

**Before you begin**

- Store the STANDARD™ M10 MDR-TB cartridges at 2 ~ 28°C (36 ~ 82°F).
- If the cartridge has been refrigerated, it is recommend to leave the cartridge for 4 hours at room temperature (20 ~ 28°C, 68 ~ 82°F).
- This test is only for 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**

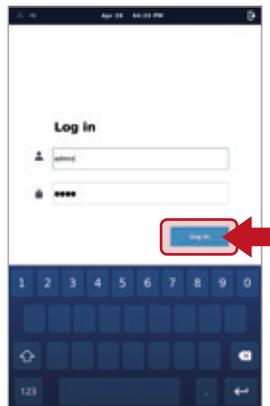
**1. Turn on M10**

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



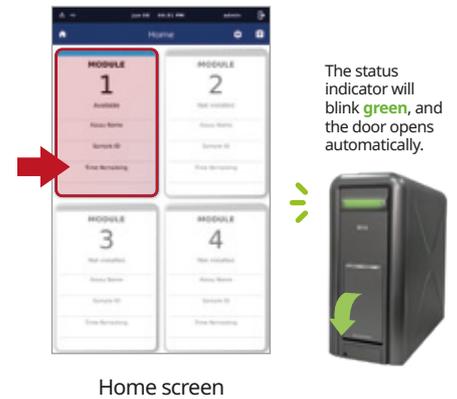
**2. Log in**

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.

- 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. If the solution is still highly viscous, add more PS in a ratio of up to 1:3. Transfer the normal sputum and PS mixture entirely into Sonicator Tube using a micropipette with filter tips. After closing the cap, Vortex vigorously twice for 10 seconds to ensure that the normal sputum and PS are mixed completely. And then, Sonicate the tube at 40°C for 15 minutes. After sonication, Remove the tube from sonicator and wipe off any moisture around it. After collecting 1.4 mL using a STANDARD™ Disposable dropper (1.4 mL), Transfer it to the barrel of the Sputum Pretreatment tool. Load the entire amount into the cartridge using the Plunger of the Sputum Pretreatment tool.
- Sputum sediment with PS method:** Add 0.067M Phosphate/H2O buffer to the sputum sediment container. Vortex sufficiently until completely suspended. Take more than 0.5 mL of the suspended sputum, then add the pretreatment solution (PS). The ratio of the suspended sputum to PS is 1:2. If the solution is still highly viscous, add more PS in a ratio of up to 1:3. Transfer the suspended sediment and PS mixture entirely into Sonicator Tube using a micropipette with filter tips. After closing the cap, Vortex vigorously twice for 10 seconds to ensure that the suspended sediment and PS are mixed completely. And then, Sonicate the tube at 40°C for 15 minutes. After sonication, Remove the tube from sonicator and wipe off any moisture around it. After collecting 1.4 mL using a STANDARD™ Disposable dropper (1.4 mL), Transfer it to the barrel of the Sputum Pretreatment tool. Load the entire amount into the cartridge using the Plunger of the Sputum Pretreatment tool.



### 1. Remove Safety Clip

Remove the Safety Clip from the Cartridge.



### 2. Pierce Cartridge

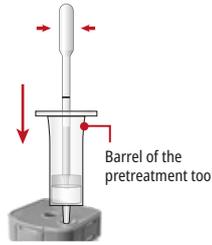
Press down on the lid to pierce the sealed cartridge.



Fully engage the cartridge groove.

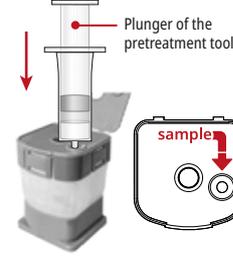
### 3. Transfer Sample

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



### 4. Inject Sample

Insert and press down the plunger.



### 5. Close Cartridge lid

Close the cartridge lid.



## III. Running a test

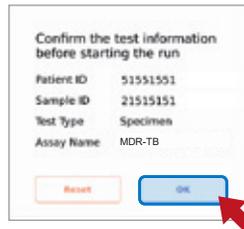
### 1. Load Cartridge into the Module

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



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

## RESULT INTERPRETATION

Result	MTBC		RIF		INH	
	MTBC	IC	RIF	IC	INH	IC
MTBC Detected / RIF Resistance Detected / INH Resistance Detected	+	+	R+	+	R+	+
MTBC Detected / RIF Resistance Detected / INH Resistance NOT Detected	+	+	R+	+	R-	+
MTBC Detected / RIF Resistance Detected / INH Resistance Indeterminate	+	+	R+	+	Rx	+
MTBC Detected / RIF Resistance NOT Detected / INH Resistance Detected	+	+	R-	+	R+	+
MTBC Detected / RIF Resistance Indeterminate / INH Resistance Detected	+	+	Rx	+	R+	+
MTBC Detected / RIF Resistance NOT Detected / INH Resistance NOT Detected	+	+	R-	+	R-	+
MTBC Detected / RIF Resistance NOT Detected / INH Resistance Indeterminate	+	+	R-	+	Rx	+
MTBC Detected / RIF Resistance Indeterminate / INH Resistance NOT Detected	+	+	Rx	+	R-	+
MTBC Detected / RIF Resistance Indeterminate / INH Resistance Indeterminate	+	+	Rx	+/-	Rx	+/-
MTBC NOT Detected	-	+	N/A	+	N/A	+
Invalid	+/-	-	N/A	+/-	N/A	+/-
	-	+	N/A	+	N/A	-
	-	+	N/A	-	N/A	+
	-	+	N/A	-	N/A	-
Error	No result					

- If an invalid result is confirmed in one or more of the pathogen results, that tests will be invalidated. Please conduct a re-test.

- If the MTB signal is detected but not strong enough to judge the resistance, Resistance Indeterminate result is possible.

Outcome (Home screen)	Result (Review screen)	Description	Result (Summary screen)	Description	Result (Summary screen)	Description
Positive Resistance Detected	R <sup>+</sup>	MTB Positive & RIF and/or INH resistance Positive	+	MTB Positive	Rx	Resistance cannot be determined
Positive Resistance Undetected	R <sup>-</sup>	MTB Positive & RIF and/or INH resistance Negative	-	MTB Negative	V	IC Valid
Positive Resistance Indeterminate	R <sup>x</sup>	MTB Positive & RIF and/or INH resistance cannot be determined	R+	Resistance Detected	!	IC Invalid
Negative	-	MTB Negative	R-	Resistance Undetected	X	Error
Invalid	!	Invalid				
Error	X	Error				

# STANDARD M10 MDR-TB QRG

Unit : mm

자재명	QRI	도수	CMYK 양면 8도
문안번호	L41MDREN4	후가공	양면 무광 라미네이팅, 4단 병풍 접지(210x74.25)
크기	A4	작업일자	2024.08.09
용지/질량	스노우화이트 150g	담당부서	상품기획본부

## STANDARD M10 MDR-TB

### QUICK REFERENCE INSTRUCTIONS (QRI)

For use with STANDARD™ M10 system

REF M10-MTB-01



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

#### Before you begin

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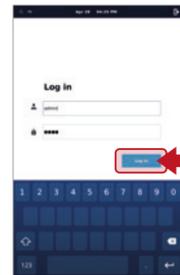
#### 1. Turn on M10

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.



The status indicator will blink green, and the door opens automatically.

#### 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

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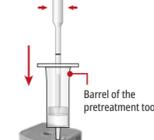
#### 2. Pierce Cartridge

Press down on the lid to pierce the sealed cartridge.



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



#### 4. Inject Sample

Insert and press down the plunger.



#### 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

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The remaining time is displayed on the M10 Console monitor.



Running screen

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MTBC Detected / RIF Resistance NOT Detected / INH Resistance Detected	+	+	R-	+	R+	+
MTBC Detected / RIF Resistance Indeterminate / INH Resistance Detected	+	+	Rx	+	R+	+
MTBC Detected / RIF Resistance NOT Detected / INH Resistance NOT Detected	+	+	R-	+	R-	+
MTBC Detected / RIF Resistance NOT Detected / INH Resistance Indeterminate	+	+	R-	+	Rx	+
MTBC Detected / RIF Resistance Indeterminate / INH Resistance NOT Detected	+	+	Rx	+	R-	+
MTBC Detected / RIF Resistance Indeterminate / INH Resistance Indeterminate	+	+	Rx	+/-	Rx	+/-
MTBC NOT Detected	-	+	N/A	+	N/A	+
	+/-	-	N/A	+/-	N/A	+/-
Invalid	-	+	N/A	+	N/A	-
	-	+	N/A	-	N/A	+
	-	+	N/A	-	N/A	-

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Positive Resistance Indeterminate	+/-	MTB Positive & RIF and/or INH resistance cannot be determined	+/-	Resistance Detected	!	IC Invalid
Negative	-	MTB Negative	R+	Resistance Undetected	X	Error
Invalid	!	Invalid				
Error	X	Error				

L41MDREN4  
Issue date : 2024.08