

**Before you begin**

- Store the STANDARD™ M10 MTB/NTM cartridges at 2 ~ 28°C (36~ 82°F).
- If the cartridge has been refrigerated, it is recommended to leave the cartridge for 4 hours at room temperature (20~28°C, 68~82°F).
- This test is only for human normal sputum or sputum sediment 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, 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.



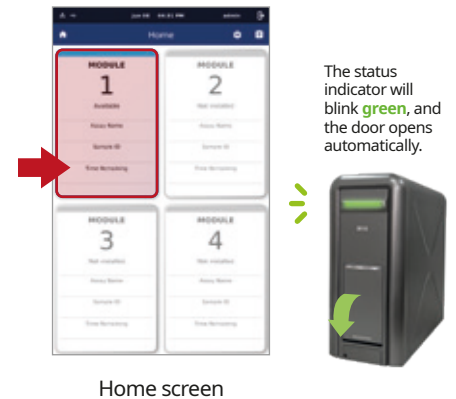
**2. Log in**

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



Sputum specimens must be processed by one of the following methods prior to loading into cartridges.

1. Normal sputum with PS method: Add the pretreatment solution (PS) to the normal sputum. The ratio of sputum to PS is 1:2, and sputum volume should be larger than 0.5 mL. Vortex the sample vigorously twice for at least 10 seconds, and incubate for 15 minutes at room temperature. If the solution is still highly viscous, add more PS in a ratio of up to 1:3.
2. Sputum sediment with PS method: Add 0.067M Phosphate/H<sub>2</sub>O buffer to the sputum sediment container. Vortex sufficiently until completely suspended. Take more than 0.5 mL of suspended sputum, then add the pretreatment solution (PS). The ratio of the suspended sputum to PS is 1:2. Vortex the sample vigorously twice for at least 10 seconds, and incubate for 15 minutes at room temperature. If the solution is still highly viscous, add more PS in a ratio of up to 1:3.

### 1. Remove Safety Clip

Remove the Safety Clip from the Cartridge.



### 2. Pierce Cartridge

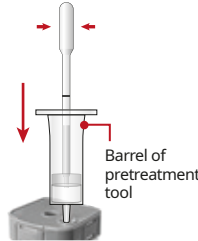
Press down on the lid to pierce the sealed cartridge.



Fully engage the cartridge groove.

### 3. Transfer Sample

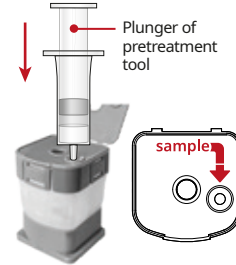
Open the lid and transfer appropriate volume of the prepared sample using disposable dropper with volume indication.



Barrel of pretreatment tool

### 4. Inject Sample

Insert and press down the plunger.



Plunger of pretreatment tool



### 5. Close Cartridge lid

Close the cartridge lid.



## III. Running a test

### 1. Load Cartridge into the Module

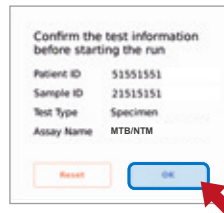
Place the cartridge into the assigned M10 Module and close the door manually.



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

### 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

## RESULT INTERPRETATION

Result	MTBC	NTM	IC	NOTE
MTBC Positive	+	-	+	
	+	+	+	NTM Ct > MTBC Ct
NTM Positive	-	+	+	
MTBC / NTM Positive (co-infection)	+	+	+	NTM Ct ≤ MTBC Ct
MTBC / NTM Negative	-	-	+	
Invalid	+/-	+/-	-	

- The NTM signal can be detected in MTBC target DNA.
- If co-infection of MTBC and NTM is suspected, additional tests such as sequencing are recommended.

Outcome (Home screen)	Result (Review screen)	Description
MTBC Positive	+	MTBC Positive
NTM Positive	+	NTM Positive
Co-infection	+	MTBC and NTM Positive
Negative	-	MTBC and NTM Negative
Invalid	!	Invalid
Error	X	Error

Result (Summary screen)	Description
+	Target Positive
-	Target Negative
V	IC Valid
!	IC Invalid
X	Error