

STANDARD M10 Arbovirus Panel

QUICK REFERENCE INSTRUCTIONS (QRI)

REF M10-AB5-01



For use with STANDARD™ M10 system

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

Before you begin

- Store the STANDARD™ M10 Arbovirus Panel cartridges at 2 ~ 28°C (36 ~ 82°F) .
- This test is only for Serum and Plasma 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, 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.



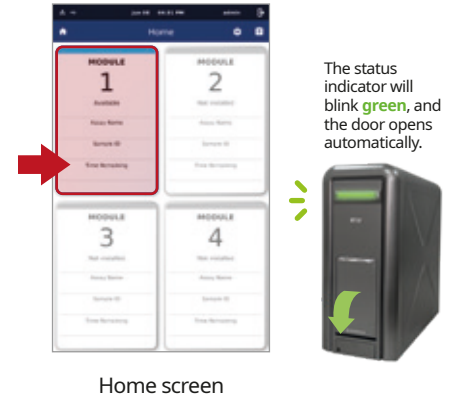
2. Log in

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 Arbovirus Panel cartridge.

1. Remove Safety Clip

Remove the Safety Clip from the Cartridge.



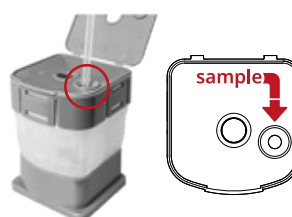
2. Pierce Cartridge

Press down on the lid to pierce the sealed cartridge.



3. Transfer Sample

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



4. Close Cartridge lid

Close the cartridge lid.



III. Running a test

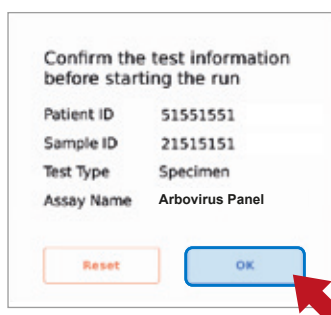
1. Load Cartridge into the Module

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

Description of results

Outcome (Home screen)	Result (Review screen)	Description
Positive	+	At least one pathogen is positive.
Negative	-	No pathogen was detected.
Invalid	!	All pathogens are not detected and IC signal does not have a Ct value within the valid range.
Error	X	The test failed because either an error occurred or the test was canceled by the user.

Description of IC results

Outcome (Summary screen)	Result (Summary screen)	Description
IC Valid	V	IC has a Ct within the valid range.
IC Invalid	!	All pathogens are not detected and IC signal does not have a Ct value within the valid range.
IC Error	X	The test failed because either an error occurred or the test was canceled by the user. Repeat the test.

* There may be co-infection for each target (DENV-1, DENV-2, DENV-3, DENV-4, ZIKV, CHIKV, YFV, and WNV).

- 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.