Start Here

Carefully read all instructions before beginning.

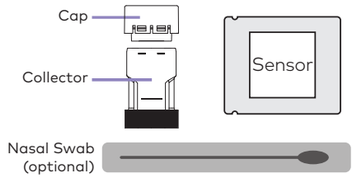
No food/drink (including water)/oral hygiene products for 30 minutes before test.

Complete the entire procedure without delay between steps.

Metrix Reader required. Available separately.

Contents

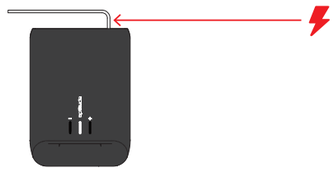
Materials required to run one test:



Scan QR code for interactive instructions and a video demonstration

01 Power Up

Connect reader to power supply. The center light will turn solid white (not flashing) when ready.



02 Collect Sample

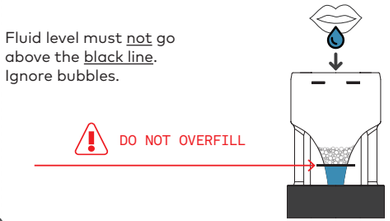
Choose one preferred sample method:

Saliva or Nasal Swab

Saliva Collection

Deposit a small amount of saliva into the collector.

Fluid level must not go above the black line. Ignore bubbles.



Nasal Swab Collection

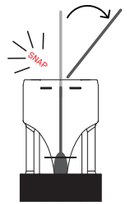
Insert the nasal swab into your nostril until the tip is fully inside. Stop when you meet resistance (about 1 inch for adults, ½ inch for children).

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

REPEAT WITH OTHER NOSTRIL

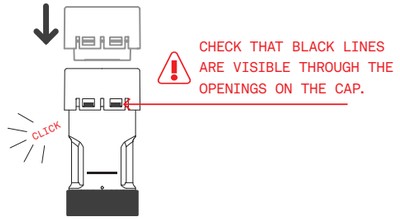
Firmly insert the swab into collector until it cannot go any further.

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.



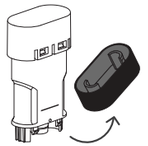
04 Shake to Mix

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.



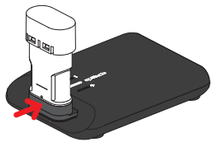
Firmly insert the collector into the sensor until it clicks and fluid enters the sensor.

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 30 minutes.



Flashing White

Test in progress

Flashing Red

Test error, see reverse for troubleshooting

07 Read Your Results

Use the following visual signifiers to note the results of the test:

Solid green = COVID Negative
SARS-CoV-2 was not present.

Solid red = COVID Positive
SARS-CoV-2 was present.

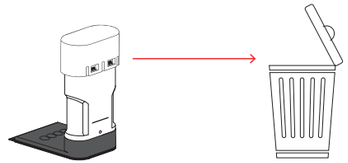
Solid purple = Invalid
Repeat test with a new kit.

IF PROOF OF TEST IS NEEDED, TAKE A PHOTO OF YOUR RESULT. THE RESULT WILL DISPLAY UNTIL THE SENSOR IS REMOVED.

08 Discard the Sensor

Pull the sensor out of the reader. and discard the sensor. Do not disassemble.

The reader is ready to begin a new test.



Meaning of Results

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

The Metrix COVID-19 Test detects active COVID-19 infections and does not test for previous infections.

After Your Test

To report your Metrix COVID-19 Test results to public health agencies, please visit:

aptitudemetrix.com/publichealth/reporting

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 1.888.934.2253 or email us at support@aptitudemetrix.com.

Fact sheets and FAQs available at AptitudeMetrix.com.

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

aptitude™

Aptitude Medical Systems
125 Cremona Dr. Suite 100
Goleta, CA 93117

Electronic Instructions For Use available at AptitudeMetrix.com

Reader Statuses

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.

Positive Result

The test is complete and SARS-CoV-2 was detected in the sample.

Negative Result

The test is complete and SARS-CoV-2 was not detected in the sample.

Indicates flashing light

Troubleshooting

Invalid Result

The test is complete and the result is invalid. Repeat with a new Metrix COVID-19 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. Discard the sensor and run the test with a new Metrix COVID-19 Test kit.

Hardware Failure

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

No Power

Check all electrical connections. The reader is not receiving power.

If troubleshooting fails to resolve any problem, please contact support. In the event that your Metrix Reader needs to be disposed of, please place in electronic waste.

Intended Use

The Metrix™ COVID-19 Test (Metrix) is a single-use molecular in vitro diagnostic test for the qualitative detection of nucleic acid from SARS-CoV-2, the virus that causes COVID-19. This test is authorized for non-prescription home use with anterior nasal (nares) swab and saliva specimens, self-collected from any individual aged 14 years or older, or adult-collected from any individual aged 2 years or older, including individuals without symptoms or other epidemiological reasons to suspect COVID-19.

This test utilizes nucleic acid amplification technology, similar to PCR, for the detection of SARS-CoV-2. SARS-CoV-2 viral RNA is generally detectable in anterior nasal (nares) swab and saliva samples during the acute phase of infection.

Positive results indicate the presence of viral RNA, 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 viruses. The agent detected may not be the definite cause of disease. Individuals who test positive with the Metrix COVID-19 Test should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

Negative results from saliva samples are presumptive and should be confirmed by molecular testing of an alternative sample type if clinically indicated. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or management decisions for the individual, including infection control decisions. Negative 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. Individuals who test negative and continue to experience COVID-19-like symptoms of fever, cough, and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow-up care with their physician or healthcare provider.

Individuals should report all results obtained with this product to their healthcare provider and the Aptitude secure web portal. This Aptitude secure web portal will report all test results received from individuals who use the authorized product to relevant public health authorities in accordance with local, state, and federal requirements using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by the CDC.

The Metrix COVID-19 Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

Warnings/Precautions

- For in vitro diagnostic use. Single use only. Do not use if kit is visibly damaged.
- 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, 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-19 Test and Metrix Reader are for 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-frame-work/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 diassesmble or open the cap/collector/sensor assembly.
- This device was not validated for use in color vision impaired individuals, including individuals with red/green vision impairment.

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 to your family and others in your community.

UG-00000 Ver 5

Metrix™ COVID-19 Test Instructions

IVD

For use under Emergency Use Authorization (EUA) only.