

Clip Analyzer User Manual

INSTRUCTIONS FOR USE

For Use Under Emergency Use Authorization (EUA) Only For Use with Nasal Swab Specimens



RONLY

ASSISTANCE

If you have any questions regarding the use of this product or if you want to report a test system problem, please contact Luminostics Technical Support at **support@luminostics.com**.

Test system problems may also be reported to the FDA through the MedWatch medical products reporting program:

Phone: 800.FDA.1088 Fax: 800.FDA.0178 Web: http://www.fda.gov/medwatch

INSIDE THIS MANUAL Intended Use 1 Product Description 1 System Components 1 Warnings and Precautions 2 System Installation, Setup, and Operation 3 Storage and Operating Conditions 3 Test Procedure for the Clip COVID Rapid Antigen Test 4 Results Interpretation 10 Limitations 11 Conditions of Authorization for the Laboratory 12 **Battery Power** 14 Maintenance 14 Cleaning and Disinfecting the Clip Analyzer 15 Potential Biohazard 15 Menu Structure 16 Troubleshooting 18 **Technical Specifications** 20

INTENDED USE

The Clip Analyzer is an analyzer intended to be used for objective readout of Cartridge-based immunoluminescent in vitro diagnostic assays manufactured by Luminostics. The Clip Analyzer is intended for professional and laboratory use. The first *in vitro* diagnostic test made available for use on the Clip Analyzer is the Clip COVID Rapid Antigen Test under FDA emergency use authorization (EUA).

PRODUCT DESCRIPTION

The Clip Analyzer comprises an Apple® iPhone® SE (2020), an Adapter (pre-assembled onto the iPhone), and the Clip COVID iOS app. The iPhone has been delivered to you in single-app mode, i.e., it is only capable of running the Clip COVID app.

SYSTEM COMPONENTS

The following system components are supplied with the Clip Analyzer:

- Analyzer
- Charging Cord and Power Adapter
- User Manual

Consumable test kits, including Cartridges and External Quality Control materials, are supplied separately. Contact Luminostics Technical Support for additional supplies at **support@luminostics.com**.

WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use.
- For prescription use only
- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an Emergency Use Authorization (EUA) for 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 product has been authorized only for the detection of proteins 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* diagnostic tests 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.
- Use of Nitrile, Latex (or equivalent) gloves is recommended when handling patient samples. Change gloves between

- Always operate the Clip Analyzer and use other components of the Clip COVID Rapid Antigen Test on a surface that is level, dry, and not in direct sunlight.
 Failure to do so may cause false positive, false negative, or invalid results. Leave room around the Analyzer for sample processing.
- Do not move or adjust the Clip Analyzer or remove the Cartridge while there is a test in progress. Doing so may cause an invalid result.
- Use only the power adapter that was provided with the Analyzer.
- Do not drop the Analyzer, as it could damage the unit.
- To avoid damaging the Analyzer, do not place objects on top of it.
- Dispose of containers and unused contents in accordance with Federal, State, and Local regulatory requirements. The used nasal swab, cartridge, extraction tube, and dropper tip are considered biohazardous waste and should be disposed of in a manner consistent with local biohazard waste disposal regulations.
- Do not spray disinfectant directly onto the analyzer.

2 patients.

- The product has not been tested for EMI compatibility with implantable cardioverter-defibrillators (ICDs) or pacemakers. Do not use the Clip Analyzer if you have an ICD or pacemaker.
- Do not open the foil pouch of the Cartridge and expose it to the ambient environment until the Cartridge is ready for immediate use. Premature exposure to ambient conditions may cause false positive, false negative, or invalid results

SYSTEM INSTALLATION, SETUP, AND OPERATION

Analyzer Setup

Place Clip Analyzer on a level surface like a table or bench top. The unit is portable and can be moved to a suitable location for testing, ideally near an electrical outlet for charging. Ensure the counter top is stable, level, dry and free of obstructions. Avoid direct sunlight. Ensure the bench provides adequate space for Clip Analyzer. There must be space to insert the Cartridge into the Analyzer. Plug the Charging Cord into the iPhone's charging port on the bottom of the Analyzer. Then plug the Charging Cord into the Power Adapter and the Power Adapter into an available electrical outlet.

Power Up

Turn on the iPhone sub-component of the Analyzer by depressing the button on the right side of the bezel. Upon insertion of the Cartridge, the Analyzer will turn on.

Run Test

Follow the assay-specific Package Insert to run a test using the Clip Analyzer.

Patient Test Result

When the test is complete, the results for the patient specimen will be displayed on the Analyzer screen.

Shutdown

Turn off the unit by removing the cartridge and holding the power switch on the right side of the unit. Shutdown is complete when the screen goes dark.

STORAGE AND OPERATING CONDITIONS

Store and operate the Clip Analyzer at room temperature, 59°F to 78°F (15°C to 26°C), out of direct sunlight, between 20%-85% humidity (non-condensing).

TEST PROCEDURE FOR CLIP COVID RAPID ANTIGEN TEST

Step 1

Place the Clip Analyzer on a table or counter top 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 bench 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.

Touch here to begin test.

Step 2

clipcovid

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.

Touch 'Type Barcode' to switch to manual entry of the Lot ID number.

Step 4

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

Scan Barcode using iPhone camera.



Or, type in the Lot ID number.



TEST PROCEDURE CONTINUED

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.

The cartridge can be handled with bare hands. However, we recommend wearing gloves during the entirety of the test procedure including this step.



Push the Cartridge into the Cartridge port until you hear a click.





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.

Touch 'Enter Barcode' to switch to manual entry of the Sample ID number.

Scan Barcode using iPhone camera.



Or, type in the Sample ID number.



TEST PROCEDURE CONTINUED

Step 7

Insert the anterior nasal swab collected from the patient all the way into the Extraction Tube and rotate the swab at least 3 times against the bottom of the tube. Additional rotations of the swab are not expected to negatively affect performance.

Leave the swab in the buffer in the Extraction Tube for 60 seconds.

Optionally, use the tube holder at the bottom of the Analyzer to hold the Extraction Tube.

Squeeze 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 the 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 port 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.

Movement of or removal of the Cartridge while analysis is in progress will result in invalid result. Do not touch or remove the Cartridge or disturb the Analyzer until a result is displayed.



Analysis in Progress screen.



30:00 Minutes Remaining

Do not disconnect the cartridge until the analysis is complete

RESULTS INTERPRETATION

When the test is complete, the result will be displayed on the Analyzer screen. The result of the lateral flow test cannot be seen with the naked eye. The Analyzer screen will display results, individually providing a positive or negative result for SARS-CoV-2. If the result is Invalid, retest with a new patient sample and a new Cartridge.

Positive Result

This display shows a valid positive result for SARS-CoV-2.

Negative Result

This display shows a valid negative result for SARS-CoV-2.

Invalid Result

This display shows an invalid result

Results ANALYSIS COMPLETE	Results ANALYSIS COMPLETE	Results ANALYSIS COMPLETE
Positive	ovid-19 ⊘ Negative	covid-19
ample ID: 887482736271 ot: CC-94582-A ost Finished: 06-15-2020 11:42 AM nalyzer: Luminostics SE05 pp Version: 1.0	Sample ID: 887482736271 Lot: CC-94582-A Test Finished: 06-15-2020 11:42 AM Analyzer: Luminostics SE05 App Version: 1.0	Sample ID: 887482736271 Lot: CC-94582-A Test Finished: 06-15-2020 11:42 AM Analyzer: Luminostics SE05 App Version: 1.0
Finish	Finish	Finish

LIMITATIONS

- This product is currently authorized to only be used for the qualitative detection of SARS-CoV-2 antigens from an anterior nasal swab.
- The Clip COVID Rapid Antigen Test detects both viable (live) and non-viable SARS-CoV-2. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
- 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 improperly.
- Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result by causing false positive or false negative results.
- Test results must be evaluated in conjunction with other clinical data available to the physician.
- 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.
- Negative test results are not intended to rule in other non-SARS viral or bacterial infections.

- Negative results, from patients with symptom onset beyond five days, should be treated as presumptive and confirmation with an FDA authorized molecular assay, if necessary, may be performed for clinical management.
- If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.
- Modifications to the assay procedure may result in false positive or false negative results.
- False negative results may occur if a specimen is improperly collected, transported or handled.
- The test has not been validated for use with viral transport media (VTM) or universal transport media (UTM). Usage of the test with samples prepared using VTM or UTM may cause false positive, false negative, or invalid results.
- The test has been validated for use in temperatures ranging from 15°C-26°C. The test has not been validated for use in temperature ranges outside of these conditions and usage outside of the validated range of conditions may result in false positive results or false negative results.

CONDITIONS OF AUTHORIZATION FOR THE LABORATORY

along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website:

https://www.fda.gov/medical-devices/emergencysituations-medical-devices/emergency-useauthorizations#covid19ivd

However, to assist clinical laboratories using the Clip COVID Rapid Antigen Test ("your product" in the conditions below), the relevant Conditions of Authorization are listed below:

¹ The letter of authorization refers to, "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate, 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." as "authorized laboratories."

- The Clip COVID Rapid Antigen Test Letter of Authorization¹, Authorized laboratories using your product will include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
 - Authorized laboratories using your product will use your product as outlined in the authorized labeling, e.g., "Clip COVID Rapid Antigen Test Package Insert (Instructions for Use" and "User Manual-Clip Analyzer." Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.
 - Authorized laboratories that receive your product will notify the relevant public health authorities of their intent to run your product prior to initiating testing.

- Authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories will collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@ fda.hhs.gov) and Luminostics, Inc. (via email: support@ luminostics.com, any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.
- All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.

• Luminostics, Inc., authorized distributors, and authorized laboratories and patient care settings using your product will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

BATTERY POWER

Battery Intended Use

Clip Analyzer includes 2 disposable AA batteries to power the Adapter and the iPhone SE(2020)'s rechargeable battery that is recharged when connected to AC power.

Battery Replacement

The iPhone sub-component of the Clip Analyzer is shipped with an internal LiPo rechargeable battery with an expected life of approximately three years. Two disposable AA batteries with an expected life of 450 tests are used to power the non-iPhone sub-component of the Analyzer.

The disposable AA batteries are user-replaceable. The internal rechargeable battery is not user replaceable.

Prior to replacing the disposable AA batteries, ensure that there is no cartridge in the Analyzer. Remove the battery cover on the rear of the Analyzer. Carefully remove the used batteries and insert the new ones.

Replace the battery cover. Recycle or dispose of the batteries in accordance with all Federal, State and Local laws. To avoid fire and explosion hazard, do not burn or incinerate the batteries.

MAINTENANCE

The Clip Analyzer must be sent to Luminostics if maintenance is required. The user should not attempt any maintenance except for changing the batteries and cleaning the external surfaces. Contact Luminostics Technical Support via email at **support@luminostics.com** for maintenance, return, or disposal of Clip Analyzer.

ASSISTANCE

If you have any questions regarding the use of this product or if you want to report a test system problem, please contact Luminostics Technical Support at **support@luminostics.com**.

Test system problems may also be reported to the FDA through the MedWatch medical products reporting program:

Phone: 800.FDA.1088 Fax: 800.FDA.0178 Web: http://www.fda.gov/medwatch

CLEANING AND DISINFECTING THE CLIP ANALYZER

Do not disassemble the Analyzer. The Analyzer contains no user-serviceable components. Possible electrical shock: turn off and unplug the Analyzer prior to cleaning. Do not clean the port on the side of the instrument.

The Clip Analyzer can be gently wiped down with typical lab disinfectants (e.g., paper towel sprayed with 70% alcohol or Clorox/Lysol wipes) for cleaning if your protocols call for it. **Do not spray disinfectant directly onto the Analyzer or immerse the Analyzer in liquid.**

Luminostics recommends disinfecting the Analyzer at least once per day.

POTENTIAL BIOHAZARD



Dispose of used specimens in accordance with Federal, State, and Local requirements for biohazard waste.

Treat specimens and patient samples as potentially biohazardous material.

Ensure the Analyzer is cleaned per the Cleaning Guidelines.

Seek specific training or guidance if you are not experienced with specimen collection and handling procedures.

Please read the entirety of this user manual and the package insert prior to executing a test.

Use of Nitrile, Latex, or other gloves is recommended when handling patient samples. Change gloves between patients.

MENU STRUCTURE

Testing Menu Touch "Begin test." Sample Set-Up

Scan the QR code or type in the current sample ID and Lot number to begin the test.

Insert Cartridge

Remove cartridge from package and insert.

See pages 6-7 for information on entering QR Codes and Barcodes.

Checking Cartridge

The device will begin checking the validity of the cartridge.



Adapter Found

If the adapter is found, it will indicate with a checkmark. Click "confirm" or "retry" to move forward.

Awaiting Sample

Apply the sample and wait approximately 30 seconds for analysis to begin.

Analysis in Progress

A clock will run to show progress. Do not disconnect the cartridge until the analysis is complete.

ANALYSIS IN PROGRESS...

Cancellation Popup

If a cancellation window appears, hit "cancel" or "accept" to move forward.

A new cartridge is required to start a new test.









30:00 Minutes Remaining

Do not disconnect the cartridge until the analysis is complete

TROUBLESHOOTING

Smartphone Low Battery

This screen is shown when the smartphone does not have sufficient power.

Please plug in the charging cable.

Adapter Low Battery

This screen is shown when the adapter has a low battery, approximately 20%.

You may be able to complete a test. Changing batteries is recommended.

Adapter Critical Battery

This screen is shown when adapter battery levels are critical, at approximately 5%.

You will not be able to complete a test. Batteries should be replaced.

Cartridge Removed

This screen is shown when the cartridge experiences an error. Do not use the cartridge further. Take another sample and, using a new cartridge, execute a test.



Cartridge Error

This screen is shown when the cartridge experiences an error. Do not use the cartridge further. Take another sample and, using a new cartridge, execute a test.

Adapter Not Found

The Adapter is not sensed by the smartphone.

Please check the Adapter batteries, confirming that the Adapter has power and a cartridge is inserted

Motion Detected

The Analyzer has sensed motion. Please secure the device in a stable location. The test should automatically resume.

Adapter Disconnected

The Adapter is not sensed by the smartphone. Please check Adapter batteries, confirming the Adapter has power and a cartridge is inserted.

The current test run and cartridge are invalid. Take another sample and, using a new cartridge, execute a test.



TROUBLESHOOTING CONTINUED

Invalid Barcode

This screen is shown when the cartridge barcode entered does not match a released lot. Please check the information and try again. If you continue to get this error, reach out to support for additional assistance.



20

TECHNICAL SPECIFICATIONS

Power Supply 1.9-3.5V DC, Max. 0.14A from 2 AA batteries
Dimensions 77 x 37 x 155mm
Weight 336 g
Display iPhone SE (2020), 5.45 x 2.65 in
Operational Temperature 15°C to 26°C
Operational Humidity 20%-85% non-condensing
The Clip Analyzer will be tested to UL 60601-1 3rd Edition.

Apple and iPhone are trademarks of Apple Inc., registered in the US and other countries.

SYMBOLS





Luminostics, Inc. 446 South Hillview Drive, Milpitas, CA 95035 USA

LUMINOSTICS, INC.

446 South Hillview Drive, Milpitas, CA 95035 USA www.luminostics.com