



Standard Operating Procedures: ClipCovid (Rapid Antigen Test)

Purpose

- The purpose of this standard operating procedure (SOP) is to provide general information, and guidance for running a ClipCovid Rapid Antigen Test on a Clip Analyzer for SARS-CoV-2.

Principle of the Test

The Clip Analyzer is an analyzer intended to be used for objective readout of cartridge-based immunoluminescent in vitro diagnostic assays manufactured by ClipHealth. SARS-CoV-2 in clinician-collected nasal or nasal mid-turbinate swab specimens or clinician-instructed self-collected (collected on site) nasal swab specimens, collected from individuals suspected of COVID-19 by their healthcare provider.

To perform the test, nasal or nasal mid-turbinate specimens are added to the SARS-CoV-2 Buffer to solubilize the sample.

External 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.

Built-in Procedures Controls

Purpose:

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.

Procedures:

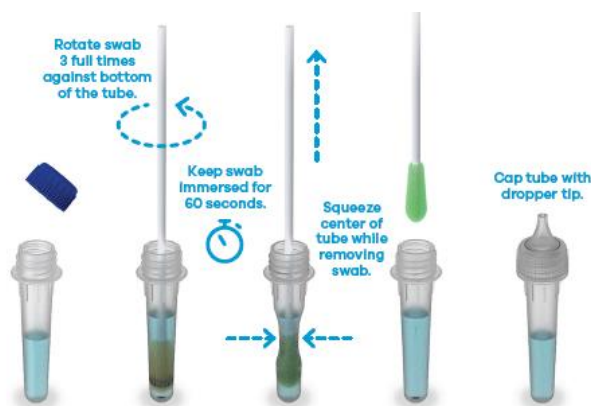
Setting Up Stations

- 1.1 Gather your materials and spreadsheet
- 1.2 Verify if you are to complete a **SARS RAPID ANTIGEN TEST**
- 1.3 Gather the correct reagent solution for the test you are performing, the pipette, reagent tube, and cartridge.
- 1.4 Label the Test Cassette with the patient's ID number with silver color marker.

Test Procedure:

- 2.1 Insert the nasal swab specimen into the SARS-CoV-2 Buffer and rotate it five times rubbing it against the wall of the vial.
- 2.2 Remove the patient nasal swab from the SARS-CoV-2 Buffer vial and discard it into a biohazardous waste container.

NOTE: If the buffer solution contacts the skin, wash the area with soap and clean water and rinse thoroughly. Consult a physician if irritation develops.



2.3 Replace the cap on the SARS-CoV-2 Buffer vial.

2.4 Check expiration date on outer box before using. Do not use any test after the expiration date on the box.

2.5 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.

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

2.7 Touch Begin Test on the home screen of the Clip COVID app on the Analyzer.



2.8 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.

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

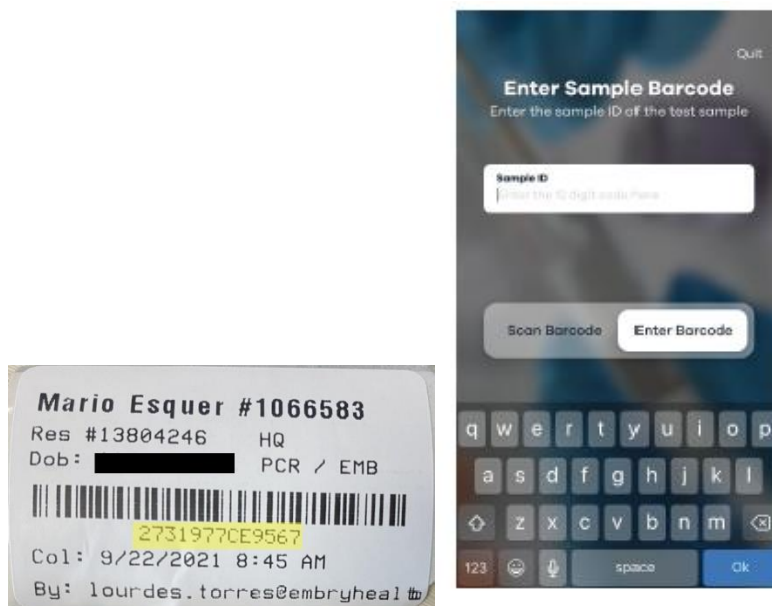
2.10 Load the Cartridge into the analyzer by pushing the cartridge into the Cartridge port until you hear a click.

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

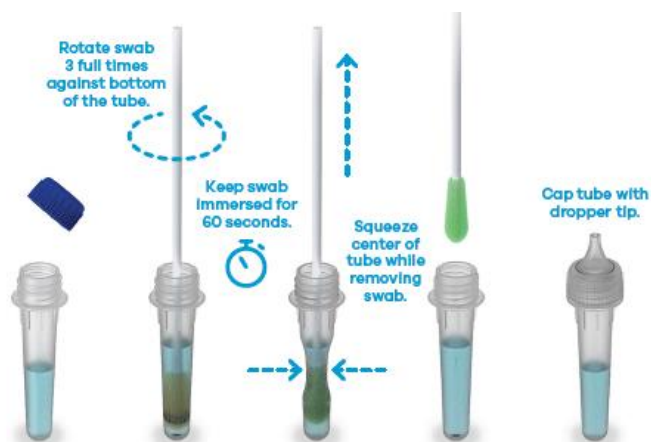


2.11 The screen will prompt you to enter the patient barcode number either by scanning the barcode printed and applied on the nasal swab tube or typing in the patient barcode number manually. To scan, face code on the tube towards the front camera of the iPhone, using the screen to help line up the image. Alternatively, user may choose to type in barcode number.

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



2.12 Insert the anterior nasal swab collected from the patient all the way into the extraction tube and rotate the swab at least 3 times against the bottom of the tube. Additional rotations of the swab are not expected to negatively affect performance. Leave the swab in the buffer in the extraction tube for 60 seconds. Optionally, use the tube holder at the bottom of the Analyzer to hold the extraction tube. Squeeze center of the extraction tube and remove the swab while keeping the center of the tube squeezed. Dispose of swab in a biohazard waste stream. Cap the extraction tube using the dropper tip.

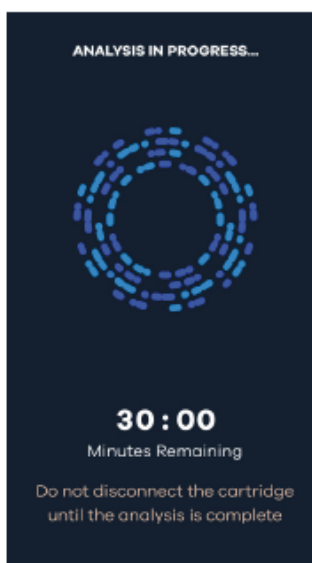


2.13 Dispense the entirety of the contents of the extraction tube into the sample well of the cartridge by turning it upside down and squeezing it. Holding the tube vertically directly above the sample port will minimize spillage. The analyzer will automatically begin analysis 30-45 seconds after sample addition, transitioning to the 'Analysis in Progress' screen. A "positive", "negative", or "invalid" result will display in 30 minutes.



2.14 Leave cartridge in analyzer during process. Movement of or removal of the cartridge while analysis is in progress will result in invalid result.

Analysis In Progress screen.



3.0 RESULTS

3.1 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.

3.2 The results will automatically post after the test is finished through BMS.

