

STANDARD M10 MPX/OPX QUICK REFERENCE INSTRUCTIONS (QRI)

REF M10-MPOP-01

RESEARCH USE ONLY



For use with STANDARD™ M10 system

Please read the complete Instruction for use (IFU) prior to use.

Before you begin

- Store the STANDARD™ M10 MPX/OPX cartridges at 2-28°C (36-82°F).
- This test is only for skin lesion, nasopharyngeal swab, oropharyngeal swab, serum, plasma and *whole blood specimens. (*Add 200µl of PBS to 100µl of whole blood and vortex 10 seconds to use the whole blood specimen.)
- 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.



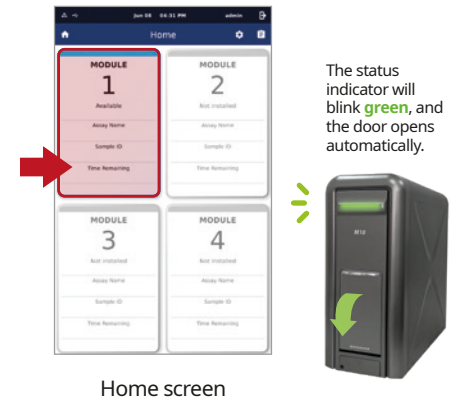
2. Log in

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 MPX/OPX cartridge.

1. Remove Safety Clip

Remove the Safety Clip from the Cartridge.



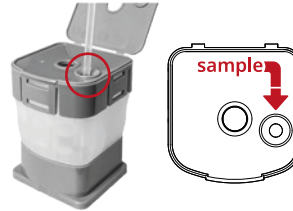
2. Pierce Cartridge

Press down on the lid to pierce the sealed cartridge.



3. Transfer Sample

Open the lid and dispense 300µl 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

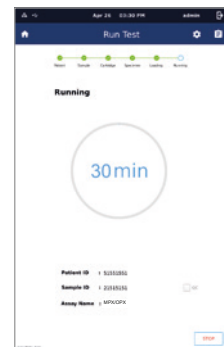
After confirm the sample and cartridge information, touch the 'OK' button.



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

Interpretation	OPX	MPX	IC
OPX Positive	+	-	+/-
MPX Positive	+	+	+/-
Negative	-	-	+
Invalid	-	+	+/-
	-	-	-

- If the IC is negative and the results for any of the targets are positive, the results for all targets are considered valid. A high copy number of target-specific gene can lead to reduced or absent IC.
- If an invalid result is confirmed in one or more of the pathogen results, that tests will be invalidated. Please conduct a re-test.