SARS-CoV-2+Influenza A and B Antigen Assay

Catalog Number: AU2033

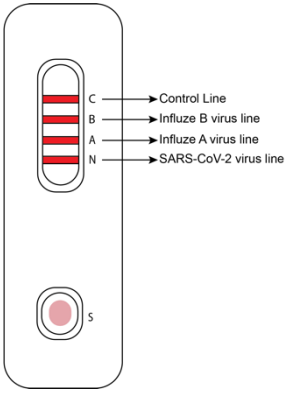
For Research Use Only. Not for use in Diagnostic Procedures.

1. Intended Use

The SARS-CoV-2+Influenza A and B Antigen Assay device is a rapid visual immunoassay for the qualitative, presumptive detection of influenza A and B viral antigens and SARS-CoV-2 Antigen form Nasal swabs and nasopharyngeal swab specimens. The test is intended for use as an aid in the rapid differential diagnosis of acute influenza type A and type B virus and SARS-CoV-2 infection.

2. Introduction

Influenza is a highly contagious, acute, viral infection of the respiratory tract. The causative agents of the disease are immunologically diverse, single- strand RNA viruses known as influenza viruses. There are three types of influenza viruses: A, B, and C. Type A viruses are the most prevalent and are associated with most serious epidemics. Type B viruses produce a disease that is generally milder than that caused by type A. Type C viruses have never been associated with a large epidemic of human disease. Both type A and B viruses can circulate simultaneously, but usually one type is dominant during a given season. Influenza antigens may be detected in clinical specimens by immunoassay.



The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source.

Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue, and dry cough. Nasal congestion, runny nose, sore throat, myalgia, and diarrhea are found in a few cases.

The SARS-CoV-2+Influenza A and B Antigen Assay is a lateral-flow immunoassay using highly sensitive monoclonal antibodies that are specific for influenza types A and B and SARS-CoV-2 antigens. The test is specific to influenza types A and B and SARS-CoV-2 antigens with no known cross- reactivity to normal flora or other known respiratory pathogens.

3. Principle

The SARS-CoV-2+Influenza A and B Antigen Assay device detects influenza A and B viral antigens and SARS-CoV-2 Antigen through visual interpretation of color development on the strip. Anti-influenza A and B antibodies and Anti-SARS-CoV-2 antibodies are immobilized on the test region A, B and N of the membrane respectively. During testing, the extracted specimen reacts with anti-influenza A, B and SARS-CoV-2 antibodies conjugated to colored particles and precoated onto the sample pad of the test. The mixture then migrates through the membrane by capillary action and interacts with reagents on the membrane. If there is sufficient influenza A and B viral antigens or SARS-CoV-2 antigen in the specimen, colored band(s) will form at the according test region of the membrane. The presence of a colored band in the A and/or B and/or N region indicates a positive result for the particular viral antigens, while its absence indicates a negative result.

The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

4. Kit Contents

Contents	Total Tests provided
Cassette Device	25 devices (each sealed foil pouch contains: 1 device, 1 desiccant)
Disposable Dropper	25 droppers
Sample Diluent	25 bottles
Collection Swabs	25 sterile single use specimen collection swabs
Instruction Manual	1 each

5. Storage and Stability

- The kit should be stored at 2~30°C, valid for 12months.
- The test must remain in the sealed pouch until use.
- Do not freeze.
- Care should be taken to protect components in this kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

6. Precautions

- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- The extraction reagent solution contains a salt solution if the solution contacts the skin or eye, flush with copious amounts of water.
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink, or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves, and eye protection when specimens are assayed.
- If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ is available to receive and culture specimens.
- Do not interchange or mix reagents from different lots.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded in accordance with local regulations.

7. Sample Collection and Storage

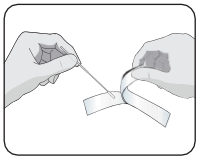
Prepare Materials

Open the package, take out the SARS-CoV-2+Influenza A and B Antigen Assay Antigen test card in pouch, the Tube filled with the extraction buffer and the swab. When you are ready to proceed with the test, open the foil pouch of the SARS-CoV-2+Influenza A and B Antigen Assay Antigen test card.

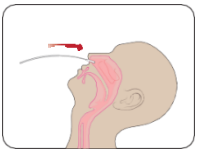
Note: Failure to swab properly may cause false negative results.

Nasopharyngeal Swab Collection Method:

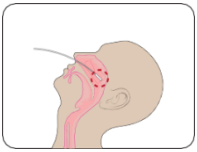
1. Remove the oropharyngeal swab from the pouch.



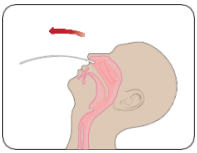
2. Tilt patient's head back 70 degrees. Gently and slowly insert the swab into one of patient's nostrils until it reaches the posterior nasopharynx; keep insert until resistance is equivalent to that from the ear to the nostril of the patient.



3. Slowly rotate 3-5 times the swab over the surface of the posterior nasopharynx.

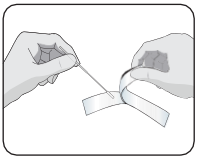


4. Leave swab in place for several seconds to absorb secretions. Slowly remove the swab from the nostril while rotating it.

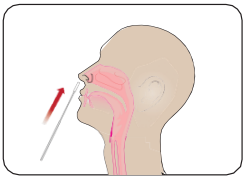


Anterior Nasal Swab Collection Method:

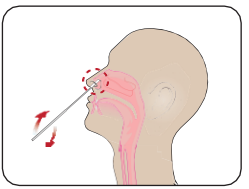
1. Remove the oropharyngeal swab from the pouch.



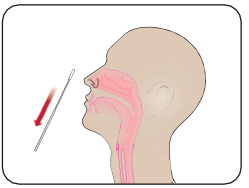
2. Insert the swab into one of patient's nostrils up to 1 inch from the edge of the nostril.



3. Slowly roll the swab 5 times over the surface of the nostril. Using the same swab repeat this collection process in the other nostril. Take approximately 15 seconds to collect the specimen.

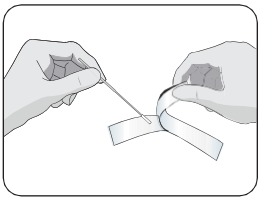


4. Slowly remove the swab from the nostril while rotating it.

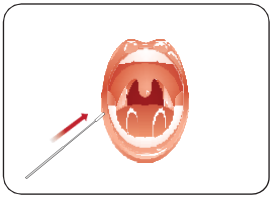


Oropharyngeal Swab Collection Method:

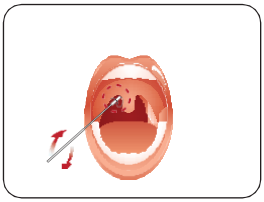
1. Remove the oropharyngeal swab from the pouch.



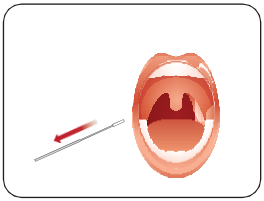
2. Tilt patient's head back 70 degrees.



3. Insert swab into the oral cavity without touching the gums, teeth, and tongue (A tongue depressor may be used.) Swab the posterior pharyngeal wall using a rotatory motion.



4. Withdraw the swab from the oral cavity.



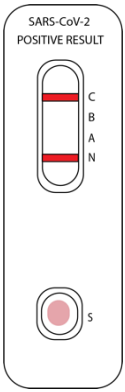
Sample Treatment:

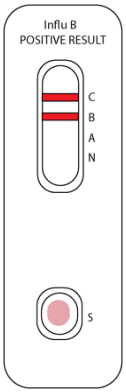
- Dip the swab after sample collection into the Sample Diluent solution tube, make the solution fully permeate the swab.
- Rotate and squeeze the swab against tube wall, then pull out the swab, and take the remained liquid as the sample to be tested.

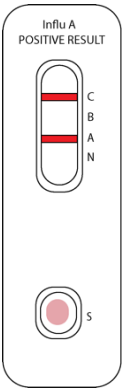
Assay Procedure:

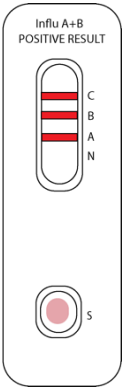
- Apply the treated Sample Diluent solution vertically into the sample well of the test cassette.
- The results are observed after 20 minutes and showed on clinical significance after 20 minutes.

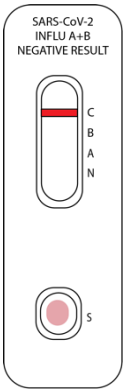
8. Interpretation of Results

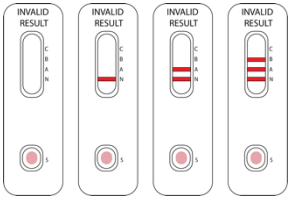
SARS-CoV-2 Positive	
	In addition to the presence of C band, if N band is developed, indicates for the presence of SARS-CoV-2; the result suggests SARS-CoV-2 infection.

Influenza B Positive	
	In addition to the presence of C band, if only B band is developed, indicates for the presence of Influenza B virus; the result suggests Influenza B virus infection.

Influenza A Positive	
	In addition to the presence of C band, if only A band is developed, indicates for the presence of Influenza A virus; the result suggests Influenza A virus infection.

Influenza A/B Positive	
	In addition to the presence of C band, if B and A bands are developed, indicates for the presence of Influenza A virus and Influenza B virus; the result suggests Influenza A virus and Influenza B virus infection.

Negative Results	
	If only the C band is present, the absence of any burgundy color in the both test bands (A,B,N) indicates that no Influenza A, Influenza B, SARS-CoV-2 are detected. The result is negative or non-reactive.

Invalid Result	
	**Control line (C) fails to appear.** Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the procedure with a new test device. If the problem persists, discontinue using the test kit immediately and contact Attogene at 512-333-1330.

9. Note

- The intensity of color in the test region (A/B/N) may vary depending on the concentration of analyses present in the specimen. Therefore, any shade of color in the test region (A/B/N) should be considered positive. Please note that this is a qualitative test only and cannot determine the concentration of analytes in the specimen.
- Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

10. Quality Control

Internal Procedural Controls:

Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.

External Control:

External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

Good Laboratory Practice recommends using the external controls, positive and negative, to assure the proper performing of the assay, in particularly, under the following circumstances:

- New operator uses the kit, prior to performing testing of specimens.
- A new lot of test kit is used.
- A new shipment of kits is used.
- The temperature used during storage of the kit fall outside of 2°C -30°C.
- The temperature of the test area falls outside of 15°C -30°C.

11. Limitations of the Test

1. The SARS-CoV-2+Influenza A and B Antigen Assay is for professional use and should only be used for the qualitative detection of influenza A and/or B and/or SARS-CoV-2 antigen.
2. The etiology of respiratory infection caused by microorganisms other than influenza A or B virus, or SARS-CoV-2 will not be established with this test. The SARS-CoV-2+Influenza A and B Antigen Assay is capable of detecting both viable and non-viable influenza or SARS-CoV-2 particles. The performance of the SARS-CoV-2+Influenza A and B Antigen Assay device depends on antigen load and may not correlate with cell culture(influenza) or PCR (SARS-CoV-2 Antigen) performed on the same specimen.
3. 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 rule out the presence of influenza A and/or B and/or SARS-CoV-2 viral antigens in specimen, as they may be present below the minimum detection level of the test. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
4. The validity of SARS-CoV-2+Influenza A and B Antigen Assay device has not been proven for

identification or confirmation of cell culture isolates.

5. Inadequate or inappropriate specimen collection, storage, and transport may yield false negative test result.
6. Although this test has been shown to detect cultured avian influenza viruses and SARS-CoV-2 viruses, including avian influenza A subtype H5N1 virus, the performance characteristics of this test with specimens from humans infected with H5N1 or other avian influenza viruses are unknown.
7. Performance characteristics for influenza A were established when influenza A/H3 and A/H1 were the predominant influenza A viruses in circulation. When other influenza A viruses are emerging, performance characteristics may vary.
8. Children tend to shed virus for longer periods of time than adults, which may result in differences in sensitivity between adults and children.
9. Positive and negative predictive values are highly dependent on prevalence. False positive test results are more likely during periods of low influenza activity when prevalence is moderate to low.

12. Notice

1. Must strictly follow the instructions for operation and interpretation of the results.

2. The product is qualitatively tested, and the result cannot be used as a quantitative basis.
should be tested using reagents within the validity period.

3. The Sample Diluent is for single person one-time use, cannot be reused.

4. Because the sample titer is different, the red lines of the test line will show different shades of color, all of which indicate positive results. The depth of the test line color cannot be used as the basis for determining the antigen in the sample.

5. The samples stored at low temperature should be balanced to room temperature and fully mixed before testing.

6. Samples and waste must be treated as a potential source of infection and the desiccant in the foil bag is not edible.

User Notes

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Who we are

Attogene is a biotechnology company located in Austin, Texas. Our focus is to enhance health and wellness by offering and developing customer focused Life Science Products domestically and internationally.

Our mission is to:

- Enhance detection technologies
- Enable rapid responses
- Enable impactful research discoveries

Contact Us

3913 Todd Lane, Suite 310
Austin, TX 78744

Phone: 512- 333-1330

Email: sales@attogene.com

Web: www.attogene.com

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