clipcovid Rapid Antigen Test Instructions for Use

Contents

Clip COVID RAPID ANTIGEN TEST

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. 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 from patients with symptom onset beyond five days 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.

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 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 unitized 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
- This test 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 moderate, high or waived complexity tests.
- This test 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 test 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.

- 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 counter top 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.
- 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 Extraction 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.
- 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. Change gloves between patients. ○ 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 cardioverterdefibrillators (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 the 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.

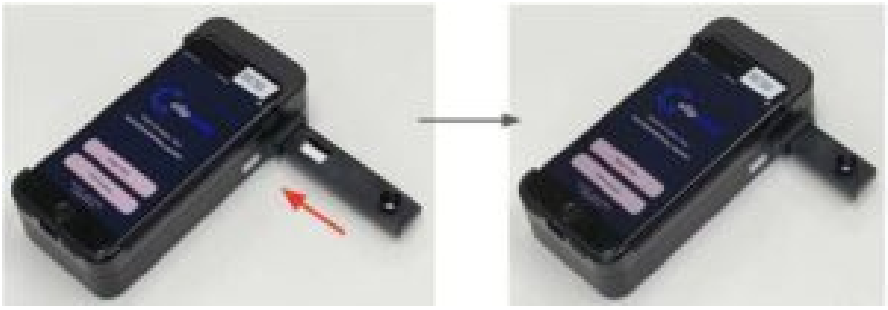
CAUTION! *Simply twirling the swab against one part of the inside of the nose or leaving the swab in the nose for 10-15 seconds, is not proper technique and may result in an insufficient sample. This may lead to a false positive, a false negative, or an invalid result.*

SPECIMEN TRANSPORT AND STORAGE

For best performance, nasal swab specimens should be tested as soon as possible (within 30 minutes stored dry at room temperature) after collection. 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.

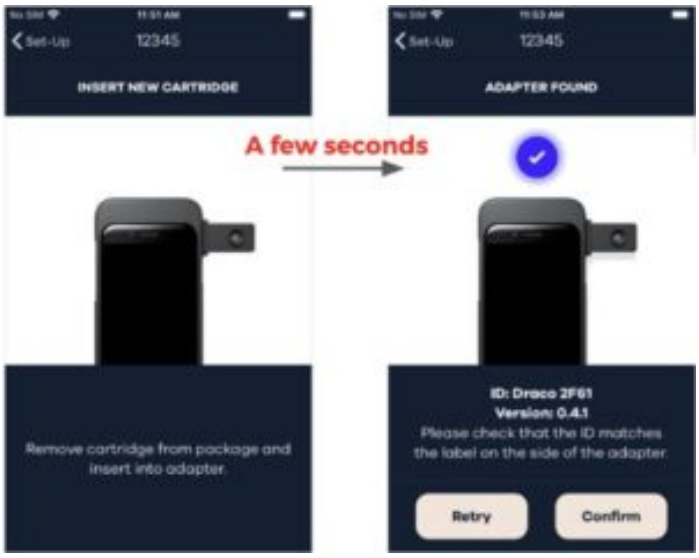
TEST PROCEDURE

1. Place the Clip Analyzer on a table or counter top and power it on as instructed in the Analyzer manual. 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.
2. Remove a Cartridge from its foil pouch after using the tear notch to open the pouch.
3. 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.



4. Touch 'Begin Test' on the home screen of the Clip COVID app on the Analyzer
5. Enter sample ID and select the Test Kit lot number from the drop-down menu. Touch 'Continue'.

6. Confirm the adapter ID by matching the label on the side of the adapter to the unit ID on the screen. Touch 'Confirm' if the ID on screen matches the ID on the side of the Analyzer. Touch 'Retry' if the ID on screen does not match the ID on the side of the Analyzer.



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

11. 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.

12. The Analyzer will automatically begin analysis 30-45 seconds after sample addition, transitioning to the ‘Analysis in Progress’ screen. A “positive”, “negative”, or “invalid” result will display in 30 minutes. Do not touch or remove the cartridge or disturb the Analyzer until a result is displayed. Movement or removal of the cartridge

while analysis is in progress may result in an erroneous or invalid result.

RESULT 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 Negative Result Invlid Result

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-30°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, 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.

CONDITIONS OF AUTHORIZATION FOR THE LABORATORY

The Clip COVID Rapid Antigen Test Letter of Authorization1, 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/emergency-situations-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:

- 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: s**upport@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.

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." 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 on-set) are available for the one hundred sixtysix (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	11	1
22 to 59 years*	147	31
60 years and older	8	0

*one of the samples in this age range was negative on the Clip COVID Rapid Antigen Test but positive by RT-PCR
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 solidphase RNA extraction step. The performance of the Clip COVID Rapid Antigen Test was established by testing 166 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	134	135
Total	32	134	166
Positive Percent Agreement: 96.9% (*95% CI:* 83.8% - 99.9%)			
Negative Percent Agreement: 100% (*95% CI:* 97.3% - 100%)			

The specimen positivity based on days post onset:

Days Post Symptom Onset	# Specimens Tested from Unique People	# Positive Specimens by RT-PCR	% Positive
0	23	0	0
1*	36	5	13.9%
2	56	12	21.4%
3	27	8	29.6%
4	14	6	42.9%
5	10	1	10%

- One specimen was Clip COVID Rapid Antigen Test Negative and Positive by 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 (5×106 RADs) on dry ice, followed by sonication. The material was supplied frozen at a concentration of 2.8 x105 TCID50 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 natural 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:

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 x102 TCID50 per mL.
LoD Confirmation
The analyte concentration 0.88 x102 TCID50 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 x102 per mL.

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.

Potential cross-reactant or interferent		Concentration
OC43Viruses	Human Coronavirus 229E	1.52 x 10^5 TCID$_{50}$/mL
	Human Coronavirus OC43	5.05 x 10^4 TCID$_{50}$/mL
	Human Coronavirus NL63	1.71 x 10^6 TCID$_{50}$/mL
	Adenovirus Type 1	1.03 x 10^7 TCID$_{50}$/mL
	Human Metapneumovirus 9 (hMPV) Type A1	1.18 x 10^4 TCID$_{50}$/mL
	Parainfluenza Virus Type 1	3.42 x 10^6 TCID$_{50}$/mL
	Parainfluenza Virus Type 2	5.05 x 10^4 TCID$_{50}$/mL
	Parainfluenza Virus Type 3	8.58 x 10^6 TCID$_{50}$/mL

Bacteria	*Haemophilus influenzae* Type b Strain Eagan	5.43 x 10^5 CFU/mL
	Streptococcus pneumoniae Type 19F; 2022	2.26 x 10^6 CFU/mL
	Bordetella pertussis Strain A639	1.13 x 10^6 CFU/mL
	Chlamydophila pneumoniae Strain AR-39	1.4 x 10^7 IFU/mL
	Legionella pneumophila Philadelphia	1.88 x 10^6 CFU/mL
	Pneumocystis jirovecii Recombinant W303-PJI	1.56 x 10^7 CFU/mL
	Streptococcus pyogenes	2.66 x 10^6 CFU/mL
	Mycoplasma pneumoniae	3.16 x 10^7 CCU/mL
	Staphylococcus aureus	5.5 x 10^6 CFU/mL
	Staphylococcus epidermidis	7.7 x 10^6 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 and determined to not be cross-reactive or highly unlikely to be cross-reactive:

- 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)

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
Zicam 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 (Chloraseptic)	15% v/v
Mupirocin	10 mg/mL
Fluticasone Propionate	5% v/v

High Dose Hook Effect

No high dose hook effect was observed when inactivated SARS-CoV-2 stock was tested at concentration of 9.58 x105 TCID50 per mL.

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; **http://www.fda.gov/medwatch**).

CONTACT INFORMATION

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Milpitas, CA 95035
www.luminostics.com
info@luminostics.com

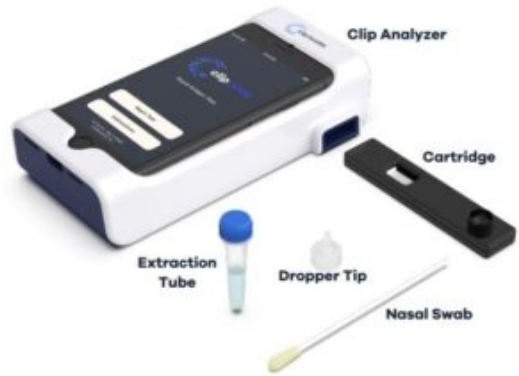
SYMBOLS

Manufacturer		Catalogue Number	REF	Prescription Only	Rx only
For in vitro diagnostic use only	IVD	Batch Code	LOT	Use by date	
Do not reuse		Consult instructions for use		Caution	
Contains sufficient materials for 25 tests		Biohazard		Keep dry	

clip COIVD Quick Reference Instructions

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

Clip COVID Rapid Antigen Test Components



The Clip COVID Rapid Antigen Test, for use with the Clip Analyzer, is intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in anterior nasal swab specimens from individuals who are suspected of COVID19 by their healthcare provider within the first five days of onset of symptoms. Manufactured by Luminostics, Inc., it is based on a diagnostics platform that uses proprietary persistent luminescent nanoparticles, which are sensitively detectable using a smartphone's camera, as lateral flow assay reporters. The Clip Analyzer is comprised of an iPhone SE, an Adapter (pre-assembled onto the iPhone), and the Clip COVID App.

Study the Clip Analyzer User Manual and Clip COVID Rapid Antigen Test Kit Package Insert thoroughly before using these Quick Reference Instructions or performing a test. This is not a complete product insert. Perform the Clip COVID Rapid Antigen Test at room temperature between 15°C and 30°C (59°F and 86°F). Nasal swab specimens must be processed within 30 minutes of collection. Specimens and kit components must be at room temperature before testing. Check expiration date on outer test kit carton and each individual test package before using. Do not use any test component beyond its expiration date. Refer to the Clip COVID Rapid Antigen Test Kit Package Insert for Specimen Collection, Warning and Precautions, and Limitations.

TEST PROCEDURE

1. Place the Clip Analyzer on a table or countertop and power it on by holding down the power button on the right side of the iPhone. The Analyzer is portable and can be moved to a suitable location for testing. Ensure the surface is stable, level, dry and free of obstructions. Ensure the surface provides adequate space for the Clip Analyzer. There must be space to
   access the Clip Analyzer port for insertion of the Cartridge. We recommend that you keep the Analyzer plugged in to a power outlet using the provided charging cord during operation/testing.
2. Remove a Cartridge from its foil pouch after using the tear notch to open the pouch.
3. 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.
4. Touch 'Begin Test' on the home screen of the Clip COVID app on the Analyzer. Enter sample ID and select the Test Kit Touch "Begin Test" lot number — printed on the Cartridge foil pouch label — from the dropdown menu. Touch 'Continue'.

In the USA, this test has not been FDA cleared or approved, but has been authorized by FDA under an EUA for emergency use by laboratories certified under the CLIA, 42 U.S.C. §263a, that meet the requirements to perform high, moderate, or waived complexity tests. This test is for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. This test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. In the USA, the emergency use of this test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1),

unless the declaration is terminated or authorization is revoked sooner.

5. Confirm the adapter ID by matching the label on the
adapter to the unit ID on the screen. Touch ‘Confirm’if the ID on screen matches 5 the ID visible on the Analyzer. Touch ‘Retry’ if the ID on screen does not match the ID on the side of
the Analyzer.

6. Insert the nasal swab from the patient all the way into the bottom Extraction Tube and rotate the swab 3 times against the bottom of the tube. Leave the swab in the buffer in the Extraction Tube for 60 seconds. 6 Squeeze the center of the Extraction Tube and remove the swab while keeping the center of the tube squeezed. Dispose of swab in a biohazard waste stream. Cap Extraction Tube using the Dropper Tip.

7. Dispense the entirety of the contents of the Extraction Tube into the sample well of the Cartridge by turning 7 it upside down and squeezing it. Holding the tube vertically directly above the sample well will minimize spillage.

8. The Analyzer will automatically begin analysis 30-45 seconds after sample addition, transitioning to the ‘Analysis in Progress’ screen. A “positive”, “negative”, or 8 “invalid” result will display in 30 minutes. Do not touch or remove the Cartridge or disturb the Analyzer until a result is displayed.

RESULT INTERPRETATION

Positive. SARS-CoV-2 antigen present; does not rule out coinfection with other pathogens.
Negative. Negative results from patients with symptom onset beyond five days should be treated as presumptive and confirmation with a molecular assay, if necessary, may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.
Invalid. Should this occur, retest patient with a new nasal swab, Cartridge, and Extraction Tube.

QUALITY CONTROLS

QUALITY CONTROLS
It is recommended that positive and negative external control swabs are run once by each untrained operator and as deemed additionally necessary by your internal quality control procedures and in accordance with Local, State

and Federal regulations or accreditation requirements. External positive and negative control swabs are provided in the kit. The external controls should be tested using the test procedure provided in this Quick Reference Instructions Card or Package Insert. Patient tests should not be performed if the test fails to detect positive and/or negative control swabs accurately; please re-test or contact Luminostics, Inc.

CUSTOMER SERVICE

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

MANUFACTURER INFORMATION

Designed & manufactured by Luminostics, Inc. at 446 South Hillview Drive, Milpitas, CA 95035, USA.

User Manual — Clip Analyzer

For Use With: clip COVID RAPID ANTIGEN TEST

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

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 patients.
- 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.
- The product has not been tested for EMI compatibility with implantable cardioverterdefibrillators (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

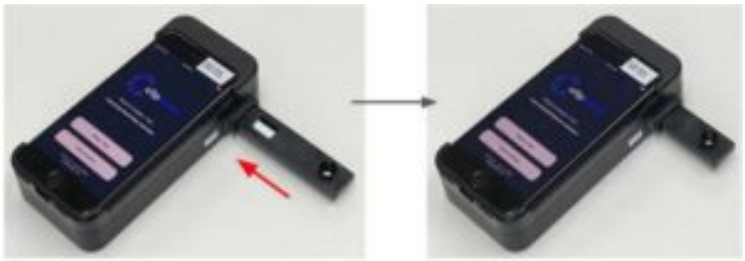
Turn off the unit by removing the cartridge and holding the power switch on the right side of the unit. Shutdown is complete when the screen goes dark.

STORAGE AND OPERATING CONDITIONS

Store and operate the Clip Analyzer at room temperature, 59°F to 86°F (15°C to 30°C), out of direct sunlight, between 20%-85% humidity (non-condensing)

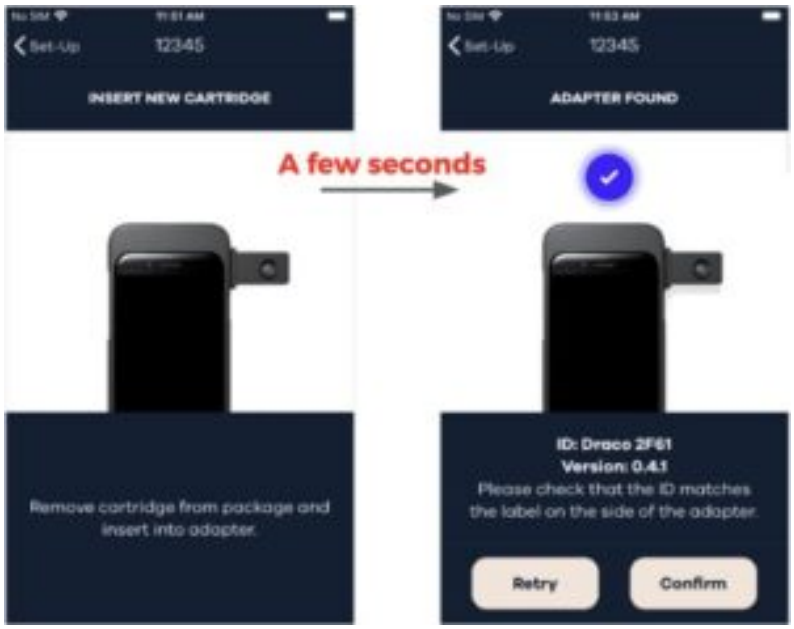
TEST PROCEDURE FOR CLIP COVID RAPID ANTIGEN TEST

1. Place the Clip Analyzer on a table or counter top and power it on as instructed in the Analyzer manual. 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.
2. Remove a Cartridge from its foil pouch after using the tear notch to open the pouch.
3. 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



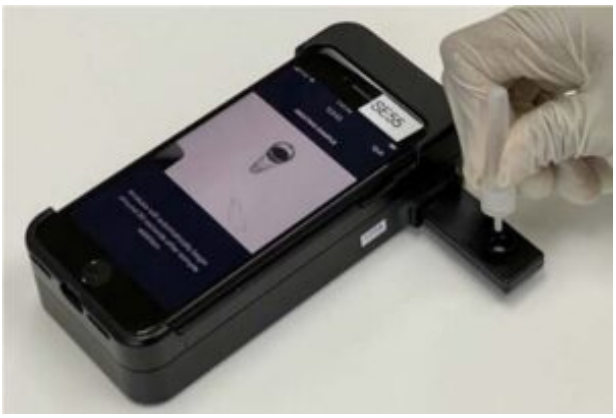
it further. The cartridge can be handled with bare hands. However, we recommend wearing gloves during the entirety of the test procedure including in this step.
4. Touch 'Begin Test' on the home screen of the Clip COVID app on the Analyzer
5. Enter sample ID and select the Test Kit lot number from the drop-down menu. Touch 'Continue'.

6. Confirm the adapter ID by matching the label on the side of the adapter to the unit ID on the screen. Touch ‘Confirm’ if the ID on screen matches the ID on the side of the Analyzer. Touch ‘Retry’ if the ID on screen does not match the ID on the side of the Analyzer.



7. Insert the anterior nasal swab collected from the patient all the way into the bottom 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.
8. Leave the swab in the buffer in the Extraction Tube for 60 seconds.
9. Squeeze the center of the Extraction Tube and remove the swab while keeping the center of the tube squeezed. Dispose of swab in a biohazard waste stream.
10. Cap Extraction Tube using the Dropper Tip.

11. 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.



12. . The Analyzer will automatically begin analysis 30-45 seconds after sample addition, transitioning to the 'Analysis in Progress' screen. A "positive", "negative", or "invalid" result will display in 30 minutes. Do not touch or remove the cartridge or disturb the Analyzer until a result is displayed. Movement of or removal the cartridge while analysis is in progress will result in invalid result.

RESULT 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	Negative Result	Invalid Result
 This display shows a valid positive result for SARS-CoV-2.	 This display shows a valid negative result for SARS-CoV-2.	 This display shows an invalid result.

LIMITATIONS

- This product is currently authorized to only be used for the qualitative detection of SARSCoV-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-30°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

The Clip COVID Rapid Antigen Test Letter of Authorization1, 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/emergency-situations-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:

- 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 “Clip COVID rapid antigen” Package Insert and User Manual. 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.

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 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 (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. 2 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.

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.

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; **http://www.fda.gov/medwatch**).

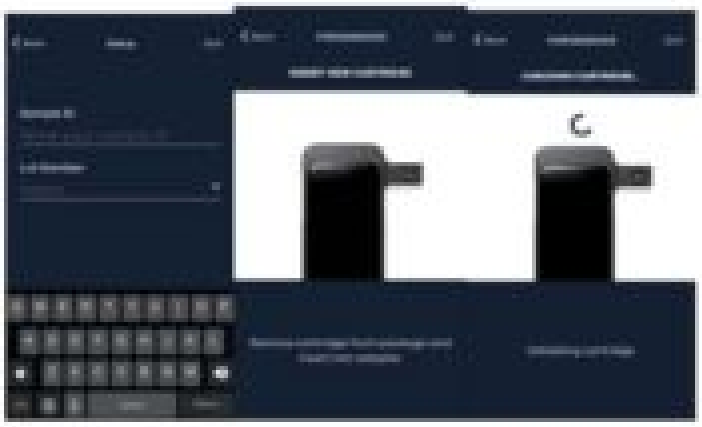
CONTACT INFORMATION

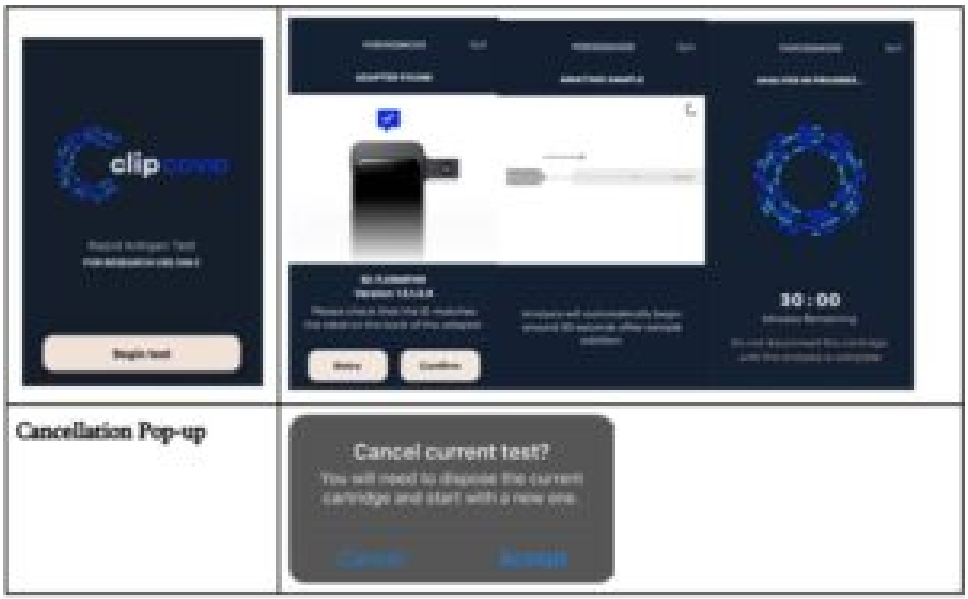
Luminostics, Inc.
446 South Hillview Drive
Milpitas, CA 95035
www.luminostics.com
info@luminostics.com

SYMBOLS

Manufacturer		Catalogue Number	REF	Prescription Only	Rx only
For in vitro diagnostic use only	IVD	Batch Code	LOT	Use by date	
Do not reuse		Consult instructions for use		Caution	
Contains sufficient materials for 25 tests	Σ	Biohazard		Keep dry	

MENU STRUCTURE

Testing Menu	
	



TROUBLESHOOTING

Smartphone Low Battery

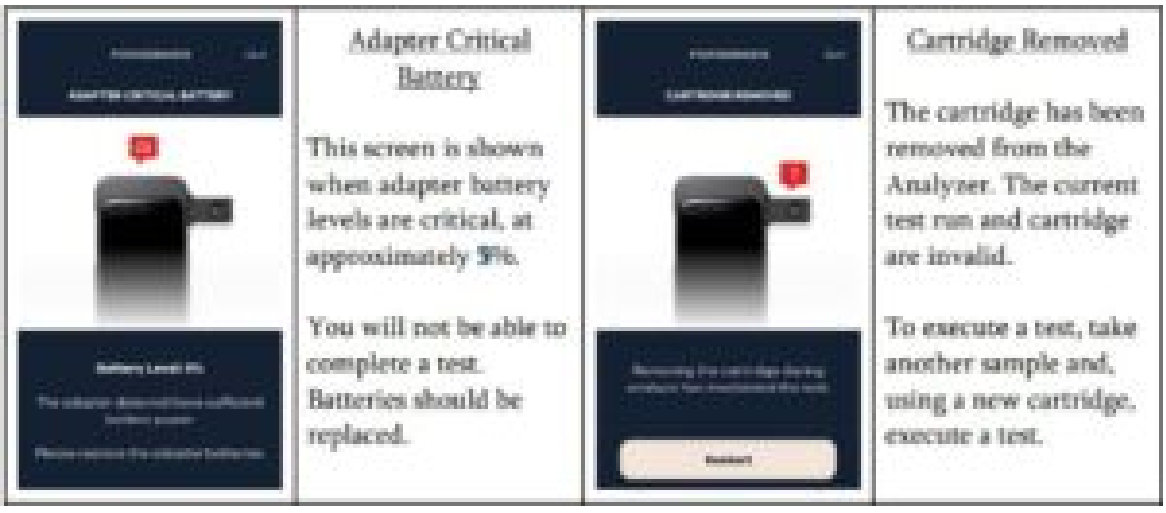
This screen is shown when the smartphone does not have sufficient power.

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. Charging 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

The cartridge has been removed from the Analyzer. The current test run and cartridge are invalid.

To execute a test, 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 the Adapter batteries, confirming that 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.	

TECHNICAL SPECIFICATIONS

Power Supply	1.9-3.5V DC, Max. 0.14A from 2 AA batteries.
Dimensions	77x37x155mm
Weight	336g
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.

clipcovid Rapid Antigen Test Instructions for Use – **Optimized PDF**
clipcovid Rapid Antigen Test Instructions for Use – **Original PDF**