TOP

Metrix® COVID/Flu Test

LEFT FLAP

REF 810-00032 Rev A
LOT GSKIT-061124-1
SN DR3C-061124-1
Use by 2025-06-11

730-00039 Rev C

730-00071 Rev A

FRONT

aptitude®

Metrix® COVID/Flu Test

Detect & Differentiate COVID, Flu A, Flu B

PCR accuracy in 20 minutes

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

FDA Authorized

For use under Emergency Use Authorization (EUA) only
Requires Metrix Reader (Gen 2), sold separately
For in vitro diagnostic use

RIGHT FLAP

Your health, in your hands

BACK

Accurate

Lab-quality results at home

Easy

Simple, straightforward steps

Fast

Results in 20 minutes

Metrix is a PCR-accurate molecular test to diagnose COVID, Flu A and Flu B.

For use by individuals with signs and symptoms of respiratory infections, including COVID-19. For self-testing by individuals aged 14+, and by adult users testing other individuals aged 2+.

Single use only. No prescription required. Read instructions before using. Keep out of reach of children. Do not ingest any part of this test kit.

This single test kit contains: instructions, collector, cap, sensor, and nasal swab. Test requires Metrix Reader (Gen 2), sold separately.

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.

Questions?
888.934.2253
support@aptitudemetrix.com
aptitudemetrix.com

BOTTOM

For use under Emergency Use Authorization (EUA) only. This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA. This product has been authorized only for the detection and differentiation 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.

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

Electronic instructions for use are available at aptitudemetrix.com

Do not use if package is damaged

Single use item. Do not reuse.

59°F 86°F
Store at 59-86 °F (15-30 °C)

IVD

8 60009 45126 1

Single Test Configuration

FRONT

aptitude®

Metrix® COVID/Flu Test

Contains 25 Metrix COVID/Flu Tests
Requires Metrix Reader (Gen 2), sold separately

BACK

888.934.2253
support@aptitudemetrix.com
aptitudemetrix.com

Metrix is a PCR-accurate molecular test to diagnose COVID, Flu A and Flu B.

For use by individuals with signs and symptoms of respiratory infection, including COVID-19. For self-testing by individuals aged 14+, and by adult users testing other individuals aged 2+.

Single use only. No prescription required. Read instructions before using.
Keep out of reach of children. Do not ingest any part of this test kit.

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.

Accurate
Lab-quality results on the spot

Fast
Results in 20 minutes

Easy
Simple, straightforward steps

This kit contains components required to run 25 COVID/Flu tests: instructions (1), collectors (25), caps (25), sensors (25), and nasal swabs (25). Test requires Metrix Reader (Gen 2), sold separately.

SIDE (L)

A New Generation of Diagnostics

TOP

aptitude®

Metrix® COVID/Flu Test

Detect & Differentiate COVID, Flu A, Flu B

PCR accuracy in 20 minutes
For individuals with signs and symptoms of respiratory tract infection, including COVID-19

FDA Authorized
For use under Emergency Use Authorization (EUA) only
Requires Metrix Reader (Gen 2), sold separately
For in vitro diagnostic use

BOTTOM

730-00072 Rev A

REF 810-00044 Rev A
LOT POC-061124-1
SN CS55-061124-1
Use by: 2025-06-11

730-00072 Rev A

For use under Emergency Use Authorization (EUA) only. This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA. This product has been authorized only for the detection and differentiation 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.

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

Electronic instructions for use are available at aptitudemetrix.com

Do not use if package is damaged

Single use item. Do not reuse.

Store at 59-86 °F (15-30 °C)

Σ 25 IVD

SIDE (R)

No Big Instruments
Just Big Innovations

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 to (805) 837-1744

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.

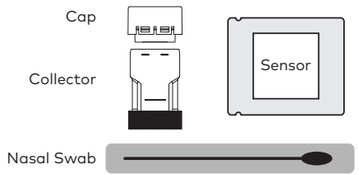
Metrix Reader (Gen 2) required, sold separately.

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.

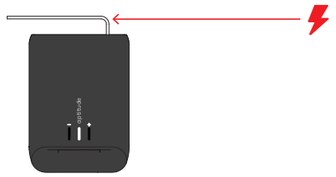
Contents

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.

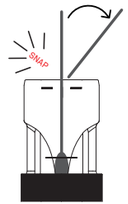
Insert the nasal swab into your nostril until the tip is fully inside. Stop when you meet resistance (about 1 inch or 2½ cm for adults, ½ inch or 1¼ cm for children).

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

⚠ REPEAT WITH OTHER NOSTRIL

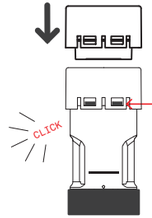
Firmly insert the swab into Collector until it cannot go any further.

Snap off and discard the swab handle.



03 Cap Sample

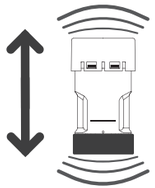
Put the Cap on the Collector and press down firmly until the Cap clicks into place.



⚠ CHECK THAT BLACK LINES ARE VISIBLE THROUGH THE OPENINGS ON THE CAP.

04 Shake to Mix

Shake the collector very hard for 20 seconds to mix.

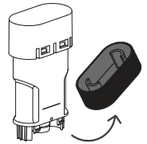


⚠ MAKE SURE THAT YOUR SAMPLE IS MIXED WELL.

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.

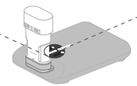
The test will begin automatically and will take 20 minutes.

Flashing White	Flashing Red
Test in progress	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.

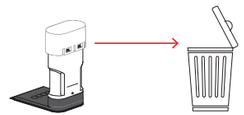


⚠ FOR PROOF OF TEST, TAKE PHOTO(S) OR VIDEO OF YOUR RESULT. RESULTS WILL DISPLAY UNTIL THE SENSOR IS REMOVED.

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 diassesmble 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.

aptitude

Electronic instructions for use available at aptitudemetrix.com

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

UG-00008 Ver 0

Metrix® COVID/Flu Test Instructions

IVD

For use under Emergency Use Authorization (EUA) only

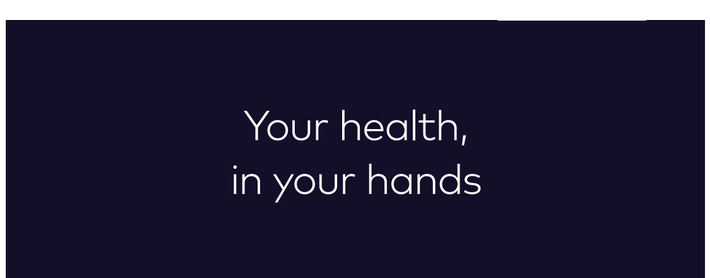
TOP EXTERIOR

BACK EXTERIOR

TOP INSIDE FLAP

BOTTOM EXTERIOR

FRONT EXTERIOR



Metrix® Reader

Quick Start Guide

Gen 2

IVD

For use with specific Metrix tests under EUA, sold separately

For use under Emergency Use Authorization (EUA) only

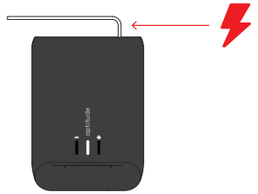
Start Here

For more information about how to use the Metrix Reader, please scan the QR code with your mobile device or visit:

aptitudemetrix.com/reader

01 Power Up

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



02 Collect and Run Your Sample

Open your Metrix Test kit (available separately) if you have not done so already. The instructions within the kit will guide you through how to collect and run your sample.

03 Read Your Results

Please refer to the instructions included in your Metrix Test kit to interpret your test results.

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 Test kit.

Indicates flashing light

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 Test kit. Ensure you are using the correct Metrix Reader for the specific EUA Metrix test under use.

Hardware Failure

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

If troubleshooting fails to resolve any problem, contact support.

If your Metrix Reader needs to be disposed of, please place in electronic waste.

For support, please contact us at:

888.934.2253
support@aptitudemetrix.com
aptitudemetrix.com

Legend of Symbols

IVD — For in vitro diagnostic use

Direct current (DC) voltage

59˚F 86˚F — Storage temperature limitations of the product

Keep dry

Please consult the instruction manual

Dispose of in electronic waste

Do not use if packaging is damaged

Manufacturer of device

Date of manufacture

REF — Manufacturer's catalog number

Certification that the electromagnetic interference from the device is under limits approved by the Federal Communications Commission.

Warnings/Precautions

- Do not use components that are visibly damaged.
- The Metrix Reader can be cleaned by wiping the exterior with disinfectant. Do not spray disinfectant into or onto the Reader.
- If a power failure occurs or if the Metrix Reader is unplugged while the Sensor is inserted, the test result is invalidated. The test should be redone with a new test kit.
- Use only the provided power cable and power adapter.
- Store the reader in a secure location and do not use if the Reader shows signs of damage or tampering.
- This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
- For in vitro diagnostic use.
- For use with specific Metrix tests under Emergency Use Authorization (EUA) only.
- For use under EUA only.
- This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA.
- When used in combination with the Metrix COVID-19 Test: This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.
- When used in combination with the Metrix COVID-19/Flu Test: This product has been authorized only for the detection and differentiation 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.

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