clip COVID

RAPID ANTIGEN TEST

REVOKED

Package Insert

INSTRUCTIONS FOR USE

For Use Under Emergency Use Authorization (EUA) Only

For Use with Nasal Swab Specimens

IVD Rx ONLY

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

The Clip COVID Rapid Antigen Test comprises the Clip Analyzer and the Clip COVID Rapid Antigen Test Kit. The Clip COVID Rapid Antigen Test is a lateral flow immunoluminescent assay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 directly from anterior nasal swab specimens collected from individuals who are suspected of COVID-19 by their healthcare provider within the first five days of onset of symptoms, or individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested twice over three days with at least 24 hours and no more than 48 hours between tests. Testing is limited 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.

The Clip COVID Rapid Antigen Test does not differentiate between SARS-CoV and SARS-CoV-2. Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in anterior nasal swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient 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. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, 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.

INTENDED USE CONTINUED

Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19, and confirmed with a molecular assay, if necessary for patient management. For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of COVID-19, such as, an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

The Clip COVID Rapid Antigen Test is intended for use by healthcare professionals or individuals trained in point of care settings. The Clip COVID Rapid Antigen Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

SUMMARY AND EXPLANATION OF THE TEST

Coronaviruses are a family of RNA viruses; a subset of coronaviruses cause illness in animals or humans. SARS-CoV-2 is a coronavirus that can cause mild to severe respiratory illness and has spread globally beginning in late 2019. The Clip COVID Rapid Antigen Test is a rapid test for the qualitative detection and diagnosis of SARS-CoV-2 directly from anterior nasal swabs. The Clip COVID Rapid Antigen Test Kit, along with the Clip Analyzer, contain all components required to perform an assay for SARS-CoV-2.

TEST PRINCIPLE

The Clip COVID Rapid Antigen Test employs persistent luminescence immunoassay technology in a sandwich lateral flow assay design to detect SARS-CoV-2 nucleocapsid protein from anterior nasal swab specimens. The patient's nasal sample is placed in the Extraction Tube, during which time the virus particles in the sample are disrupted, releasing viral nucleoproteins. The extracted sample is dispensed into the Cartridge's sample well from where it migrates through a lateral flow test strip containing various chemical environments. If SARS-CoV-2 viral antigen is present, it will be trapped in a specific location and be labeled by a persistent luminescent reporter nanoparticle. The Clip Analyzer then measures a luminescence signal from the test strip following which method-specific algorithms are used to display objective test results (Positive, Negative, or Invalid) on the screen.

MATERIALS SUPPLIED

- Cartridges (25), individually packaged in foil pouches and containing lateral flow test strips
- Extraction Tubes (25 uncapped tubes), each containing 500 µL of assay reagent
- Dropper Tips (25)
- Sterile Nasal Swabs (25)
- Positive Control Swab (1), non-infectious recombinant SARS-CoV-2 nucleocapsid antigen dried onto a swab
- Negative Control Swab (1), blank nasal swab
- Package Insert (1)

Materials required but not supplied:

- Clip Analyzer
- Timer, clock, or watch

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use.
- For prescription use only.
- In the United States only for use under Emergency Use Authorization. This product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories; use by laboratories certified under the CLIA that meet the requirements to perform moderate, high, or waived complexity tests. This product 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.
- 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.
- This product has been authorized only for detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- Do not use the Test Kit contents beyond the expiration date printed on the outside of the box.
- Do not reuse a used Test Kit or any elements therein.
- The Clip COVID Rapid Antigen Test is designed for countertop operation.
- The Clip COVID Rapid Antigen Test is not designed to withstand moisture, extreme humidity, or extreme temperatures. Use under these conditions may cause false positive or false negative results.
- Do not open the foil pouch of the Cartridge and expose it to the ambient environment until the Cartridge is ready for immediate use (within 30 seconds of opening foil pouch). Premature exposure to ambient conditions may cause false positive, false negative, or invalid results.
- EM Interference: Unit could be damaged if exposed to an electrostatic discharge event/environment above 8kV. If this occurs and there is a problem with the unit, contact Technical Support at **support@luminostics.com**.
- Discard and do not use any damaged or dropped Cartridge or material. This may result in a cracked or misaligned Cartridge which may cause false positive, false negative, or invalid results.
- The reagent in the Extration Tube contains sodium azide. If the solution contacts the skin or eye, flush with copious amounts of water.

- To obtain accurate results, the Package Insert must be followed.
- Inadequate or inappropriate sample collection, storage, and transport may yield false test results.
- As the test is based on a luminescent immunoassay, no visible results will form on the test strip. The Clip Analyzer must be used for result interpretation.
- 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. Use under these conditions may cause false positive, false negative, or invalid results.
- 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. *If running multiple tests, see Step 9.*
- Sample collection and handling procedures require specific training and guidance. Please read the entirety of this package insert and the user manual prior to executing a test.
- When collecting a nasal swab sample, use the Nasal Swab supplied in the kit.
- The Clip Analyzer must be used for result interpretation
- Wear suitable protective clothing, gloves, and eye/face protection when handling the contents of this kit.
- To reduce the risk of biohazard:
  - Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit contents.
  - Use of Nitrile, Latex (or equivalent) gloves is recommended when handling patient samples.
  - Dispose of used specimens and test kit components in accordance with Federal, State, and Local requirements.
  - Treat specimens and patient samples as well as used test kit components as potentially biohazardous materials.
  - Ensure the Analyzer is cleaned per the Cleaning Guidelines in this Package Insert and the Analyzer User Manual.
  - Wash hands thoroughly after handling.
- The Clip COVID Rapid Antigen Test contains small parts that may be dangerous if swallowed.
- 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.

STORAGE AND STABILITY

Store the Clip COVID Rapid Antigen Test at room temperature, 59°F to 86°F (15°C to 30°C), out of direct sunlight. Kit contents are stable until the expiration date printed on the outer box. *Do not refrigerate or freeze.*

QUALITY CONTROL

There are two types of Quality Controls for the Clip COVID Rapid Antigen Test: built-in procedural control features and external positive/negative controls.

Procedural Control

The Clip COVID Rapid Antigen Test contains a built-in procedural control feature. The procedural control is interpreted by Clip Analyzer after the run time of the test. If the test does not run correctly, the Analyzer will indicate that the result is invalid. Should this occur, review the procedure and repeat the test with a new patient sample and a new Cartridge, Extraction Tube, and Dropper Tip.

External Positive and Negative Controls

External Controls may also be used to demonstrate that the reagents and assay procedure perform properly. A Positive Control Swab and Negative Control Swab are included as External Controls. Luminostics recommends that Positive and Negative Control Swabs be run once for 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. Patient tests should not be performed if the test fails to detect Positive and/or Negative Control Swabs accurately; the control tests should be repeated or Luminostics Support should be contacted at **support@luminostics.com**.

SPECIMEN COLLECTION

Use the nasal swab supplied in the kit. Inadequate specimen collection may yield erroneous results. To collect an anterior nasal swab sample using the swab supplied in kit:

1. Insert the tip of the swab in the vertical position into one nostril until there is gentle resistance at the level of the turbinates (less than one inch into the nostril). The entire tip of the swab (usually ½ to ¾ of an inch) should be placed inside the nose, and the side of the swab tip should be rubbed with moderate pressure against as much of the wall of the anterior nares region as possible, moving the tip through a large circular path inside the nose.
2. Keep the swab in place and rotate FIVE (5) times against the nasal wall (five complete rotations) and gently remove from the nose. This should take approximately 10-15 seconds per nostril.
3. Gently insert the swab in the vertical position into the other nostril until there is gentle resistance at the level of the turbinates (less than one inch into the nostril). Keep the swab in place and rotate FIVE (5) times against the nasal wall (five complete rotations) and gently remove from the nose. This should take approximately 10-15 seconds per nostril.

CAUTION! Simply twirling the swab against one part of the inside of the nose or leaving the swab in the nose for 10-15 seconds, is not proper technique and may result in an insufficient sample. This may lead to a false positive, a false negative, or an invalid result.

SPECIMEN TRANSPORT AND STORAGE

For best performance, nasal swab specimens should be tested as soon as possible after collection. Based on testing data generated using the Clip COVID Rapid Antigen Test, nasal swabs are stable for up to 48-hours at 4°C. No stability data is available for specimens stored in extraction buffer, and storage or retesting from specimens in extraction buffer is not recommended. The Clip COVID Rapid Antigen Test kit has not been tested for use with viral transport media or banked (frozen) samples.

CLIP COVID RAPID ANTIGEN TEST PROCEDURE

STEP 1 Setup Analyzer

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.

Note: if you are testing multiple samples, the timingof each test is critical to successfully processing each sample.

We recommend that you stay near the Analyzer so you can respond to prompts and alerts from the App within the allotted time.

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 Begin Test

Touch **Begin Test** on the home screen of the Clip COVID App on the Analyzer

Touch here to begin test.

To learn more about the Clip COVID Rapid Antigen Test Procedure, please watch the training video at https://training.clipcovid.com/

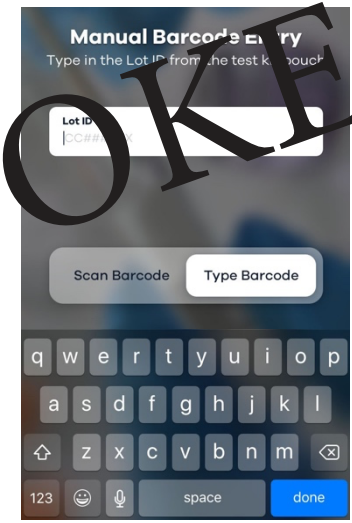
STEP 3 Scan Pouch

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.

Either scan the Test Kit Barcodeusing iPhone camera...



STEP 4 Unwrap Cartridge

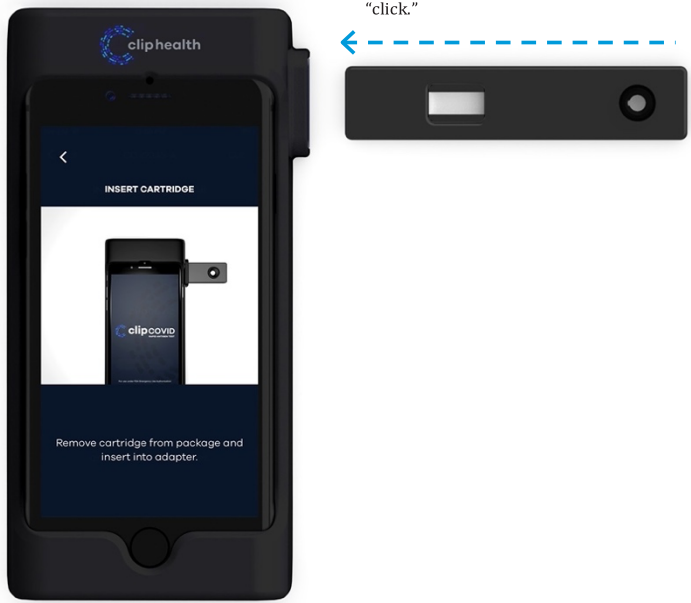
Tear at the notch to open the foil Test Kit pouch — then remove the Cartridge.

STEP 5 Load Cartridge

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.

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



STEP 6 Scan Sample

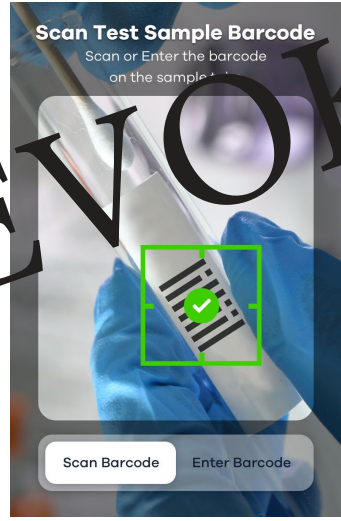
The screen will prompt you to enter the Test Sample Barcode either by scanning the Barcode on the nasal swab tube or typing in the Sample ID number manually.

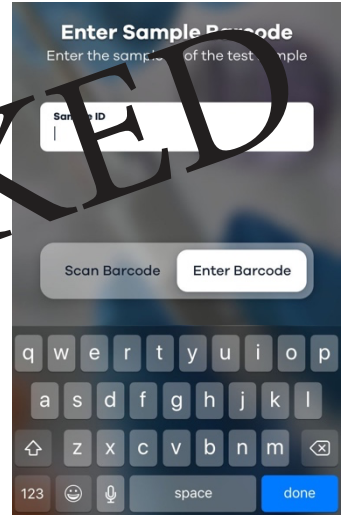
To scan, face the Barcode on the tube towards the front camera of the iPhone, using the screen to help line up the image.

Alternatively, you may choose to type in custom Sample ID text.

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

Either scan the Test Sample Barcodeusing iPhone camera...





TEST PROCEDURE CONTINUED

STEP 7 Extract Sample

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 swab rotations are not expected to negatively affect performance.

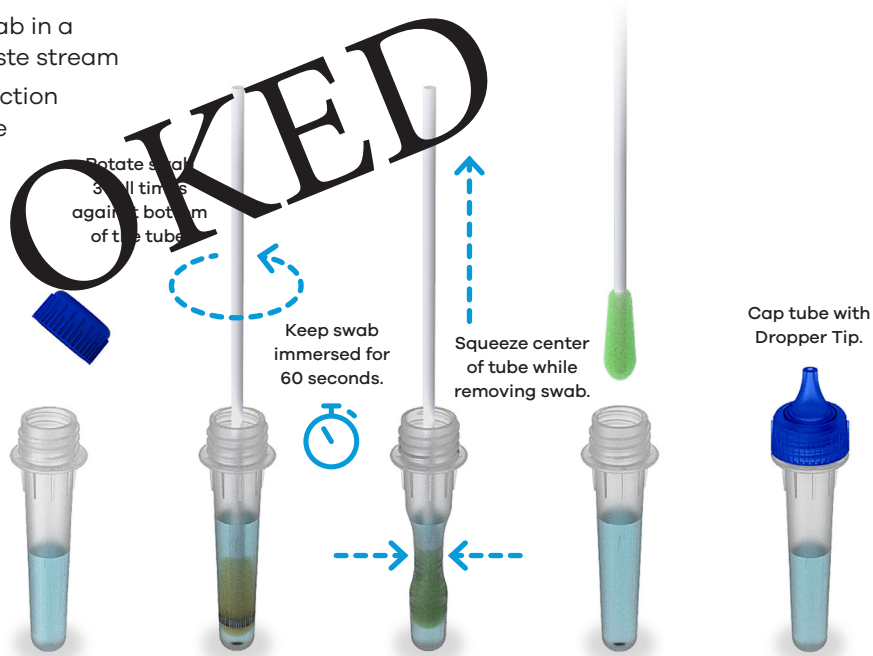
Leave swab in the buffer in the tube for 60 seconds.

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 Sample

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 a sample is added. The Analyzer will transition to the Dashboard screen when processing begins.

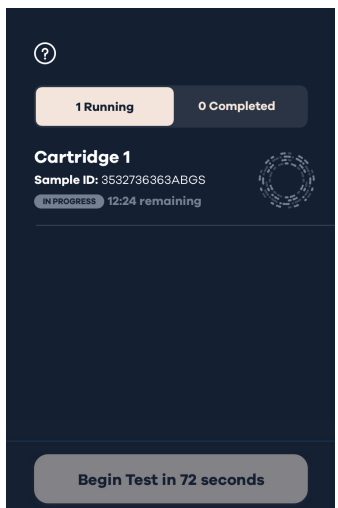
If processing a single test, do not remove the Cartridge.

Wait 30 minutes until processing is complete, then skip ahead to **Step 10**.

Or, you can start additional tests while waiting for results.

To do so, proceed to **Step 9**.

Analyzer will transition to the Dashboard screen when processing begins.



IMPORTANT NOTE

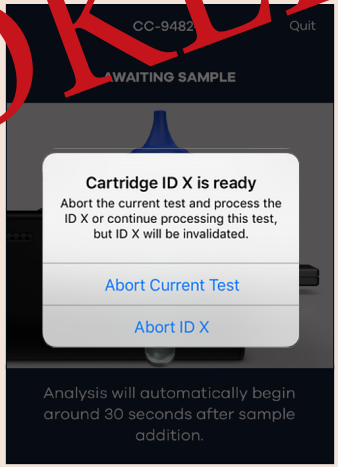
ABORTING A TEST

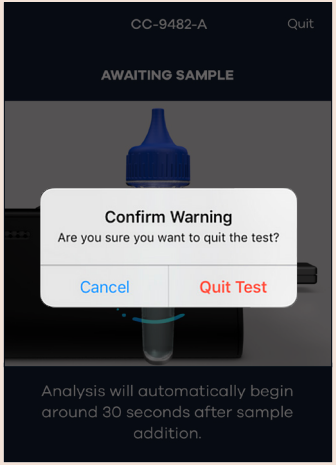
Should you need to abort a test before a sample has begun processing, you will have 30 seconds to act.

Touch **Quit** in the upper right corner of the Awaiting Sample screen.

When prompted, confirm the Test Sample ID and select **Abort Test**.

When prompted, confirm **Quit Test** — then remove the Cartridge and dispose of in a biohazard waste stream.



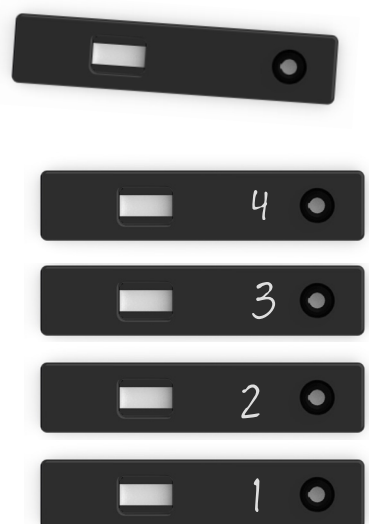


STEP 9 Identify Cartridge

When running multiple tests, once sample processing has begun, remove the Cartridge from the Analyzer when prompted by the App and mark it with the Cartridge ID using the pen provided.

To begin testing a new sample, follow the test procedure for each additional test beginning with **Step 1** each time.

Remove Cartridge when prompted and mark it using the pen provided.



TEST PROCEDURE CONTINUED

STEP 10 Process Sample

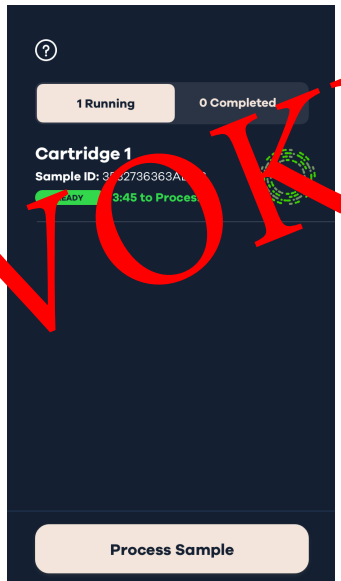
When a sample is ready to process, its Cartridge indicator will turn green. Touch **Process Sample** on the Dashboard screen to start sample processing.

Note: When the sample timer expires, you will have 90 seconds to process the sample, otherwise the Cartridge will expir

Insert the Cartridge with the ID shown on the screen and wait for the Analyzer to validate the Cartridge.

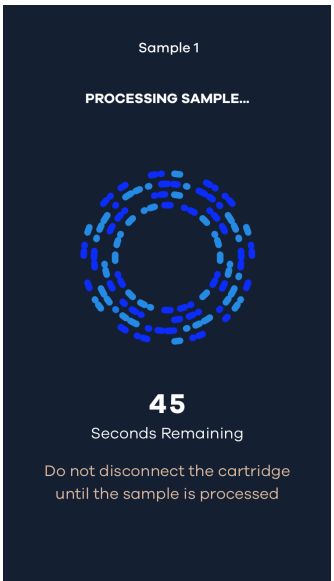
The Analyzer will automatically begin processing the sample once the Cartridge is validated.

Touch Process Sample when the Cartridge indicator turns green...



Reinsert the Cartridge...

Wait 30-45 seconds for the sample processing to begin.



STEP 11 Test Completion

Wait 45 seconds and remove the Cartridge when prompted.

Do not remove the Cartridge early or the test will be marked invalid.

Dispose of the Cartridge in a biohazard waste stream.

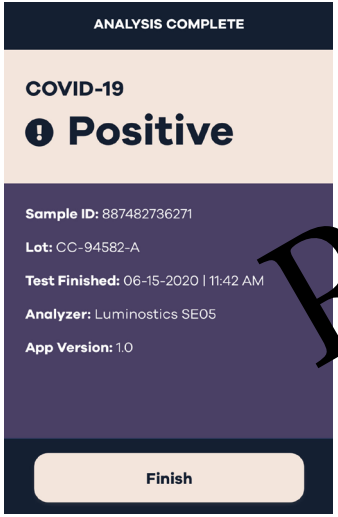
When the test is complete, the result will be displayed in the completed section of the Dashboard screen. Select a completed sample to view the test results.

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**, **Expired** or **Aborted**, retest with a new patient sample and a new Cartridge following the full test procedure.

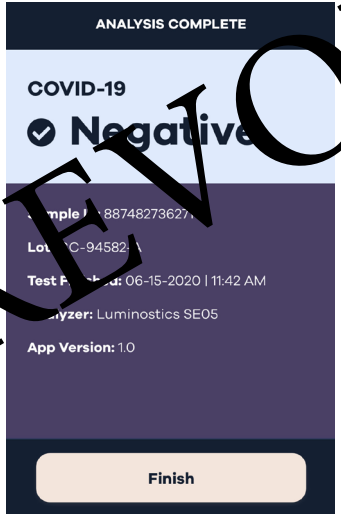
See next page for Test Results displays.

RESULTS INTERPRETATION CONTINUED

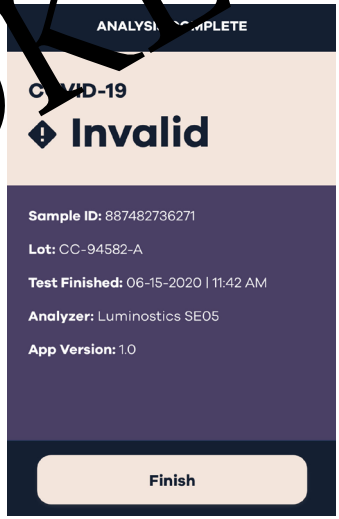
Positive Result
This display shows a valid positive result for SARS-CoV-2.



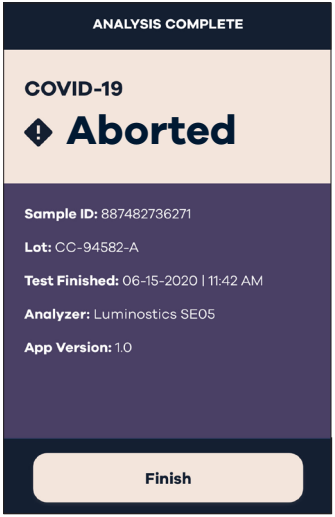
Negative Result
This display shows a valid negative result for SARS-CoV-2. **See NOTE 1.**



Invalid Result
This display shows an invalid result.



Aborted Result
This display indicates an aborted test.



NOTE 1 — Negative results warning

Please note that negative results do not rule out COVID-19. A negative result is presumptive and confirmation with a molecular assay, if necessary, for patient management may be performed. If the test result is negative and the patient does not show symptoms of COVID-19, testing should be repeated with a new specimen collected at least 24 to 48 hours later to confirm result.

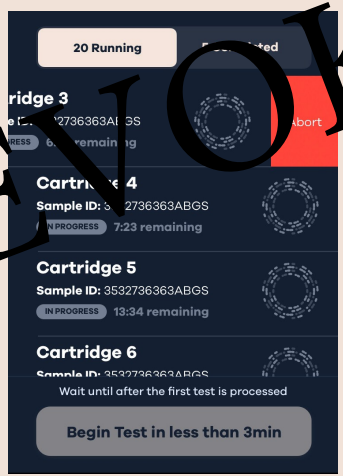
IMPORTANT NOTE — ABORTING A TEST

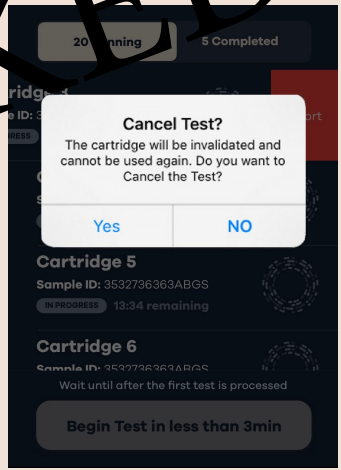
Follow this procedure to abort one, or multiple tests after sample processing has already begun. To cancel multiple samples, repeat each of the steps shown.

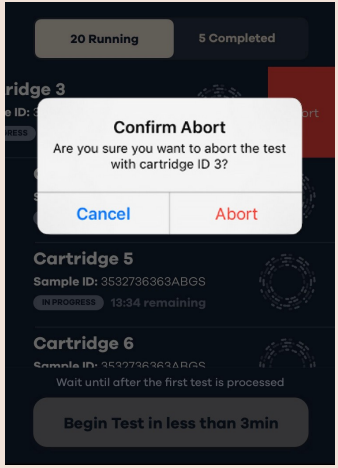
Select a sample in the Dashboard and slide left — then select **Abort**.

To cancel or abort the test, select **Yes** when prompted.

Confirm your selection, then choose **Abort** when prompted. Dispose of the Cartridge in a biohazard waste stream.







LIMITATIONS

- The contents of this kit are to be used for the qualitative detection of SARS-CoV-2 antigens from an anterior nasal swab.
- This 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.
- 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.
- 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 are presumptive, do not rule out COVID-19, and it may be necessary to obtain additional testing with a molecular assay if needed for patient 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.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected from August to September 2020. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
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CONDITIONS OF AUTHORIZATION FOR THE LABORATORY

The Clip COVID Rapid Antigen Test Letter of Authorization[1], 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/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas

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:

- Authorized laboratories using your product must 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 must 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 authorizedinstruments, 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 must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- Authorized laboratories using your product must have a process in place for reporting test results to healthcareproviders and relevant public health authorities, as appropriate.

[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."

- Authorized laboratories must 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 must 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.

CLINICAL PERFORMANCE

The clinical performance characteristics of the Clip COVID Rapid Antigen Test were evaluated in a multi-site prospective clinical study at two sites in the United States between late August and early October 2020. In this study, testing using the Clip COVID Rapid Antigen Test (and the Package Insert and User Manual) was performed by operators with no laboratory experience or additional training using only the package insert, and who are representative of the intended users at CLIA waived testing sites. In this study testing was conducted by eighteen (18) intended users.

Patient Demographics

Patient demographics (age, elapsed time from date of onset) are available for the one hundred sixty-six (166) samples used in the study. The specimen positivity breakdown based on age of the patient:

Age Range	Total # of Enrolled Subjects	Total # Positive by RT-PCR
Under 5 years	0	0
6 to 21 Years	9	1
22 to 59 years*	146	31
60 years and older	8	0

* One of the samples in this age range was negative on the Clip COVID RapidAntigen Test but positive by RT-PCR

CLINICAL PERFORMANCE CONTINUED

All patients enrolled in the study were symptomatic and provided at least one nasal and one nasopharyngeal swab. At both sites, one nasal swab was tested directly in the Clip COVID Rapid Antigen Test, within 30 minutes of collection, according to product instructions. Nasopharyngeal swabs were eluted in viral transport media (VTM) and immediately frozen before being batched and shipped to a central laboratory for RT-PCR testing on an EUA-authorized assay that includes a solid phase RNA extraction step. The performance of the Clip COVID Rapid Antigen Test was established by testing 163 nasal swabs from individual symptomatic patients who were enrolled into the study within 5 days of symptom onset.

Clip COVID Rapid Antigen Test by Luminostics, Inc. Comparator RT-PCR Assay

	Positive	Negative	Total
Positive	31	0	31
Negative	1	131	132
Total	32	131	163

Positive Percent Agreement: 96.9% (95% CI: 83.8% - 99.9%)
Negative Percent Agreement: 100% (95% CI: 97.2% - 100%)

The specimen positivity based on days post onset:

Days Post Symptom Onset	# SpecimensTested from Unique People	# Positive Specimens by RT-PCR	% Positive
0	23	0	0
1*	35	5	14.2%
2	55	12	21.8%
3	26	8	30.8%
4	14	6	42.9%
5	10	1	10%

* One specimen was Clip COVID Rapid Antigen Test Negative and Positiveby Reference Extracted PCR.

ANALYTICAL PERFORMANCE

Limit of Detection

The Limit of Detection (LoD) of the Clip COVID Rapid Antigen Test was determined using limiting dilutions of gamma-irradiated SARS-CoV-2 (BEI Resources NR-52287). NR-52287 is a preparation of SARS-Related Coronavirus 2 (SARS-CoV-2), isolate USA-WA1/2020, that has been gamma-irradiated (5x10^6 RADs) on dry ice, followed by sonication. The material was supplied frozen at a concentration of 2.8 x10^5 $TCID_{50}$ per mL. The study to determine the Clip COVID Rapid Antigen Test's LoD was designed to reflect the assay when using direct swabs. Presumed negative nasal swab specimens were eluted, combined, and mixed thoroughly to create a human nasal swab extract clinical matrix pool (pooled nasal swab extract) to be used as the diluent. For each replicate tested in this study, a nasal swab was spiked with 50 µL of the virus dilution in pooled nasal swab extract. The spiked swab was processed on the Clip COVID Rapid Antigen Test according to the package insert. The LoD was determined in two steps:

1 LoD Screening

Five (5) dilutions of the gamma irradiated virus were made in pooled nasal swab extract and processed for each study as described above. These dilutions were tested in triplicate. The lowest concentration demonstrating 3 of 3 positives was chosen for LoD confirmation. Based on this testing, the concentration chosen was of 0.88 x 10^2 $TCID_{50}$ per mL.

2 LoD Confirmation

The analyte concentration 0.88 x 10^2 $TCID_{50}$ per mL was tested twenty times to confirm. Twenty (20) of twenty (20) results were positive. Based on this testing the LoD was confirmed to be 0.88 x 10^2 $TCID_{50}$ per mL.

ANALYTICAL PERFORMANCE CONTINUED

Cross-Reactivity

Cross-reactivity and potential interference of the Clip COVID Rapid Antigen Test was evaluated by testing 24 commensal and pathogenic microorganisms spiked into pooled human nasal wash, using the Clip COVID Rapid Antigen Test. Each of the microorganisms were tested in triplicate in the absence or presence of inactivated SARS-CoV-2 at 3x LoD. No cross-reactivity or interference was seen with any of the following microorganisms when tested at the concentration presented in the table below.

VIRUSES

Potential cross-reactant or interferent	Concentration
Human Coronavirus 229E	1.52 x 10[illegible] $TCID_{50}$/mL
Human Coronavirus OC43	5.05 x 10^4 $TCID_{50}$/mL
Human Coronavirus NL63	7.[illegible] x 10^4 $TCID_{50}$/mL
Adenovirus Type 1	1.0[illegible] x 10^7 $TCID_{50}$/mL
Human Metapneumovirus 9 (hMPV) Type A1	1.18 x 10^4 $TCID_{50}$/mL
Parainfluenza Virus Type [illegible]	3.42 x 10^6 $TCID_{50}$/mL
Parainfluenza Virus Type [illegible]	5.05 x 10^4 $TCID_{50}$/mL
Parainfluenza Virus Type 3	8.58 x 10^6 $TCID_{50}$/mL
Parainfluenza Virus Type 4B	1.16 x 10^6 $TCID_{50}$/mL
Influenza A H3N2 Brisbane/10/07	3.55 x 10^4 $TCID_{50}$/mL
Influenza A H1N1 New Caledonia/20/99	4.17 x 10^4 $TCID_{50}$/mL
Influenza B Brisbane/33/08	1 x $10^{4.07}$ $TCID_{50}$/mL
Enterovirus Type 68	1.51 x 10^5 $TCID_{50}$/mL
Respiratory Syncytial Virus Type A (RSV-A)	4.17 x 10^4 $TCID_{50}$/mL
Human Rhinovirus 17	1.6 x 10^7 $TCID_{50}$/mL

BACTERIA

Potential cross-reactant or interferent	Concentration
Haemophilus influenzae Type b Strain Egan	5.43 x 10^7 CFU/mL
Streptococcus pneumoniae Type 19F; Z022	2.26 x 10^8 CFU/mL
Bordetella pertussis Strain A639	1.13 x 10^9 CFU/mL
Chlamydophila pneumoniae Strain AR-39	1.4 x 10^7 IFU/mL
Legionella pneumophila Philadelphia	1.88 x 10^9 CFU/mL
Pneumocystis jiroveci Recombinant W303-PJI	1.56 x 10^7 CFU/mL
Streptococcus pyogenes	2.66 x 10^8 CFU/mL
Mycoplasma pneumoniae	3.16 x 10^7 CCU/mL
Staphylococcus aureus	5.5 x 10^8 CFU/mL
Staphylococcus epidermidis	7.7 x 10^8 CFU/mL
YEAST	
Candida albicans	4.5 x 10^7 CFU/mL

Due to lack of availability for wet testing, the following pathogens were analyzed *in silico* by comparing sequence homology on NCBI BLAST. The following organisms were found to show low homology, however, cross reactivity cannot be ruled out:

- MERS
- Coronavirus HKU1
- *M. tuberculosis*

Due to lack of availability for wet testing, the following pathogens were analyzed in silico and determined to be cross-reactive:
- Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV)

High Dose Hook Effect

No high dose hook effect was observed when inactivated SARS-CoV-2 stock was tested at concentration of 9.58×10^5 $TCID_{50}$ per mL.

Endogenous Interference

The following 18 substances which can be expected to be naturally present in respiratory specimens or be artificially introduced, were evaluated with the Clip COVID Rapid Antigen Test at the concentrations listed below and were found not to affect test performance (i.e., they were found to not cross-react or interfere).

POTENTIAL INTERFERING SUBSTANCE

	Concentration in sample
Zanamivir	282.0 ng/mL
Oseltamivir	2.2 µg/mL
Flonase	0.7 g/mL
Saline nasal spray	15% v/v
Rhinocort	5% v/v
Nasacort Allergy 24 hour	5% v/v
Afrin	5% v/v
Vicam Cold Remedy	5% v/v
Neo-Synephrine	5% v/v
Human Blood	5% v/v
Purified Mucin Protein	2.5 mg/mL
Tobramycin	1.25 mg/mL
Naso GEL (NeilMed)	5% v/v
CVS Nasal Spray (Cromolyn)	15% v/v
Homeopathic (Alkalol)	10% v/v
Sore Throat Phenol Spray	15% v/v
Mupirocin	10 mg/mL
Fluticasone Propionate	5% v/v

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.

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**

SYMBOLS

Manufacturer		Use by date	
Catalogue number	REF	Do not reuse	
Prescription only	℞ ONLY	Contains sufficient materials for 25 tests	Σ 25
For *in-vitro* diagnostic use only	IVD	Keep dry	
Batch code	LOT	Biohazard	
Consult instructions for use		Caution	

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

REVOKED

LUMINOSTICS, INC.
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www.luminostics.com

PL001 Rev. D

The Clip COVID Rapid Antigen Test comprises the Clip Analyzer and the Clip COVID Rapid Antigen Test Kit. The Clip COVID Rapid Antigen Test is a lateral flow immunoluminescent assay intended for the qualitative detection of nucleocapsid protein antigen fromSARS-CoV-2 directly from anterior nasal swab specimens collected from individuals who are suspected of COVID-19 by their healthcare provider within the first five days of onset of symptoms, or individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested twice over three days with at least 24 hours and no more than 48 hours between tests. Testing is limited 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. The Clip COVID Rapid Antigen Test does not differentiate between SARS-CoV and SARS-CoV-2. Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in anterior nasal swab specimens during the acute phase of infection. Positive results indica te the presence of viral antigens, but clinical correlation with patient 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. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities. Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, 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. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19, and confirmed with a molecular assay, if necessary for patient management. For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of COVID-19, such as, an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection. The Clip COVID Rapid Antigen Test is intended for use by healthcare professionals or individuals trained in point of care settings. The Clip COVID Rapid Antigen Test is only for u se under the Food and Drug Administration's Emergency Use Authorization.

Study the Clip Analyzer User Manual (available at www.clipanalyzermanual.luminostics.com) and Clip COVID Rapid Antigen Test Kit Package Insert thoroughly before before using these Quick Reference Instructions or performing a test. This is not a comple te product insert. Store and operate the Clip COVID Rapid Antigen Test and Clip Analyzer at room temperature between 15°C and 30°C (59°F and 86°F), out of direct sunlight, between 20%-85% humidity (non-condensing). Nasal swab specimens must be processed within 30 minutes of collection. Specimens and kit components must be at room temperature before testing. Check expiation 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.

CLIP ANALYZER AND TEST KIT

QUALITY CONTROLS

It is recommended that positive and negative external control swabs are run once by each untrained operator and as deemed additionally necessaryby 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 be performed after test results to determine positive and/or negative control swabs accurate response re-test or contact Luminostics, Inc.

PL021 Rev. D

In the USA, this product has not been FDA cleared or approved; but has been authorized by FDA under an EUA for use by authorized laboratories; use by laboratories certified under the CLIA, 42 U.S.C. §263a, that meet requirements to perform moderate, high or waived complexity tests. This product 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.

This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and in the USA, 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 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 declaration is terminated or the authorization is revoked.

SPECIMEN COLLECTION PROCEDURE

To collect an anterior nasal swab sample using the swab supplied in kit:

1) Insert the tip of the swab in the vertical position into one nostril until there is gentle resistance at the level of the turbinates (less than one inch into the nostril). The entire tip of the swab (usually ½ to ¾ of an inch) should be placed inside the nose, and the side of the swab tip should be rubbed with moderate pressure against as much of the wall of the anterior nares region as possible, moving the tip through a large circular path inside the nose.

2) Keep the swab in place and rotate FIVE (5) times against the nasal wall (five complete rotations) and gently remove from the nose. This should toke approximately 10-15 seconds per nostril.

3) Repeat Steps 1 and 2 with the other nostril.

CAUTION! Simply twirling the swab against one part of the inside of the nose or leaving the swab in the nose for 10-15 seconds, is not proper technique and may result in an insufficient sample, leading to false or invalid results.

CUSTOMER SERVICE

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

clip COVID
RAPID ANTIGEN TEST

Quick Reference Instructions

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

IVD ℞ ONLY

Designed and manufactured by

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

CLIP COVID RAPID ANTIGEN TEST PROCEDURE

STEP 1 Setup Analyzer

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 stay near the Analyzer so you can respond to prompts and alerts from the App within the alloted time.

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

STEP 2 Begin Test

Touch **Begin Test** on the home screen of the Clip COVID App on the Analyzer.

STEP 2

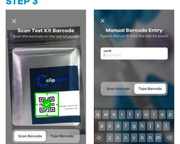
STEP 3 Scan Pouch

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 Unwrap Cartridge

Tear at the notch to open the foil Test Kit pouch — then remove the Cartridge.

STEP 3



STEP 5 Load Cartridge

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.

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

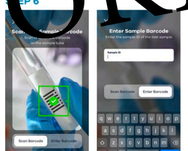
STEP 5

STEP 6 Scan Sample

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 Barcode 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.

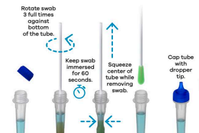
STEP 6



STEP 7 Extract Sample

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 swab into biohazard waste stream.** Cap Extraction Tube using the Dropper Tip.

STEP 7



STEP 8 Dispense Sample

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

The Analyzer will automatically begin analysis 30-45 seconds after a sample is added and will transition to the Dashboard screen when processing begins.

STEP 8

Note: If processing a single test, do not remove the Cartridge. Wait 30 minutes until processing is complete, then skip ahead to **Step 10**.

STEP 9 Identify Cartridge

When running multiple tests, once processing begins, remove the Cartridge from the Analyzer when prompted and mark it with the Cartridge ID. Follow the test procedure for each added test beginning with **Step 1** each time.

STEP 9

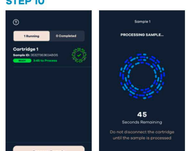
STEP 10 Process Sample

When a sample is ready to process, its Cartridge indicator will turn green. Touch **Process Sample** to start processing.

Note: When the sample timer expires, you will have 90 seconds to process the sample, otherwise Cartridge will expire.

Insert Cartridge with ID shown on the screen and wait for it to be validated — Analyzer will begin processing at that time.

STEP 10



STEP 11 Test Completion

Wait 45 seconds and remove the Cartridge when prompted.

Do not remove the Cartridge early or disturb the Analyzer until a result is displayed otherwise test will be invalidated.

Dispose of the Cartridge in a biohazard waste stream. The Clip Analyzer can be gently wiped down, after unplugging, 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 clean the port on the side of the instrument. Do not spray disinfectant directly onto the Analyzer or immerse the Analyzer in liquid.

STEP 11

RESULT INTERPRETATION

Result will be displayed in the completed section of the Dashboard screen when test is complete. Select a completed sample to view the test results.

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, Expired or Aborted, retest with new patient sample and new Cartridge following the full test procedure.

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

Negative: Negative results from patients 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. If the test result is negative and the patient does not show symptoms of COVID-19, testing should be repeated with a new specimen collected at least 24 to 48 hours later to confirm result.

Invalid: Should this occur, retest patient with a new nasal swab, Cartridge, and Extraction Tube.

clip COVID

RAPID ANTIGEN TEST

Clip Analyzer User Manual

INSTRUCTIONS FOR USE

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

IVD Rx ONLY

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 FDAthrough 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

The Clip Analyzer is an analyzer intended to be used for objective readout of Cartridge-based immunoluminescentin vitro diagnostic assays manufactured by Luminostics.
The Clip Analyzer is intended for professional and laboratory use. The first *in vitro* diagnostic testmade available for use on the Clip Analyzer is the Clip COVID Rapid Antigen Test under FDA emergency use authorization (EUA). Please refer to the instructions for use (IFU) of the Clip COVID Rapid Antigen Test for the Intended Use of that specific test.

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 youin single-app mode, i.e., it is only capable of running the Clip COVID App.

SYSTEM COMPONENTS

The following system components are supplied withthe Clip Analyzer:

- Analyzer
- Charging Cord and Power Adapter
- User Manual
- Two Disposable AA Batteries

Consumable test kits, including Cartridges and ExternalQuality Control materials, are supplied separately.
Contact Luminostics Technical Support for additionalsupplies 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 bylaboratories 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 detectionof 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-19under 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 recommendedwhen handling patient samples. Change gloves between patients.
- Always operate the Clip Analyzer and use other components of the Clip COVID Rapid Antigen Test ona 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. *If running multiple tests, see Step 9.*
- Use only the Power Adapter that was provided withthe Analyzer.
- Do not drop the Analyzer, as it could damage the unit.
- To avoid damaging the Analyzer, do not place objectson top of it.
- Dispose of containers and unused contents in accordancewith 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.

WARNINGS AND PRECAUTIONS CONTINUED

- 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 anICD or pacemaker.
- Do not open the foil pouch of the Cartridge until the Cartridge is ready for immediate use. Premature exposureto ambient conditions may cause false positive, false negative, or invalid results.
- EM Interference: Unit could be damaged if exposed to an electrostatic discharge event/environment above 8kV.If this occurs and there is a problem with the unit, please contact Luminostics Technical Support at **support@luminostics.com**.

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 topis 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'scharging 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 thebezel. Upon insertion of the Cartridge, the Analyzer will turn on.

Run Test: Follow the assay-specific Package Insert to runa test using the Clip Analyzer.

Patient Test Result: When the test is complete, the resultsfor the patient specimen will be displayed on the Analyzerscreen.

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 86°F (15°C to 30°C), out of direct sunlight, between 20%-85% humidity (non-condensing).

CLIP COVID RAPID ANTIGEN TEST PROCEDURE

STEP 1 Setup Analyzer

Place the Clip Analyzer ona table or countertop and power it on by holding downthe 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.

Note: if you are testing multiple samples, the timingof each test is critical to successfully processing each sample.

We recommend that you stay near the Analyzer so you can respond to promptsand alerts from the App within the alloted time.

There must be space to access the Clip Analyzerport for insertion of the Cartridge.

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

To learn more about the Clip COVID Rapid Antigen Test Procedure, please watch the training video at https://training.clipcovid.com/

STEP 2 Begin Test

Touch **Begin Test** on the home screen of the Clip COVID App on the Analyzer.

TEST PROCEDURE CONTINUED

STEP 3 Scan Pouch

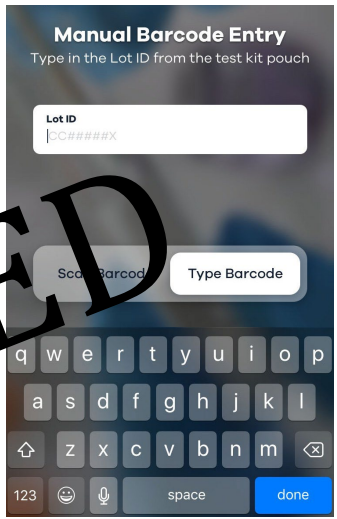
The screen will prompt youto enter the Test Kit Lot ID number either by scanningthe Barcode on the Test Kitpouch or typing in the Lot ID number manually.

To scan, face code on the pouch towards the front camera of the iPhone, usingthe screen to help line up the image.

Touch **Type Barcode** to switch to manual entry ofthe Lot ID number.

Either scan the Test Kit Barcodeusing iPhone camera...

Or type in the Lot ID number from the Test Kit pouch.



STEP 4 Unwrap Cartridge

Tear at the notch to open the foil Test Kit pouch — then remove the Cartridge.

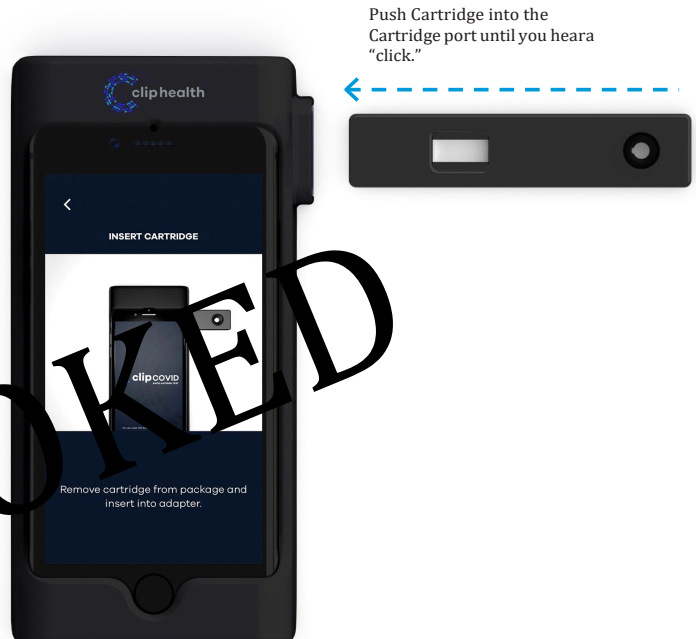
TEST PROCEDURE CONTINUED

STEP 5 Load Cartridge

Load the Cartridge into the Analyzer by pushing the Cartridge into the Cartridgeport until you hear a click.

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

A Cartridge can be handledwith bare hands. However, we recommend wearing gloves during the entirety of the test procedure — including this step.



TEST PROCEDURE CONTINUED

STEP 6 Scan Sample

The screen will prompt you to enter the Test Sample Barcode either by scanningthe Barcode on the nasal swab tube or typing in the Sample ID number manually.

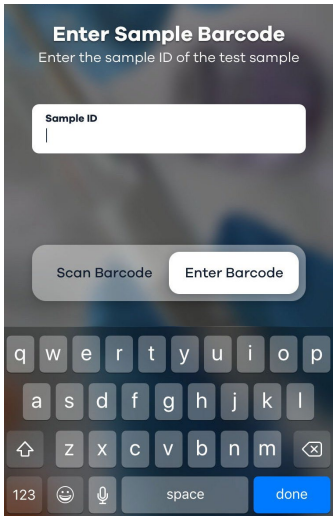
To scan, face the Barcode on the tube towards the front camera of the iPhone, using the screen to help lineup the image.

Alternatively, you may choose to type in custom Sample ID text.

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

Either scan the Test Sample Barcodeusing iPhone camera...

Or type in the Sample ID numberfrom the nasal swab tube.



TEST PROCEDURE CONTINUED

STEP 7 Extract Sample

Insert the anterior nasal swab collected from the patient all the way into theExtraction Tube and rotate

the swab at least 3 times against the bottom of the tube. Additional swab rotations are not expectedto negatively affect performance.

Leave swab in the buffer in the 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.

TEST PROCEDURE CONTINUED

STEP 8 Dispense Sample

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 automatically begins analysis 30-45 seconds after a sample is added and will transition to the Dashboard screen whenprocessing begins.

If the Dashboard doesn't appear within 2 minutes of sample addition, please quit the current test, then retest with a new patient sample and new Cartridge.

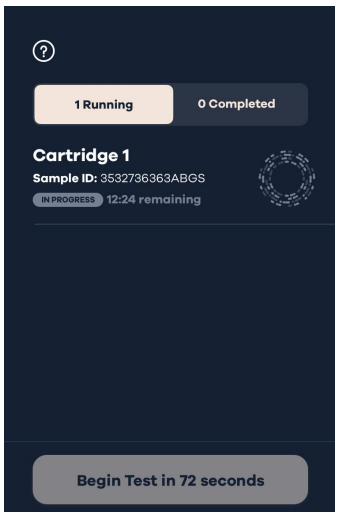
If processing a single test, do not remove the Cartridge.

Wait 30 minutes until processing is complete, thenskip ahead to **Step 10**.

Or, you can start additional tests while waiting for results.

To do so, proceed to **Step 9**.

Analyzer will transition to the Dashboard screenwhen processing begins.



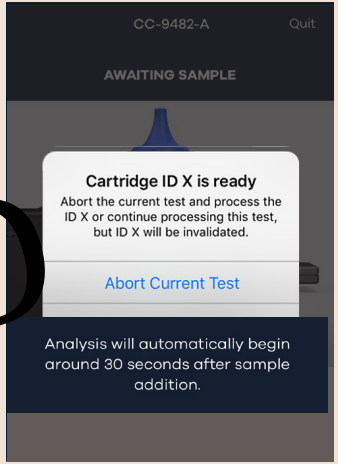
IMPORTANT NOTE

ABORTING A TEST

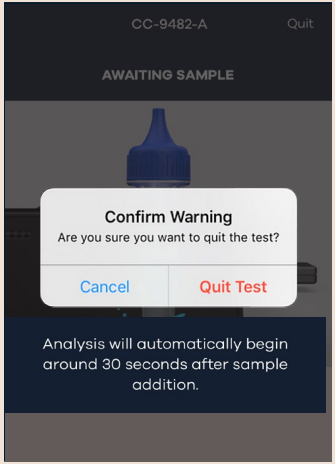
Should you need to abort a test before a sample has begun processing, you will have 30 seconds to act.

Touch **Quit** in the upper right corner of the AwaitingSample screen.

When prompted, confirmthe Test Sample ID and select **Abort Test**.



When prompted, confirm **Quit Test** — then remove the Cartridge and dispose of in a biohazard waste stream.



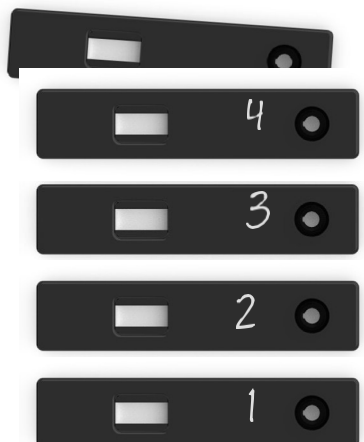
TEST PROCEDURE CONTINUED

STEP 9 Identify Cartridge

When running multiple tests, once sample processing has begun, remove the Cartridgefrom the Analyzer when prompted by the App and mark it with the Cartridge IDusing the pen provided.

To begin testing a new sample, follow the test procedure for each additional test beginning with **Step 1** each time.

Remove Cartridge when promptedand mark it using the pen provided.



TEST PROCEDURE CONTINUED

STEP 10 Process Sample

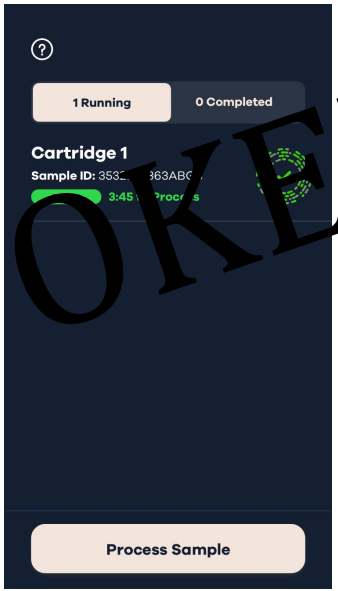
When a sample is ready to process, its Cartridge indicator will turn green. Touch **Process Sample** on the Dashboard screen to start sample processing.

Note: When the sample timer expires, you will have 90 seconds to process the sample, otherwise the Cartridge will expire.

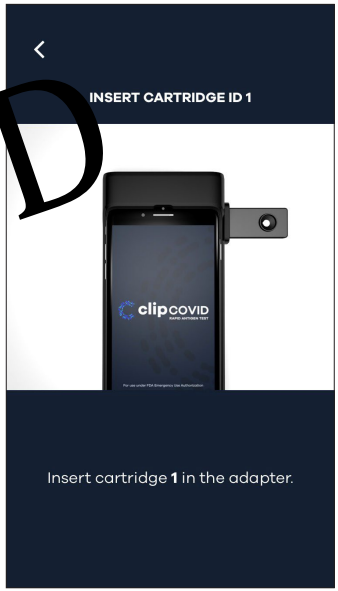
Insert the Cartridge with the ID shown on the screen and wait for the Analyzer to validate the Cartridge.

The Analyzer will automatically begin processing the sample once the Cartridge is validated.

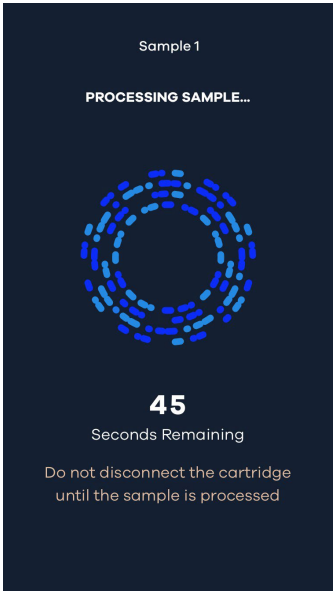
Touch Process Sample when the Cartridge indicator turns green...



Reinsert the Cartridge...



Wait 30-45 seconds for the sample processing to begin.



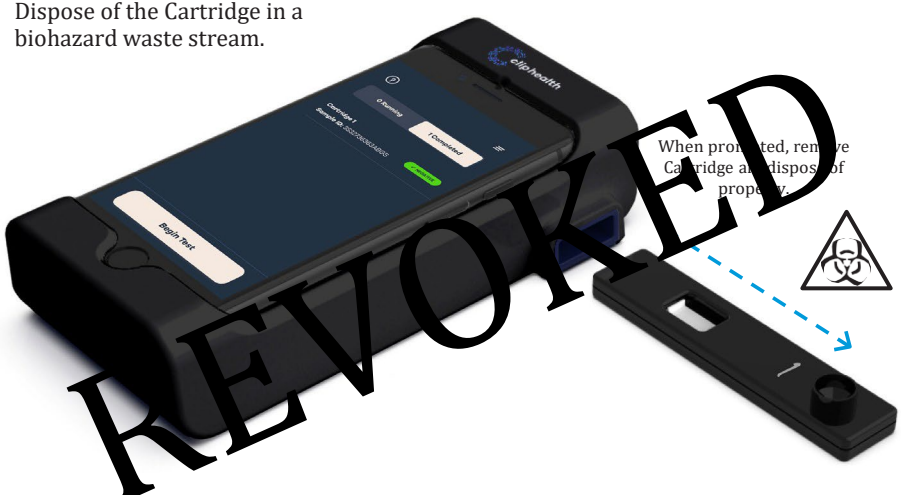
TEST PROCEDURE CONTINUED

STEP 11 Test Completion

Wait 45 seconds and remove the Cartridge when prompted.

Do not remove the Cartridge earlyor the test will be marked invalid.

Dispose of the Cartridge in a biohazard waste stream.



RESULT INTERPRETATION

When the test is complete, the result will be displayed in the completed section of the Dashboard screen. Select a completed sampleto view the test results.

The result of the lateral flow test cannot be seen with the naked eye. The Analyzerscreen will display results, individually providing a **Positive** or **Negative** result for SARS-CoV-2. If the result is **Invalid**, **Expired** or **Aborted**, retest with a new patient sample and a new Cartridge followingthe full test procedure.

See next page for Test Results displays.

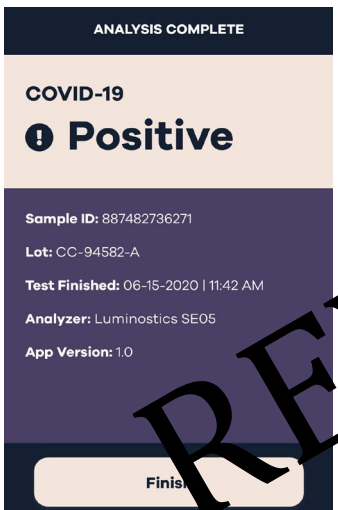
RESULT INTERPRETATION CONTINUED

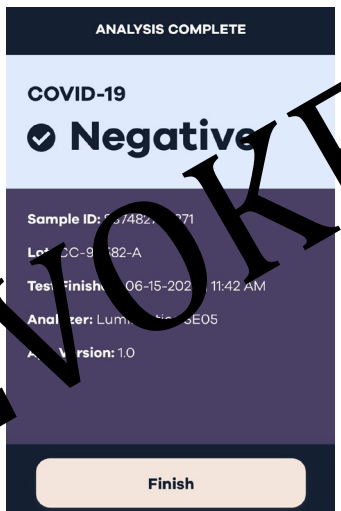
Positive Result
This display shows a valid positive result for SARS-CoV-2.

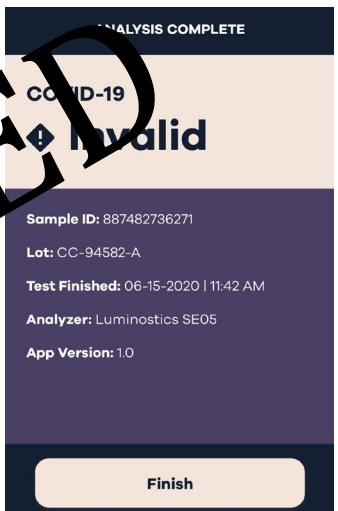
Negative Result
This display shows a valid negative result forSARS-CoV-2. **See NOTE 1**

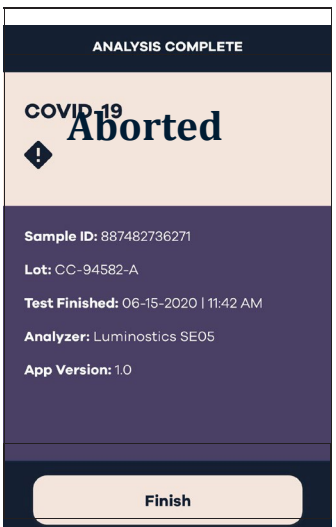
Invalid Result
This display showsan invalid result.

Aborted Result
his display indicatesan d test.









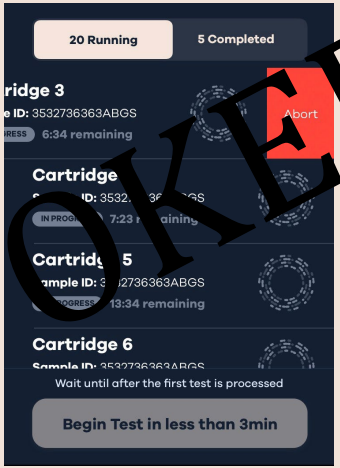
NOTE 1: Warning for Negative Results: Please note that negative results do not rule out COVID-19. A negative result is presumptive and confirmation with a molecular assay, if necessary, for patient management may be performed.

IMPORTANT NOTE

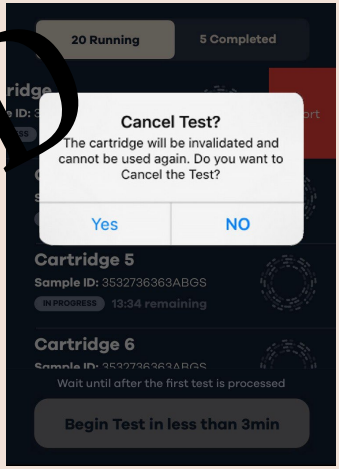
ABORTING A TEST

Follow this procedure to abort one, or multiple tests after sample processing has already begun. To cancel multiple samples, repeat each of the steps shown.

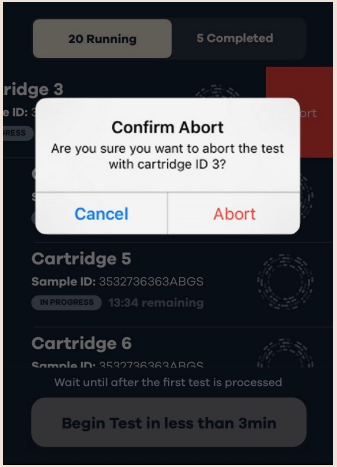
Select a sample in the Dashboard and slide left — then select **Abort**.



To cancel or abort the test, select **Yes** when prompted.



Confirm your selection, then choose **Abort** when prompted. Dispose of the Cartridge in a biohazard waste stream.



LIMITATIONS

- The contents of this kit are to be used for the qualitative detection of SARS-CoV-2 antigens from an anterior nasalswab.
- This 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 withviral culture results performed on the same sample.
- A negative test result may occur if the level of antigen ina sample is below the detection limit of the test or if the sample was collected improperly.
- Failure to follow the Test Procedure may adversely affecttest performance and/or invalidate the test result.
- The test has not been validated for use with viral transportmedia (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.
- 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, are presumptive, do not rule out COVID-19 and it may be necessary to obtain additional testing with a molecular assay, if needed for patient management.
- If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state orlocal public health departments, is required.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected from August to September 2020. The clinical performance has not been established in all circulating variants, but is anticipated to be reflective of the prevalent variants in circulation at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence which change over time.

CONDITIONS OF AUTHORIZATION FOR THE LABORATORY

The Clip COVID Rapid Antigen Test Letter of Authorization[1],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/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas

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

- Authorized laboratories using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which mayinclude mass media.
- Authorized laboratories using your product must 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 specimentypes, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.
- Authorized laboratories that receive your product must notify the relevant public health authorities of their intentto run your product prior to initiating testing.

[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."

CONDITIONS OF AUTHORIZATION FOR THE LABORATORY CONTINUED

- Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories must 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 deviationsfrom the established performance characteristics of your product of which they become aware.
- All operators using your product must be appropriatelytrained 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 labelling.
- Luminostics, Inc., authorized distributors, and authorized laboratories and patient care settings using your product must 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.

HAZARDS can result from unauthorized or modificationof this MEDICAL EQUIPMENT!

WARNING: No modification of this equipment is allowed.

WARNING: Do not modify this equipment without authorization of the manufacturer.

WARNING: If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.

BATTERY POWER

Battery Intended Use

Clip Analyzer includes two disposable AA batteries to power the Adapter. The iPhone SE(2020)'s rechargeablebattery is recharged when connected to AC power.

Battery Replacement

The iPhone sub-component of the Clip Analyzer is shippedwith an internal LiPo rechargeable battery with an expected life of approximately three years. Two disposableAA 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 thatthere 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 end-of-service-life disposal ofthe 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 FDAthrough 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 theside of the instrument.

The Clip Analyzer can be gently wiped down with typical lab disinfectants (e.g., paper towel sprayed with70% 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 requirementsfor biohazard waste.

Treat specimens and patient samples as potentially biohazardous material.

Ensure the Analyzer is cleaned per the Cleaning Guidelines.

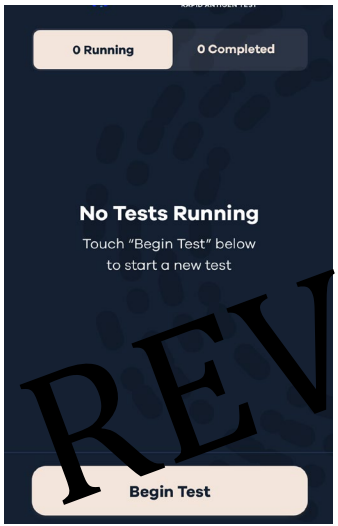
Seek specific training or guidance if you are not experienced with specimen collection and handling procedures.

Please read the entirety of this User Manual and thePackage Insert prior to executing a test.

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

MENU STRUCTURE

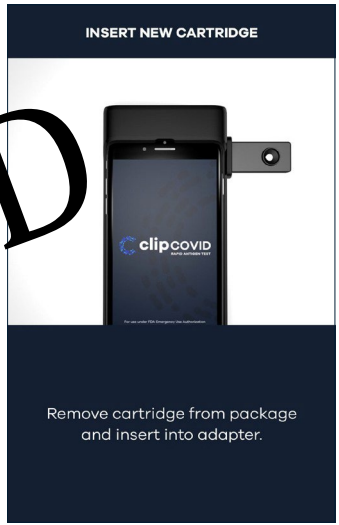
Testing Menu
Touch **Begin Test**.



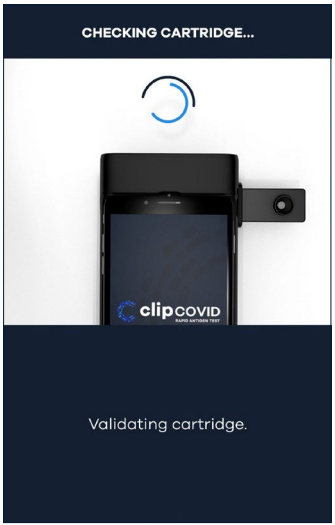
Sample Set-Up
Scan the Test Kit Barcode or typein the current Sample ID and Lotnumber to begin the test.

Insert Cartridge
Remove Cartridge from packageand insert.

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



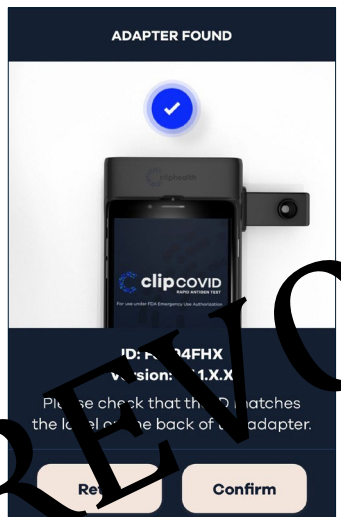
Checking Cartridge
The device will begin checkingthe validity of the Cartridge.



MENU STRUCTURE CONTINUED

Adapter Found

If the Adapter is found, it will indicatewith a checkmark. Touch **Confirm** or **Retry** to move forward.



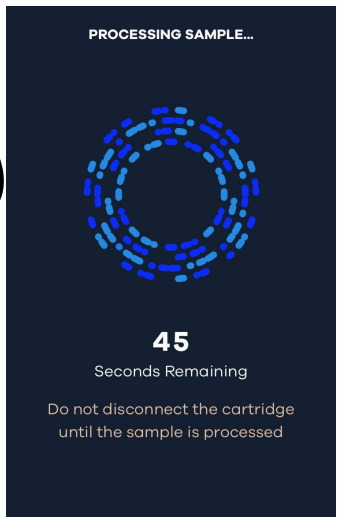
Awaiting Sample

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

Analysis in Progress

A clock will run to show progress.

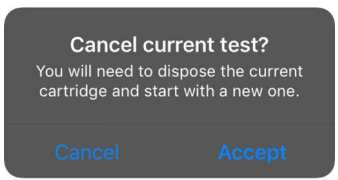
Do not disconnect the Cartridgeuntil the analysis is complete.



Cancellation Popup

If a cancellation window appears, hit “Cancel” or “Accept” to move forward.

A new Cartridge is required to start a new test.

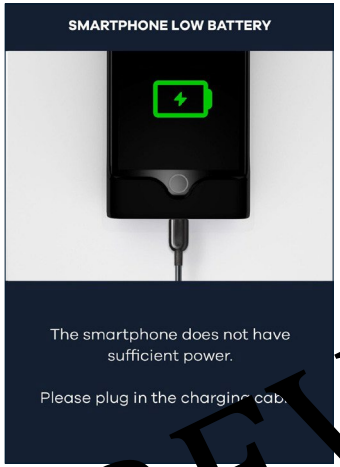


TROUBLESHOOTING

Smartphone Low Battery

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

Please plug in the charging cable.



Adapter Low Battery

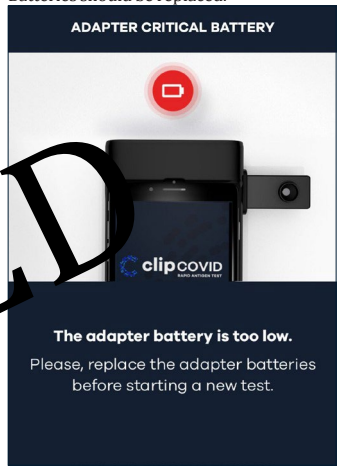
This screen is shown when the Adapter has a low battery, approximately 20%.

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%.

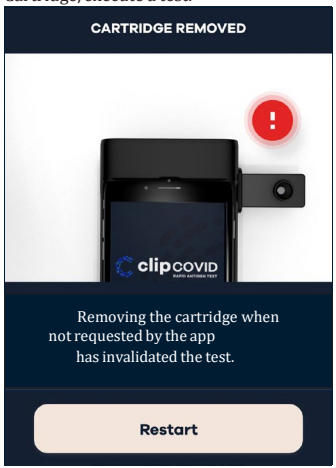
You will not be able to complete a test. Batteries should be replaced.



Cartridge Removed

This screen is shown when the Cartridge experiences an error. Do not use the Cartridge further.

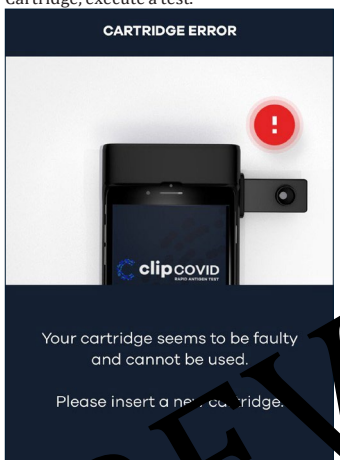
Take another sample and, using anew Cartridge, execute a test.



Cartridge Error

This screen is shown when the Cartridge experiences an error. Do not use the Cartridge further.

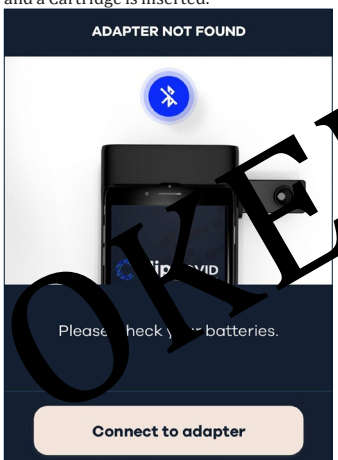
Take another sample and, using anew Cartridge, execute a test.



Adapter Not Found

The Adapter is not sensed by the smartphone.

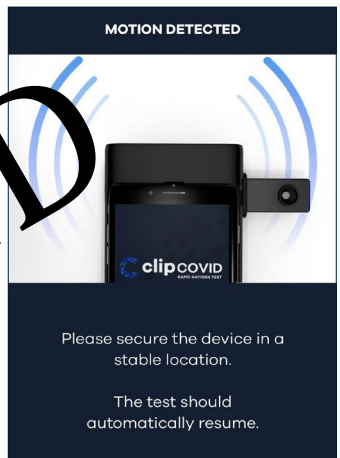
Please check the Adapter batteries, confirming that the Adapter has power and a Cartridge is inserted.



Motion Detected

The Analyzer has sensed motion.

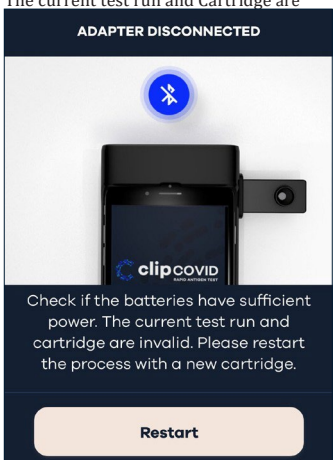
Please secure the device in a stable location. The test should automatically resume.



Adapter Disconnected

The Adapter is not sensed by the smartphone. Please check Adapter batteries, confirming the Adapter haspower and a Cartridge is inserted.

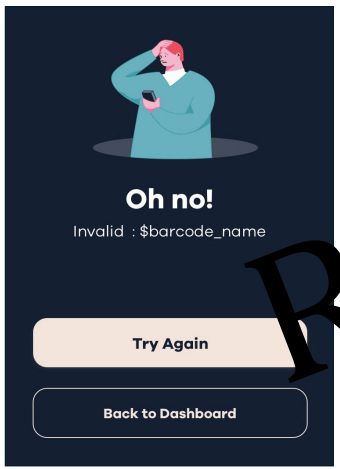
The current test run and Cartridge are



TROUBLESHOOTING CONTINUED

Invalid Barcode

This screen is shown when the Cartridge Barcode entered does notmatch a released lot. Please check the information and try again. If youcontinue to get this error, contact **support@luminostics.com**.



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 30°C **Operational Humidity** 20%-85% non-condensing

The Clip Analyzer will be tested to UL 60601-1 3rd Edition.

SYMBOLS

Manufacturer		Consult instructionsfor use	
Catalogue number	REF	Keep dry	
Prescription only	Rx ONLY	Biohazard	
For *in-vitro* diagnostic use only	IVD	Caution	
Serial number	SN		

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