PATHKITS

INFLUENZA A/B ANTIGEN TEST

Product Code: **PKRK046**
Kit Contents (**25 Kits**)
Shelf Life: **24 Months**

Kit Components	Quantity (Units)
Test Strips	25
Extraction Buffer	1 Bottle
Nasal Swabs	25
Sample Collection Tubes	25
IFU	1

Intended Use

Influenza A/B Antigen Test is a rapid chromatographic immunoassay for the qualitative detection of Influenza A and B antigens in nasal swab specimens. It is intended to aid in the rapid differential diagnosis of influenza A and B viral infections. A negative test is presumptive and it is recommended these results be confirmed by cell culture. Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other management decisions

Test Principle

The Influenza A/B Antigen Test is a qualitative, lateral flow immunoassay for the detection of Influenza A and Influenza B nucleoproteins in nasal swab specimens. In this test, antibody specific to the Influenza A and Influenza B nucleoproteins are separately coated on the test line regions of the test cassette. During testing, the extracted specimen reacts with the antibody to Influenza A and/or Influenza B that are coated onto particles. The mixture migrates up the membrane to react with the antibody to Influenza A and/or Influenza B on the membrane and generates one or two colored lines in the test regions. The presence of this colored line in either or both of the test regions indicates a positive result.

Warnings and Precautions

1. Read these Instructions for Use completely before performing the test. Failure to follow the instructions could lead to inaccurate test results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15-30°C) before use.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test. Follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other bloodborne pathogens.
7. Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
8. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
9. Handle the negative and positive controls in the same manner as the patient specimens

Reagent Preparation and Storage Instructions

All reagents are ready to use as supplied. Store unused test devices unopened at 2-40°C. If stored at 2-8°C, ensure that the test device is brought to room temperature (15-30°C) before opening. The test device is stable through the expiration date printed on the pouch. Do not freeze or expose the kit to temperatures above 30°C.

Specimen Collection and Handling

- Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.

Materials Required but not provided

1. Timer or Stopwatch
2. PPE and other consumables for collection and disposal of samples

Specimen transport and storage:

Test specimens as soon as possible after collecting. If not tested immediately, swab specimens can be stored in a clean and closed container at 2-8°C for up to 24 hours.

Limitations of Test

1. Rapid Detection Flu A/B antigen Test can only be used with the Pathkits Rapid Detection Reader.
2. Additional testing is required to differentiate any specific Influenza A subtypes or strains, in consultation with state or local public health departments.
3. Children tend to shed virus more abundantly and for longer periods of time than adults. Therefore, testing specimens from adults may yield lower sensitivity than testing specimens from children.
4. Positive and negative predictive values are highly dependent on prevalence. False negative test results are more likely during peak activity when prevalence of disease is high. False positive test results are more likely during periods of low influenza activity when prevalence is moderate to low.

Mfg By: PathKits Healthcare Pvt Ltd, Plot 28, 29 Sector 18(P), Gurgaon -122001, India Customer care No.: +91-7303429198
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5. Individuals who have received nasal administered Influenza A vaccine may test positive in commercially available influenza rapid diagnostic tests for up to three days after vaccination.
6. Tests using monoclonal antibodies may fail to detect, or detect with less sensitivity, Influenza A viruses that have undergone minor amino acid changes in the target epitope region.
7. Sample types, swabs or viral transport media other than those listed have not been evaluated and should not be used

Procedure

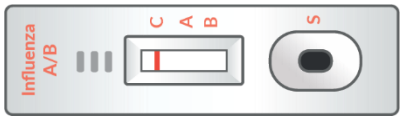
1. Allow the test cassette to reach room temperature (appropriately 30minutes).

For swab sample: Put swab to be tested into the virus lysis vial. Rotate swab vigorously some (no less than 3) times in the liquid to make the samples dissolved in the liquid. Press the swab against the side of the vial and turn as you remove it from the vial. Then discard the swab. Slowly add 80µL sample prepared into the middle of the sample well. Do not allow the sample to overflow. Place the cassette on a flat surface, read the result within 15 minutes after adding the sample.

For liquid sample: Add 500uL liquid sample into the virus lysis vial, mix the liquid vigorously. Slowly add 80µL sample prepared into the middle of the sample well. Do not allow the sample to overflow. Place the cassette on a flat surface, read the result within 15 minutes after adding the sample. Read the test results between 15 and 20 minutes. Do not read the results after 20 minutes.

Interpretation of results

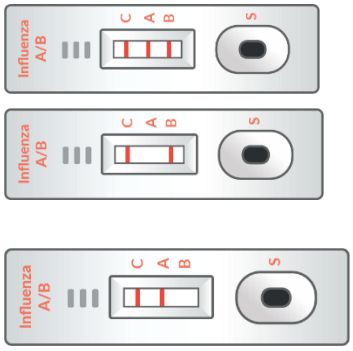
NEGATIVE RESULT: If only the C line develops, the test indicates that no detectable influenza A and B virus is not present in the specimen. The result is negative or non-reactive.



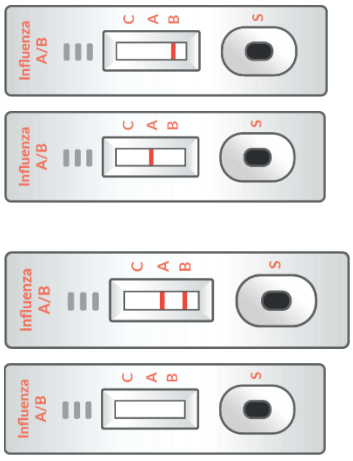
POSITIVE Influenza A: Two distinct colored lines appear in the right window. One colored line should be in the control region (C) and another colored line should be in the Influenza A region (A). A positive result in the Influenza A region indicates that Influenza A antigen was detected in the sample.

POSITIVE Influenza B: Two distinct colored lines appear in the right window. One colored line should be in the control region (C) and another colored line should be in the Influenza B region (B). A positive result in the Influenza B region indicates that Influenza B antigen was detected in the sample.

POSITIVE Influenza A and Influenza B: Three distinct colored lines appear in the right window. One colored line should be in the control region (C) and two colored line should be in the Influenza A region (A) and Influenza B region (B). A positive result in the Influenza A region and Influenza B region indicates that Influenza A antigen and Influenza B antigen were detected in the sample



INVALID: If no C line develops, the assay is invalid regardless of color development on the T line. Repeat the assay with a new device.



Technical Assistance

For customer support, please contact our Technical Support:
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Email: info@pathkits.com

Central Drugs Standard Control Organisation

Directorate General of Health Services

Ministry of Health & Family Welfare

(Medical Device & Diagnostic Division)

FDA Bhawan, Kotla Road
New Delhi-110002
Phone No-011-23236965
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File No. : NZ/MD/2021/000174

Dated : 19-FEB-2022

M/s PATHKITS HEALTHCARE PRIVATE LIMITED,
Plot No-28-29, Sector-18
Gurgaon, Gurgaon, Haryana (India) - 122001
Telephone No.: 8802872273 FAX: 8802872273

Sub:- Licence to manufacture for Sale or for Distribution of Class C or Class D medical devices in Form MD-9 under Medical Device Rules, 2017- regarding.

Sir,

Manufacturing licence No. MFG/IVD/2021/000068 in Form MD-9 is hereby forwarded to you. This licence is subject to following conditions:

1. Licence shall be produced when requested by the Medical Device Officer or any other senior officer under the control of Central Licensing Authority.
2. The licence holder shall inform the Central Licensing Authority of the occurrence of any suspected unexpected serious adverse event and action taken thereon including any recall within fifteen days of such event coming to the notice of licence holder
3. The licence holder shall obtain prior approval from the Central Licensing Authority, before any major change as specified in the Sixth Schedule is carried out and the Central Licensing Authority shall indicate its approval or rejection within forty five days and in case where no communication is received within the stipulated time from such Authority, such change shall be deemed to have been approved
4. The licence holder shall inform any minor change as specified in the Sixth Schedule to the Central Licensing Authority within a period of thirty days after such minor change take place
5. The licence holder shall carry out test of each batch of product manufactured prior to its release for compliance with specifications either in his own laboratory or in any other laboratory registered under sub-rule (3) of rule 83;

6. The licence holder shall, on being informed by the Central Licensing Authority that any part of any lot of the medical device has been found not conforming with the provisions specified under the Act and these rules, and on being directed so to do by such licensing authority, withdraw the remainder of that lot from sale and, so far as may, in the particular circumstances of the case, be practicable, recall the issues already made from that lot;
7. The licence holder shall maintain an audit or inspection book in Form MD-11 to enable the Notified Body or Medical Device Officer to record his observations and non-conformity, if any;
8. The licence holder shall maintain at least one unit of sample from each batch of invasive medical device and in vitro diagnostic medical device manufactured for reference purpose for a period of one hundred and eighty days after the date of expiry of such batch;
9. The licence holder shall maintain records of manufacturing and sales which shall be open to inspection by a Medical Device Officer;
10. The medical device, when offered for sale, shall be accompanied by either its package insert or user manual, wherever applicable;
11. The manufacturing or testing activity of medical device shall be undertaken only under the direction and supervision of the competent technical staff;
12. If the manufacturer has stopped manufacturing activity or closed the manufacturing site for a period of thirty days or more, the same shall be intimated to the Central Licensing Authority.

13. This licence is being issued with condition that , firm shall submit three lots of Performance Evaluation report from any Government Hospital with in 120 days of issuance of this licence

Yours faithfully

VENUGOPAL G SOMANI

Licensing Authority

Seal/Stamp

सत्यमेव जयते

FORM MD-9

[See sub-rule (1) rule 25]

Licence to Manufacture for Sale or for Distribution of Class C or Class D medical device

Licence Number: MFG/IVD/2021/000068

Endorsement No. 4

1. M/s PATHKITS HEALTHCARE PRIVATE LIMITED, Plot No-28-29, Sector-18Gurgaon, Gurgaon, Haryana (India) - 122001 Telephone No.: 8802872273 FAX: 8802872273 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s PATHKITS HEALTHCARE PRIVATE LIMITED, 28, 29 Electronic City, Sector -18, Gurgaon, Haryana (India) - 122001 Telephone No.: 8588869343 FAX: 8588869343

2. Details of medical device(s) [Annexed]

3. The names, qualifications and experience of the competent technical staff responsible for the manufacture and testing of the above mentioned medical device(s): As per records maintain by the manufacturer

4. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

ANNEXURE

S.No.	Details Of Device(s)
1	Generic Name:Influenza A/B Antigen Test Kit Model No.:NIL Intended Use:Influenza A/B Antigen Test is a rapid chromatographic immunoassay for the qualitative detection of Influenza A and B antigens in nasal swab or Nasopharyngeal Swab or Saliva or Oral Swab specimens. It is intended to aid in the rapid differential diagnosis of influenza A and B viral infections. Class of medical device:Class C Material of construction:NA Dimension(if any):NA Shelflife:24 Months Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):SIMPLE Influenza A/B Antigen Test Kit

VENUGOPAL G SOMANI

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Date: 2022.02.21 14:29:22 +05'30'

Place:

Date:19-Feb-22

Central Licensing Authority

सत्यमेव जयते

FORM MD-9

[See sub-rule (1) rule 25]

Licence to Manufacture for Sale or for Distribution of Class C or Class D medical device

Licence Number: MFG/IVD/2021/000068

Endorsement No. 4

1. M/s PATHKITS HEALTHCARE PRIVATE LIMITED, Plot No-28-29, Sector-18Gurgaon, Gurgaon, Haryana (India) - 122001 Telephone No.: 8802872273 FAX: 8802872273 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s PATHKITS HEALTHCARE PRIVATE LIMITED, 28, 29 Electronic City, Sector -18, Gurgaon, Haryana (India) - 122001 Telephone No.: 8588869343 FAX: 8588869343

2. Details of medical device(s) [Annexed]

3. The names, qualifications and experience of the competent technical staff responsible for the manufacture and testing of the above mentioned medical device(s): As per records maintain by the manufacturer

4. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

ANNEXURE

S.No.	Details Of Device(s)
1	Generic Name:Influenza A/B Antigen Test Kit Model No.:NIL Intended Use:Influenza A/B Antigen Test is a rapid chromatographic immunoassay for the qualitative detection of Influenza A and B antigens in nasal swab or Nasopharyngeal Swab or Saliva or Oral Swab specimens. It is intended to aid in the rapid differential diagnosis of influenza A and B viral infections. Class of medical device:Class C Material of construction:NA Dimension(if any):NA Shelflife:24 Months Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):SIMPLE Influenza A/B Antigen Test Kit

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Date: 2022.02.21 14:29:22 +05'30'

Place:

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Central Licensing Authority