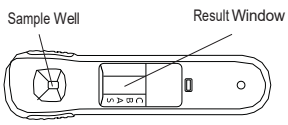
QUICK™ REFERENCE INSTRUCTIONS

ViraDx SARS-CoV-2/Flu A+B Rapid Antigen Test

Anterior Nasal or Nasopharyngeal Swab Specimens

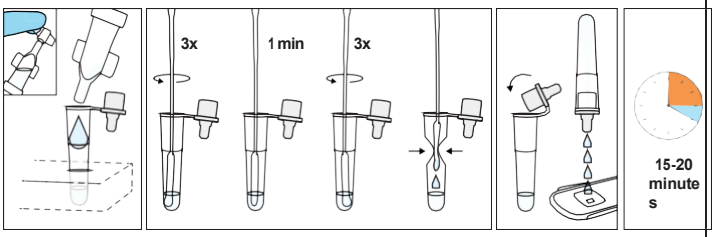
Study the Package Insert thoroughly before using Quick Reference Instructions. This is not a complete Package Insert.

TEST DEVICE



SAMPLE COLLECTION

PROCEDURE



Tear the tab off the Extraction Reagent capsule and squeeze it to dispense all of the solution into the Extraction Tube.

Insert the specimen swab into the Extraction Tube and rotate it 3 times to mix the specimen. Incubate for 1 minute with the swab in Extraction Tube. Rotate swab 3 times again to mix the specimen. Squeeze swab against the Extraction Tube to retain as much of the liquid as possible, then remove and discard the swab.

Place cap on Extraction Tube, invert and empty the contents of the Extraction tube onto the sample well of the test device.

Start timing – 15 minutes.

Read test results at 15 minutes.

NOTE: False positive or false negative results can occur if the test is not read between 15 and 20 minutes.

- For use under the Emergency Use Authorization (EUA) only.
- For in vitro diagnostic use.
- Rx only.
- Refer to the Package Insert for complete instructions. Read the complete test procedure, including recommended Quality Control procedures, before performing the test.
- All clinical specimens must be at room temperature before beginning the assay.
- Performing the assay outside the time and temperature ranges provided may produce invalid results.
- Assays not performed within the established time and temperature ranges must be repeated.
- Expiration date: Check expiration on each individual test package or outer box before using. Do not use any test past the expiration date on the label.
- Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing. Consistent with serial testing recommendations for SARS-CoV-2, for multi-analyte tests, symptomatic individuals who test positive for influenza A or B on the initial test but test negative for SARS-CoV-2 should be tested again in 48 hours to evaluate for co-infection with SARS-CoV-2 infection.

QUALITY CONTROL

Internal Quality Control:

Each ViraDx SARS-CoV-2/Flu A+B Rapid Antigen Test device has built-in controls. The Control line at the C position can be considered as an internal positive procedural control; i.e., a proper amount of sample was used, sample was properly added to the Extraction Well, sample migrated properly and the reagent system worked properly.

A distinct reddish-purple Control line should always appear if the test has been performed correctly. If the Control line does not appear, the test result is invalid and a new test should be performed.

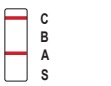
External Quality Control:

It is recommended that external control testing be performed by each new operator and before using a new lot or shipment of ViraDx SARS-CoV-2/Flu A+B Rapid Antigen Tests to confirm the expected test performance, using the external controls provided in the kit. The frequency of additional Q.C. tests should be determined according to your laboratory's standard Q.C. procedures and local, state and federal regulations or accreditation requirements.

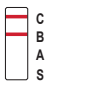
Upon confirmation of the expected results, the kit is ready for use with patient specimens. If external controls do not perform as expected, do not use the test results.

INTERPRETATION OF RESULTS

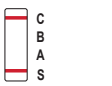
A reddish-purple S, A and/or B line(s) with C line is POSITIVE.



A line: Influenza type A

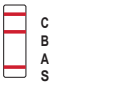


B line: Influenza type B



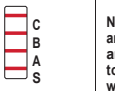
S line: COVID-19

A & S lines: Influenza type A & COVID-19*



B & S lines: Influenza type B & COVID-19*

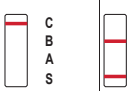
A & B lines: Influenza type A & B*



A, B & S lines: Influenza type A, B & COVID-19*

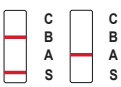
***NOTE: Co-infection with influenza A, B and/or SARS-CoV-2 is rare. If results are positive for more than one antigen, i.e., influenza A, B and/or COVID-19, the patient specimens should be re-tested.**

C line only
NEGATIVE (-)



Negative results are presumptive and may need to be confirmed with a molecular assay.

No C line
INVALID



Any combination of test lines is invalid if the C line is not present. Repeat with new sample and device.

INTERPRETATION OF RESULTS

Positive:

At (15) minutes, the appearance of a reddish purple Control line (C position) and a reddish purple Test line (A, B or S) indicate that influenza A, B and/or SARS-CoV-2 antigen has been detected. Lines at the A and C positions indicate the presence of influenza type A viral antigen, lines at the B and C positions indicate the presence of influenza type B viral antigen and lines at the S and C positions indicate the presence of SARS-CoV-2 viral antigen in the specimen. A positive result does not rule out co-infections with other pathogens or identify any specific influenza A virus subtype. Any faint visible reddish-purple lines at A, B, and S with control line (Ctrl) should be read as positive.

Repeat testing does not need to be performed if patients have a positive result at any time.

A positive S test result means that the virus that causes COVID-19 was detected in the sample, and it is very likely the individual has COVID-19 and is contagious. Please contact the patient's doctor/primary care physician (if applicable) and the local health authority immediately and instruct your patient to adhere to the local guidelines regarding self-isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive).

Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Individuals who test positive with the ViraDx SARS-CoV-2/Flu A+B Rapid Antigen Test Status™ COVID-19/Flu A&B should self-isolate and seek follow up care with their physician or healthcare provider as additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

Note: *The Test line (reddish purple line) may vary in shade and intensity (light or dark, weak or strong) depending on the concentration of antigen detected. The intensity of the Control line should not be compared to that of the Test line for the interpretation of the test result. Even a light or faint Test line should be interpreted as a positive result.*

Negative:

A reddish purple Control line (C position) only, with no Test line at the A, B, and S positions, indicates that influenza A, B antigen or SARS-CoV-2 antigen has not been detected. A negative result does not exclude influenza viral or SARS-CoV-2 viral infection. Determination of negative results should not be made before 15 minutes.

To increase the chance that the negative result for COVID-19 is accurate, you should:

- Test again in 48 hours if the individual has symptoms on the first day of testing.
- Test 2 more times at least 48 hours apart if the individual does not have symptoms on the first day of testing.

Negative Results are presumptive and may need to be confirmed with a molecular assay.

A negative test result indicates that the viruses that cause COVID-19 and the influenza viruses were not detected in the sample. A negative result does not rule out COVID-19 and Influenza. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19 and flu-like symptoms, e.g., fever, cough, and/or shortness of breath, continue, follow up testing for SARS-CoV-2 or influenza with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider.

All negative results should be treated as presumptive and confirmation with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.

Invalid:

A reddish purple line should always appear at the Control line position (C position). If a line does not form at the Control line position in 15 minutes, the test result is invalid and the test should be repeated with a new ViraDx SARS-CoV-2/Flu A+B Rapid Antigen Test device.

NOTE: Co-infection with influenza A, B and/or SARS-CoV-2 is rare. If results are positive for more than one antigen, i.e., influenza A, B and/or COVID-19, the patient specimens should be re-tested. Repeatable multiple positive results (more than one test line) should be confirmed by molecular assay before reporting results. Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results. Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

Status on First Day of Testing	Day 0 (Test 1)	Day 2 (Test 2)
With Symptoms	COVID-19 (-) Serial testing recommended for COVID Flu A or B (-) Flu A or B result is negative	COVID-19 (-) COVID result is Negative COVID-19 (+) COVID result is positive Flu A or B (-) Flu result is Negative Flu A or B (+) Flu result is positive
	COVID-19 (-) Serial testing recommended for COVID Flu A or B (+) Flu A or B result is positive	COVID-19 (-) COVID-19 result is Negative COVID-19 (+) COVID-19 result is Positive Flu A or B (-) **Maintain Flu positive interpretation** Flu A or B (+) Flu A or B result is Positive
	COVID-19 (+) COVID Positive Flu A or B (-) Flu A or B Negative	No serial testing recommended
	COVID-19 (+) COVID Positive Flu A or B (+) Flu A or B positive	No serial testing recommended

INTENDED USE

ViraDx™ SARS-CoV-2/Flu A+B Rapid Antigen Test is a lateral flow immunoassay intended for the in vitro rapid, simultaneous qualitative detection and differentiation of nucleocapsid protein antigen from SARS-CoV-2, influenza A and influenza B directly from anterior nasal or nasopharyngeal swab specimens collected from individuals, who are suspected of respiratory viral infection consistent with COVID-19 by their healthcare provider, within the first five (5) days of onset of symptoms, when tested at least twice over three days with at least 48 hours between tests. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar.

Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate, high or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance or Certificate of Accreditation.

The ViraDx SARS-CoV-2/Flu A+B Rapid Antigen Test does not differentiate between SARS-CoV or SARS-CoV-2 viruses.

Results are for the simultaneous in vitro detection and differentiations of nucleocapsid protein antigens of SARS-CoV-2, influenza A and influenza B, and is not intended to detect influenza C antigens. These viral antigens are generally detectable in anterior nasal or nasopharyngeal swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but the clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of the disease.

All negative SARS-CoV-2 results are presumptive and should be confirmed with a molecular assay, if necessary, for patient management. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control measures such as isolating from others and wearing masks. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

All negative influenza A and B test results are presumptive. It is recommended these results be confirmed by an FDA-cleared influenza A and B molecular assay. Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other management decisions.

Performance characteristics for influenza A and B were established during the 2007-2009 and the 2014-2016 influenza seasons when influenza A/H1N1, A/H1N1 pandemic, A/H3N2, influenza B/Victoria lineage and B/Yamagata lineage were the predominant influenza viruses in circulation according to the Flu Activity & Surveillance reports from the CDC. When other influenza viruses are emerging, performance characteristics may vary.

If infection with a novel influenza 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. A viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

ViraDx SARS-CoV-2/Flu A+B Rapid Antigen Test is intended for use by medical professionals and laboratory personnel trained to perform the test. ViraDx SARS-CoV-2/Flu A+B Rapid Antigen Test is only for in vitro diagnostic use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

Refer to the Package Insert for Warnings and Precautions, Specimen Collection and Handling and Quality Control.

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use.
2. For prescription use only.
3. For use under FDA Emergency Use Authorization only
4. This product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories; laboratories certified under CLIA that meet the requirements to perform moderate, high or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance or Certificate of Accreditation. This product has been authorized only for the detection of proteins from SARS-CoV-2, influenza A, and influenza B, not for any other viruses or pathogens. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §360bbb-3(b)(1), unless the declaration is terminated, or authorization is revoked sooner.
5. Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.
6. Consistent with serial testing recommendations for SARS-CoV-2, for multi-analyte tests, symptomatic individuals who test positive for influenza A or B on the initial test but test negative for SARS-CoV-2 should be tested again in 48 hours to evaluate for co-infection with SARS-CoV-2 infection.
7. Do not use after the expiration date printed on the outside of the box.
8. Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
9. Ensure that there is sufficient lighting for testing and interpretation.
10. ViraDx SARS-CoV-2/Flu A+B Rapid Antigen Test is only intended for use with direct anterior nasal or nasopharyngeal swab specimens and is not validated or authorized for use with viral transport media. Use only the swabs provided for collecting specimens. Other swabs may not work properly.
11. Test components are single-use. Do not reuse used test devices, swabs, extraction tubes or control swabs.
12. Inadequate or inappropriate sample collection, storage and transport may yield false test results.
13. To obtain accurate results, the Package Insert instructions must be followed. Failure to follow the instructions may result in inaccurate test results.
14. The ViraDx SARS-CoV-2/Flu A+B Rapid Antigen Test device should remain in its original sealed pouch until ready for use. Once opened, the test should be used immediately. Do not use the test if the seal is broken or the pouch is damaged.
15. Do not read test results before 15 minutes or after 20 minutes. Results read before 15 minutes or after 20 minutes may lead to a false positive, false negative, or invalid result.
16. Dispose of containers and unused contents in accordance with federal, state and local regulatory requirements.
17. Do not smoke, eat or drink in areas in which specimens or kit reagents are handled. Extraction Reagent is slightly caustic. Avoid contact with eyes, sensitive mucous membranes, cuts, abrasions, etc. If the reagent comes in contact with skin or eyes, flush with a large volume of water. Do not ingest any kit components. The reagent solution contains harmful chemicals (see table below). If the solution contacts your [e.g., skin, eyes, nose, or mouth], flush with large amounts of water. If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222.

Chemical Name	GHS Code for Ingredients	Concentrations
Sodium Azide	H300, Acute Tox, Oral H310, Acute Tox, Dermal	0.09%

18. Wear a safety mask or other face-covering when collecting a specimen from a child or another individual. Wear disposable gloves while handling kit reagents or specimens and thoroughly wash hands afterwards.
19. All specimens should be handled as if they are capable of transmitting disease. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens and test devices.
20. If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, the specimen should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health departments for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.
21. For more information on EUAs please visit: https://www.fda.gov/emergencypreparedness-and-response/mcm-legalregulatory-and-policy-framework/emergencyuse-authorization
22. For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19.

LIMITATIONS

- The performance of this test for SARS-CoV-2 was established based on the evaluation of a limited number of clinical specimens collected between September 2020 and April 2021 and February to November 2022. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 as compared to a molecular test, especially in samples with low viral load.
- A negative test result does not exclude infection with SARS-CoV-2, influenza A or B.
- Negative test results are presumptive and may need to be confirmed with a molecular test. Therefore, the results obtained with ViraDx SARS- CoV-2/Flu A+B Rapid Antigen Test should be used in conjunction with clinical findings to make an accurate diagnosis. Additional testing is required to confirm the absence of infection, in consultation with state or local public health departments.
- If the patient continues to have symptoms of COVID-19, and both the patient's first and second tests are negative, the patient may not have COVID-19; however, additional follow-up may be needed.
- If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample, and the individual likely has COVID-19.
- This test detects both viable (live) and non-viable SARS-CoV-2, influenza A and B. Test performance depends on the amount of virus (antigen) in the specimen and may or may not correlate with viral culture or molecular assay results performed on the same specimen.
- A negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly.
- Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.
- This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision. Because test lines can be very faint, users with conditions affecting their vision- such as far-sightedness, glaucoma, or color blindness-are encouraged to seek assistance to interpret results accurately (e.g., reading glasses, additional light source, or another person).
- Positive test results do not rule out co-infections with other pathogens.
- Positive test results do not differentiate between SARS-CoV and SARS-CoV-2. Additional testing is needed if differentiation between SARS-CoV and SARS-CoV-2 is needed.
- Positive test results can distinguish among influenza A, B and SARS-CoV-2 viruses but do not differentiate specific influenza A virus subtypes.
- If differentiation of specific SARS or influenza A subtypes and strains is needed, additional testing, in consultation with state or local public health departments, is required.
- ViraDx SARS-CoV-2/Flu A+B Rapid Antigen Test uses highly target epitope specific monoclonal antibodies. As in most immunoassays, it may fail to detect, or detect with less sensitivity, influenza A viruses that have undergone minor amino acid changes in the target epitope region.
- Performance of the ViraDx SARS-CoV-2/Flu A+B Rapid Antigen Test has not been established for monitoring antiviral treatment of influenza and SARS-CoV-2.
- 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 emerge, performance characteristics may vary.
- The performance of this test has not been evaluated for use in patients without signs and symptoms of respiratory infection.
- The performance of this test has not been evaluated for specimen types other than those specified in the Intended Use.
- The performance of this test has not been evaluated for immunocompromised individuals.
- The performance of ViraDx SARS-CoV-2/Flu A+B Rapid Antigen Test was not evaluated for SARS-CoV-2 detection with samples collected in viral transport media and should not be used with this test.
- Children tend to shed influenza virus more abundantly and for longer periods of time than adults. Therefore, testing specimens from adults will result in lower sensitivity than testing specimens from children.
- 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 activity when prevalence is moderate to low.
- Individuals who received nasally administered influenza A vaccine may produce positive test results for up to three days after vaccination.

ASSISTANCE

If you have any questions regarding the use of this product, please call Lumos Diagnostics Technical Support at 1.855.LumosDx or email technical.support@lumosdiagnostics.com.

Please scan code for the electronic ViraDx Package insert or go to the following webpage: https:lumosdiagnostics.com/viradx/PM-169

SCAN ME

ViraDx

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