







STANDARD™ M10 & Puncher Flu/RSV/SARS-CoV-2

General information





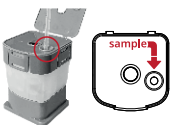

- Store the STANDARD™ M10 Flu/RSV/SARS-CoV-2 cartridges at 2-28°C.
- The test is only suitable for nasopharyngeal swab specimens.
- Always wear clean gloves and follow your institution's safety guidelines when handling patient samples.

Refer to IFU for warnings and precautions, sample collection, transport, storage, and quality control.

Starting the STANDARD™ M10 system

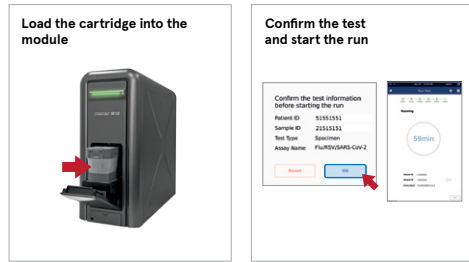
Turn on the M10	Log in	Select an M10 module	Scan Patient ID/Sample ID	Scan the test cartridge	Sample loading guide
					
1 Connect the M10 console and modules, then turn on each switch.	2 Enter username and password and press the Log in button.	3 Press one of the available modules on the Home screen. The status indicator will flash green and the door will open automatically.	4 Scan the Patient ID/sample ID with the integrated barcode scanner of the M10 console (or type in using a virtual keyboard). Patient ID is an option that can be turned off in the Settings.	5 Scan the barcode on the cartridge with the integrated barcode scanner of the M10 console. After scanning the cartridge, the next step starts automatically.	6 Watch the animated guide for cartridge preparation and sample loading. Press the next screen to continue.

STANDARD™ M10 Puncher / Loading a sample into the cartridge

Remove the safety clip	Place the cartridge	Push the cartridge	Grasp puncher handle	Transfer Sample	Close Cartridge lid
					
1 Remove clip from the cartridge. Be careful not to touch the amplification wells.	2 Place the cartridge with the safety pin removed on the holder of the punching machine.	3 Push the cartridge in the direction of the arrow.	4 Grasp puncher handle and press down to punch a hole in the cartridge.	5 Open the lid and add 300 µl of the sample into the sample chamber.	6 Close the lid.

! Load the sample within 10 minutes after piercing the cartridge. Start the test within 30 minutes of loading the sample into the cartridge.

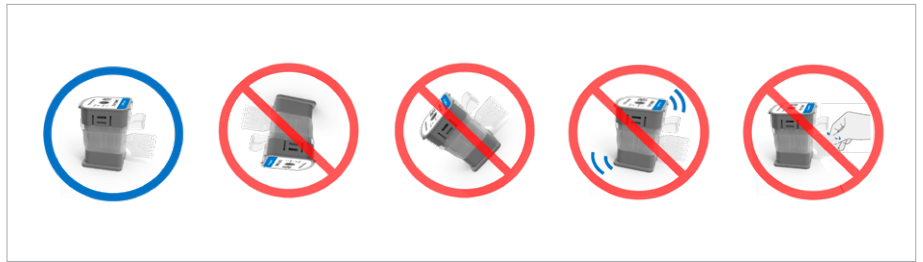
Running a test



1 Place the cartridge into the selected M10 module and close the door manually.

2 After confirming the sample and cartridge information, press OK. Start the run. The remaining time is displayed on the M10 console screen.

Proper cartridge handling/storage



DO NOT tilt, turn over, shake the cartridge!
DO NOT touch the NA amplification chamber!

Interpretation results

Results	Flu			RSV		SARS-CoV-2		
	Flu A	Flu B	IC	RSV	IC	ORF1AB	N	IC
Flu A positive	+	-	+/-	-	+	-	-	+
Flu B positive	-	+	+/-	-	+	-	-	+
RSV Positive	-	-	+	+	+/-	-	-	+
SARS-CoV-2 Positive	-	-	+	-	+	+	-	+/-
	-	-	+	-	+	-	+	+/-
	-	-	+	-	+	+	+	+/-
Negative	-	-	+	-	+	-	-	+
Invalid	-	-	-	-	-	-	-	-

- If the IC is negative and the result of corresponding target gene is positive, the result is considered as 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.

Contact and orders

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Product	Product no.	Order no.
SD BIOSENSOR STANDARD M10 CONSOLE 1 PC	11M1011	155067
SD BIOSENSOR STANDARD M10 MODULE, 1 PC	11M1012	155068
SD BIOSENSOR M10 PUNCHER, 1 PC	X9001	155299
SD BIOSENSOR M10 FLU/RSV/SARS-COV-2, 10 tests	11FLU10A	155176

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