 9 drops (or 300uL) of diluent and mix for one minute.
6. Dispense 3 drops (or 100uL) of the sample mix into the circular window.
7. Read the result at 10 minutes. Do not read the results after 10 minutes as they may be inaccurate.

QUALITY CONTROL PROCEDURE

It is recommended that a positive and negative control be used to ensure that the test is performing as expected.

The control line (C) is a procedural control and will show that the test has been performed correctly; proper flow occurred and that the test reagents functioned as expected. When a green line appears at the control line position this indicates the test has been performed correctly. The control line will appear on all valid tests, whether or not the sample is reactive or non-reactive (refer to the Interpretation of Results section). A positive control swab is provided in the kit.

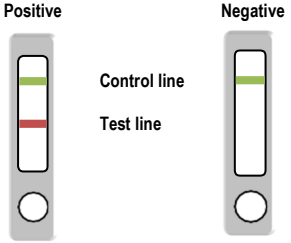
INTERPRETATION OF RESULTS

Positive

A pink/red line of any intensity appears at the test line position; a green line of any intensity appears at the control line position. This indicates a reactive result that is interpreted as positive for influenza A antigen.

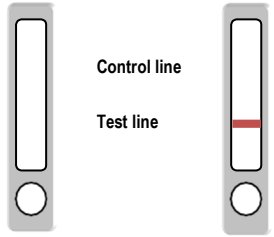
Negative

A single green line of any intensity appears in the test window at the control line position. There is no line at the test line position. This indicates a non-reactive result that is interpreted as negative for influenza A antigen.



Invalid

No line appears in the test window at the control line position. This is an invalid result and cannot be interpreted. This is irrespective of whether or not a pink/red line appears in the test window at the test line position. If either condition below occurs, the test should be repeated with a new test.



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LIMITATIONS OF THE PROCEDURE

- Proflow™ Influenza A test will only indicate the presence of influenza A in the sample (qualitative detection) and should be used for the detection of influenza type A antigens in nasopharyngeal samples only (from swab, aspiration or wash). Neither the quantitative value nor the rate of increase in influenza A antigen concentration can be determined by this test.
- The test must be carried out within 2 hours of opening the sealed pack.
- 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 A infection.
- This test provides a presumptive diagnosis for influenza A infections. All results must be interpreted together with other clinical information and laboratory findings available to the clinician.

PERFORMANCE CHARACTERISTICS

EXPECTED VALUES

Influenza type A virus causes epidemics of disease almost every winter. In the US, these winter influenza epidemics can cause illness in 10 to 20% of people and are associated with an average of 36,000 deaths and more than 200,000 hospitalisations per year.

SENSITIVITY AND SPECIFICITY

An evaluation was conducted comparing results obtained using the Proflow™ Influenza A test against another commercial rapid test. Different virus extract dilutions were tested directly in the sample diluent or spiked in a negative nasal specimen in accordance with kit instructions. The Proflow™ Influenza A test showed:

Specificity >99%
Sensitivity >99%

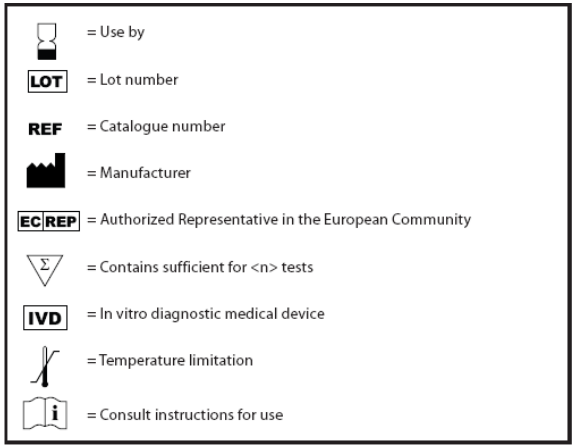
CROSS-REACTIVITY

An evaluation was performed to determine the cross-reactivity of the Proflow™ Influenza A test. There was no cross-reactivity with common respiratory pathogens, other organisms and substances occasionally present in nasopharyngeal samples:

- Respiratory Syncytial Virus
- Adenovirus

REFERENCES

- 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, pp.2824-2828.



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