

Before you begin

- Store the STANDARD™ M10 SARS-CoV-2 cartridges at 2-28°C (36-82°F).
- This test is only for nasopharyngeal swab specimens.
- Always wear clean gloves and follow your institution's safety policy when handling patient samples.

Refer to IFU for Warnings and Precautions, Specimen Collection, Transport, and Storage, and Quality Control.

TEST PROCEDURE

I. Starting the STANDARD™ M10 system

1. Turn on M10

Connect the M10 Console and Modules, then turn on each switch.



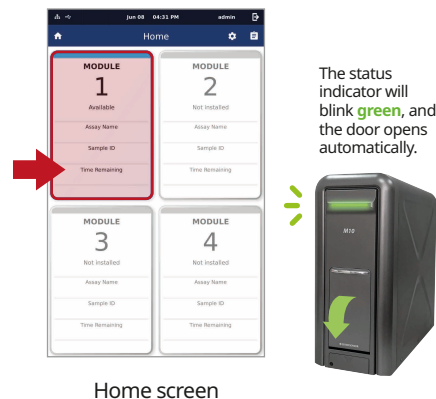
2. Log in

Enter user name and password, and touch the Log in button.



3. Select M10 Module

Touch the button of an available Module on the Home screen.



4. Scan/Type Patient/Sample ID

Scan the Patient/Sample ID using the integrated barcode reader of the M10 Console. (or type in using a virtual keyboard)



Patient ID is optional and can be turned off in the 'SETTINGS'.

5. Scan test Cartridge

Scan the Cartridge barcode using the integrated barcode reader of the M10 Console.



After scanning the cartridge, it automatically proceeds to the next step.

6. Sample loading guide

Watch the animated guide for cartridge preparation and sample loading. Touch the screen to continue.



Sample Guide screen

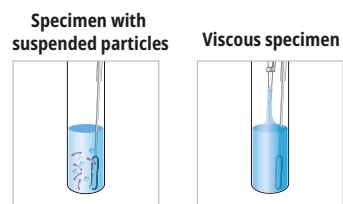


TEST PROCEDURE (continued)

II. Loading a sample into the cartridge

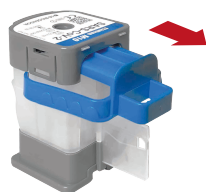


- Start the test within 10 minutes of loading the sample into the STANDARD™ M10 SARS-CoV-2 cartridge.
- If the sample contains a lot of suspended matter or is highly viscous, as shown in the example on the right, it is recommended to use only the supernatant for testing after brief vortexing and centrifugation.



1. Remove Safety Clip

Remove the Safety Clip from the Cartridge.



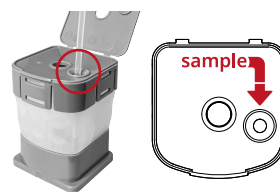
2. Pierce Cartridge

Press down on the lid to pierce the sealed cartridge.



3. Transfer Sample

Open the lid and dispense 600 µl of the sample into the sample chamber.



4. Close Cartridge lid

Close the cartridge lid.



III. Running a test

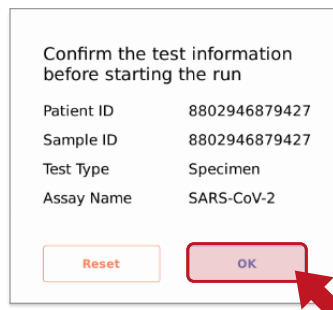
1. Load Cartridge into the Module

Place the cartridge into the assigned M10 Module and close the door manually.



2. Confirm the test

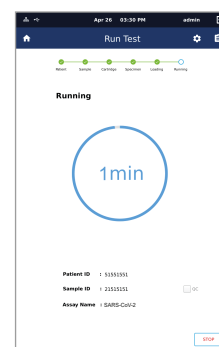
After confirm the sample and cartridge information, touch the 'OK' button.



Confirm the Test screen

3. Start Run

The remaining time is displayed on the M10 Console monitor.



Running screen



The PCR chamber of the cartridge should face the inside of the M10 module.

RESULT INTERPRETATION

Result		ORF1ab gene	E gene	Internal Control*
SARS-CoV-2 Positive	+	+	+ / -	+ / -
SARS-CoV-2 Presumptive Positive**	+	-	+	+ / -
SARS-CoV-2 Negative	-	-	-	+
Invalid / Re-test	!	-	-	-

* **Internal Control (IC)** can be negative or positive in a positive sample.

** **SARS-CoV-2 Presumptive Positive** - Sample should be retested. In case the retest result is the same, additional confirmatory testing may be conducted. E gene positivity could be caused by other sarbecovirus.