

Start Here



For individuals with signs and symptoms of respiratory tract infection, including COVID-19.

Before testing, watch how it's done!

Go to metrixdemo.com/covidflu

OR

Text [demo](tel:8058371744) to [\(805\) 837-1744](tel:8058371744)

OR

Scan the QR code with the camera on your mobile device



Carefully read all instructions before beginning. If you do not follow the instructions, you may obtain incorrect results.

Complete the entire procedure without delay between steps.

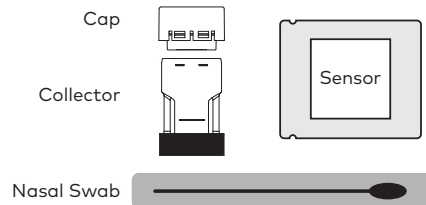
Metrix Reader (Gen 2) required, sold separately.

Metrix Reader (Gen 1) is not compatible with this test.

Results from this test are read visually. Color-blind users may be unable to differentiate between all color status lights. Users with conditions affecting their vision, including color-blind users should seek assistance to interpret results accurately.

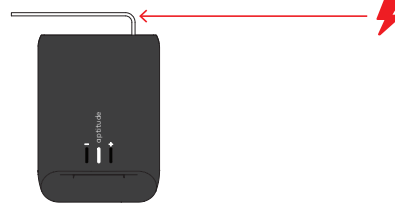
Contents

Materials required to run one test:



01 Power Up

Connect the Metrix Reader (Gen 2) to power supply. The center light will turn solid white (not flashing) when ready.



02 Collect Nasal Swab Sample

TOUCH ONLY THE HANDLE OF THE SWAB WITH YOUR HANDS TO AVOID CONTAMINATING THE SOFT TIP.

Insert the nasal swab into your nostril until the tip is fully inside. Stop when you meet resistance (about 1 inch or 2½ cm for adults, ½ inch or 1¼ cm for children).

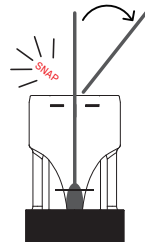


Roll the swab against the inside of your nostril 5 times.

REPEAT WITH OTHER NOSTRIL

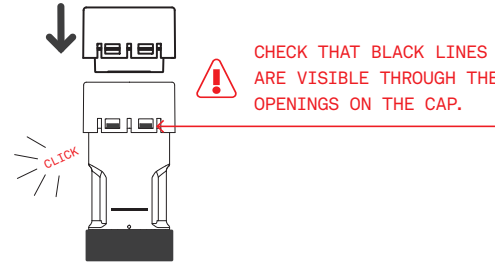
Firmly insert the swab into Collector until it cannot go any further.

Snap off and discard the swab handle.



03 Cap Sample

Put the Cap on the Collector and press down firmly until the Cap clicks into place.



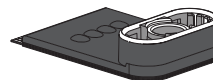
04 Shake to Mix

Shake the collector very hard for 20 seconds to mix.



05 Attach to Sensor

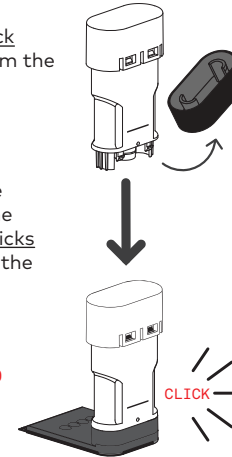
Open Sensor pouch and place Sensor on a flat surface.



Remove the black plastic cover from the bottom of the Collector.

Firmly insert the Collector into the Sensor until it clicks and fluid enters the Sensor.

PRESS FIRMLY TO LOCK IN PLACE

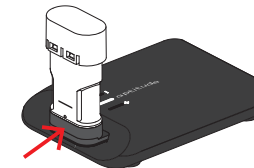


06 Run the Test

CONFIRM THAT THE READER IS READY. THE CENTER LIGHT WILL BE SOLID (NOT FLASHING).

Insert Sensor into reader until it cannot go further.

The test will begin automatically and will take 20 minutes.

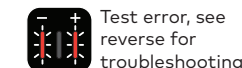


Flashing White



Test in progress

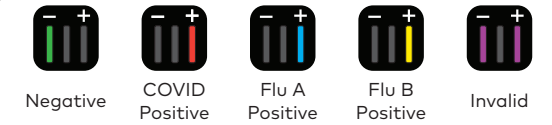
Flashing Red



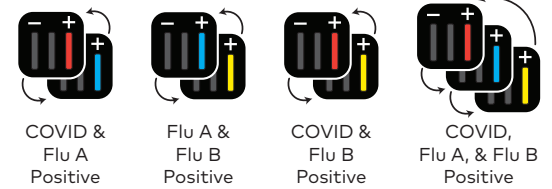
Test error, see reverse for troubleshooting

07 Read Your Results

The reader lights will display your result.



WHEN MORE THAN ONE VIRUS IS DETECTED, THE "+" LIGHT WILL FLASH THE COLOR OF EACH DETECTED VIRUS.

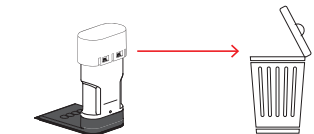


FOR PROOF OF TEST, TAKE PHOTO(S) OR VIDEO OF YOUR RESULT. RESULTS WILL DISPLAY UNTIL THE SENSOR IS REMOVED.

08 Discard the Sensor

Pull the Sensor out of the reader. Discard the sensor. Do not disassemble.

The Reader is ready for a new test.



Meaning of Results

A negative test result indicates that SARS-CoV-2 (the virus that causes COVID-19), Flu A, and Flu B were not detected in your sample. However, it is possible for this test to give a negative result that is not correct (false negative) in some people with viral infection. Negative results do not preclude SARS-CoV-2/Flu A/Flu B infection and should not be used as the sole basis for treatment of an individual, including infection control decisions. If you have symptoms, contact a healthcare provider for additional testing.

A positive test result indicates that SARS-CoV-2 (the virus that causes COVID-19), Flu A, and/or Flu B was detected in your sample. It is very likely that you have COVID-19 (if the test was positive for COVID-19) and/or Flu (if the test was positive for Flu A and/or Flu B). Positive test results do not rule out bacterial infection or co-infection with other viruses. Individuals who test positive with the Metrix COVID/Flu Test should self-isolate and seek follow-up care with a healthcare professional as additional testing may be necessary.

If you receive an invalid result, please repeat with a new Metrix COVID/Flu Test kit.

The Metrix COVID/Flu Test detects active COVID-19 and Influenza A/B infections and does not test for previous infections.

What is Influenza A & B?

The two most common types of influenza are Influenza A & B. This test tests for both of these types of flu. If the test is positive for either Influenza A (Flu A) or Influenza B (Flu B), the tested individual has the flu. While seasonal influenza viruses are detected year-round in the United States, flu viruses typically circulate during the fall and winter during what's known as the flu season.

How accurate is this test?

The Metrix COVID/Flu Test was compared to an FDA-authorized known high sensitivity SARS-CoV-2 PCR test and an FDA-cleared known high sensitivity Influenza A and B PCR test. Please refer to the IFU at metrixdemo.com/covidflu for complete data.

Can this test detect new SARS-CoV-2 variants and flu strains?

Aptitude Medical Systems Inc. performs routine surveillance of emerging SARS-CoV-2 and Influenza strains and will continue to monitor the situation with emerging variants. A technical brief that lists SARS-CoV-2 variants and flu strains to which the Metrix COVID/Flu Test is reactive is available at metrixdemo.com/covidflu.

Troubleshooting



Starting Up

The Reader is starting up. Wait until the center light is solid white before inserting a Sensor.



Ready

The Reader is ready to start a test.



Test Running

The Reader is running a test. Do not remove the Sensor or unplug the Reader.



Invalid Result

The test is complete and the result is invalid. Repeat with a new Metrix COVID/Flu Test kit.



Test Error

Remove Sensor and firmly press down on Collector. Firmly reinsert Sensor into Reader. If error persists, discard Sensor and use a new test kit.



Canceled Test

The test did not complete. Ensure you are using the Metrix Reader (Gen 2). Discard the Sensor and run the test with a new Metrix COVID/Flu Test kit.



Hardware Failure

There is an error with the Reader. Disconnect and reconnect the power.



Indicates flashing light

If troubleshooting fails to resolve any problem, contact support. If your reader needs to be disposed of, please place in electronic waste.

Warnings/Precautions

- For in vitro diagnostic use.
- Single use only. Do not use if kit is visibly damaged. Do not use any kit past its expiration date.
- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA.
- This product has been authorized only for the detection of nucleic acid 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.
- The Metrix COVID/Flu Test and Metrix Reader are for use under FDA Emergency Use Authorization (EUA) Only.
- For more information on Emergency Use Authorization, please visit: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>
- Store between 59 °F (15 °C) and 86 °F (30 °C).
- Do not ingest. Keep away from children. Contains Triton X-100 (0.1%), which can be harmful if swallowed or cause skin irritation or serious eye damage. If the blue liquid contacts skin or eyes, flush with copious amounts of water. If irritation persists, call Poison Control at 1.800.222.1222.
- Once assembled, do not attempt to disassemble or open the cap/collector/sensor assembly.
- Recent patient exposure to FluMist® or other live attenuated influenza vaccines may cause inaccurate positive results.
- The test is best used in a room with adequate lighting away from glare. and the Metrix Reader (Gen 2) should be used on a level surface without movement.
- If a power failure occurs or if the Metrix Reader (Gen 2) is unplugged while the Sensor is inserted, the test result is invalid. You should retest using a new test.

Risks/Benefits

- Potential risks of this test include: (1) Possible discomfort during sample collection, (2) Possible incorrect test results.
- Potential benefits of this test include: (1) The results, along with other information, can help your healthcare provider make informed recommendations about your care, (2) The results of this test may help limit the spread of COVID-19 and/or Influenza to your family and others in your community.

Intended Use

The Metrix® COVID/Flu Test is a reverse transcription and loop-mediated isothermal amplification (RT-LAMP) test intended for the simultaneous qualitative detection and differentiation of SARS-CoV-2, influenza A, and influenza B nucleic acid. This test is authorized for non-prescription home use with anterior nasal (AN) swab specimens from individuals aged 14 years or older (self-collected) or individuals aged 2 years or older (collected by an adult) with signs and symptoms of respiratory infection consistent with COVID-19. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar.

The Metrix COVID/Flu Test is intended for use in the differential detection of SARS-CoV-2, influenza A, and influenza B nucleic acid in clinical specimens and is not intended to detect Influenza C. SARS-CoV-2, influenza A, and influenza B nucleic acid is generally detectable in anterior nasal swab specimens during the acute phase of infection.

Positive results indicate the presence of viral nucleic acid, but clinical correlation with past medical history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other pathogens not detected by the test. The agent detected may not be the definitive cause of disease. Individuals who test positive with the Metrix COVID/Flu Test should self-isolate and seek follow up care with their physician or healthcare provider as additional testing may be necessary.

Negative results do not rule out SARS-CoV-2, influenza A, and/or influenza B infection and should not be used as the sole basis for treatment or other management decisions, including infection control decisions. Negative results should be considered in the context of current prevalence of infection, an individual's recent exposures, history and the presence of clinical signs and symptoms consistent with respiratory infection. Individuals who test negative and continue to experience symptoms of fever, cough and/or shortness of breath may still have a respiratory infection and should seek follow up care with their healthcare provider.

The Metrix COVID/Flu Test is only for use under the Food and Drug Administration's Emergency Authorization.

After Your Test

If symptoms persist or if you are concerned about your health, please seek follow-up care from a healthcare professional.

For free support, or to obtain a physical copy of the product information card free of charge, please call us at 888.934.2253 or email us at support@aptitudemetrix.com.

For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID-19.

Fact sheets and FAQs available at aptitudemetrix.com.



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Electronic instructions for use available at aptitudemetrix.com



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Metrix® COVID/Flu Test Instructions

