RESULT INTERPRETATION

Positive: SARS-CoV-2 antigen present; does not rule out co-infection with other pathogens.

Negative: Negative results from patients with symptom onset beyond five days should be treated as presumptive and confirmation with a molecular assay, if necessary, may be performed. 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: Should this occur, retest patient with a new nasal swab, Cartridge, and Extraction Tube.

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PD086 Rev. A

QUALITY CONTROLS

It is recommended that positive and negative external control swabs are run once by each untrained operator and as deemed additionally necessary by your internal quality control procedures and in accordance with Local, State and Federal regulations or accreditation requirements. External positive and negative control swabs are provided in the kit. The external controls should be tested using the test procedure provided in this Quick Reference Instructions Card or Package Insert. Patient tests should not be performed if the test fails to detect positive and/or negative control swabs accurately; please re-test or contact Luminostics, Inc.

In the USA, this test has not been FDA cleared or approved, but has been authorized by FDA under an EUA for emergency use by laboratories certified under the CLIA, 42 U.S.C. §263a, that meet the requirements to perform high, moderate, or waived complexity tests. This test is 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 test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. In the USA, the emergency use of this test 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 the virus that causes 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.

CUSTOMER SERVICE

If the Clip COVID Rapid Antigen Test Kit or Clip Analyzer do not perform as expected, contact Luminostics, Inc.: **support@luminostics.com**.

Designed and manufactured by

LUMINOSTICS, INC.
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QUICK REFERENCE INSTRUCTIONS

clip COVID
RAPID ANTIGEN TEST

The Clip COVID Rapid Antigen Test, for use with the Clip Analyzer, is intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in anterior nasal swab specimens from individuals who are suspected of COVID-19 by their healthcare provider within the first five days of onset of symptoms.

Manufactured by Luminostics, Inc., it is based on a diagnostics platform that uses proprietary persistent luminescent nanoparticles, which are sensitively detectable using a smartphone's camera, as lateral flow assay reporters.

The Clip Analyzer is comprised of an Apple iPhone® SE, an Adapter (pre-assembled onto the iPhone), and the Clip COVID App.

Study the Clip Analyzer User Manual and Clip COVID Rapid Antigen Test Kit Package Insert thoroughly before using these Quick Reference Instructions or performing a test. This is not a complete product insert.

Perform the Clip COVID Rapid Antigen Test at room temperature between 15°C and 30°C (59°F and 86°F). Nasal swab specimens must be processed within 30 minutes of collection. Specimens and kit components must beat room temperature before testing. Check expiration date on outer test kit carton and each individual test package before using. Do not use any test component beyond its expiration date. Refer to the Clip COVID Rapid Antigen Test Kit Package Insert for Specimen Collection, Warning and Precautions, and Limitations.

System Components

For *in vitro* Diagnostic Use.
Rx Only.
For Use Under Emergency Use Authorization (EUA) Only.

IVD Rx ONLY

TEST PROCEDURE FOR CLIP COVID RAPID ANTIGEN TEST

Step 1
Place the Clip Analyzer on a table or countertop and power it on by holding down the power button on the right side of the iPhone.

The Analyzer is portable and can be moved to a suitable location for testing. Ensure the surface is stable, level, dry and free of obstructions. Ensure the surface provides adequate space for the Clip Analyzer. There must be space to access the Clip Analyzer port for insertion of the Cartridge.

We recommend that you keep the Analyzer plugged in to a power outlet using the provided charging cord during operation/testing.

Step 2
Touch **Begin Test** on the home screen of the Clip COVID app on the Analyzer.

Step 3
The screen will prompt you to enter the Test Kit Lot ID number either by scanning the Barcode on the Test Kit pouch or typing in the Lot ID number manually. To scan, face code on the pouch towards the front camera of the iPhone, using the screen to help line up the image.

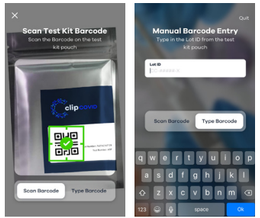
Step 4
Remove a Cartridge from its foil pouch after using the tear notch to open the pouch.

Step 5
Load the Cartridge into the Analyzer by pushing the Cartridge into the Cartridge port until you hear a click.

If you don't hear a click, continue pushing the Cartridge until you can't push it further.

Step 2

Step 3



Step 5

Step 6
The screen will prompt you to enter the Test Sample barcode either by scanning the Barcode on the nasal swab tube or typing in the Sample ID number manually. To scan, face code on the tube towards the front camera of the iPhone, using the screen to help line up the image.

Alternatively, user may choose to type in custom sample ID text.

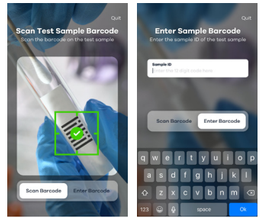
Step 7
Insert nasal swab from patient all the way into the Extraction Tube and rotate the swab 3 times against the bottom of the tube. Leave swab in the buffer in the Extraction Tube for 60 seconds. Squeeze the center of the Extraction Tube and remove the swab while keeping the center of the tube squeezed. **Dispose of swab in a biohazard waste stream.** Cap Extraction Tube using the Dropper Tip.

Step 8
Dispense the entirety of the contents of the Extraction Tube into the sample well of the Cartridge by turning it upside down and squeezing it. Holding the tube vertically directly above the sample well will minimize spillage

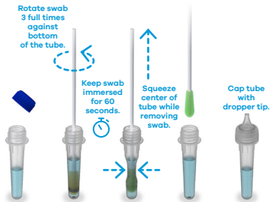
The Analyzer will automatically begin analysis 30-45 seconds after sample addition, transitioning to the 'Analysis in Progress' screen. A "positive", "negative", or "invalid" result will display in 30 minutes.

Do not touch or remove the Cartridge or disturb the Analyzer until a result is displayed.

Step 6



Step 7



Step 8