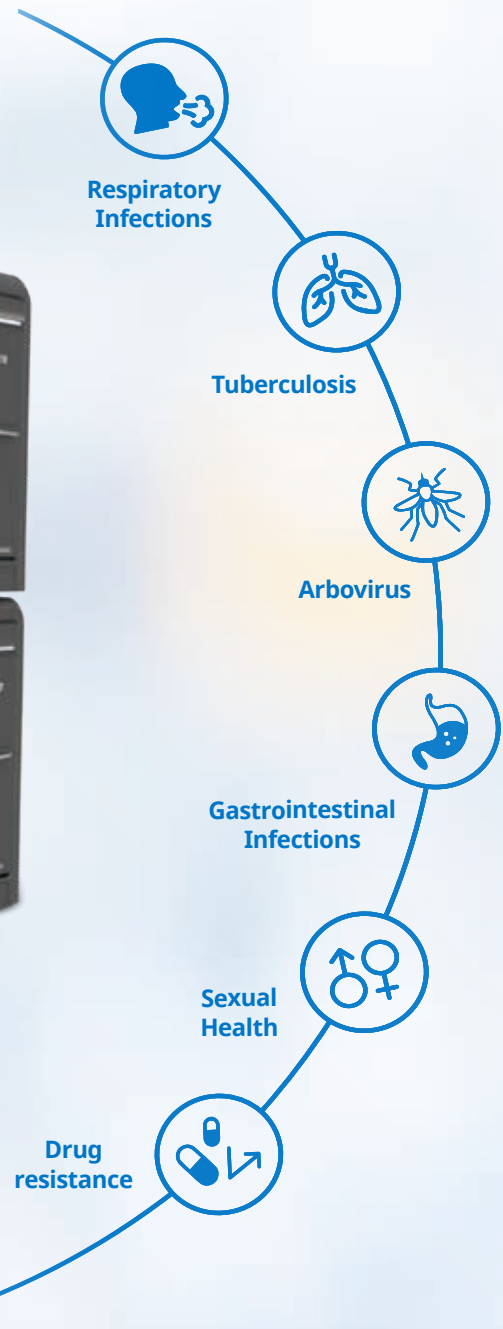


# STANDARD *M10*






## Versatile Point-of-Care MDx Platform

POC MDx Platform designed for more accurate, simpler and faster clinical decision making near-the-patient.



# Isothermal amplification + Real-time PCR in One Platform

## Assay menu

Categories	Products	Advantages
 Respiratory Infections	Flu / RSV / SARS-CoV-2 C € MFDS Approved	✓ Multiplexed detection of respiratory pathogens in a sample
	SARS-CoV-2 C € MFDS Approved	✓ Sensitive result with real-time RT-PCR
	SARS-CoV-2 Turbo C €	✓ Fast result with patented isothermal amplification technology, IB-DFO
 Tuberculosis	MDR-TB C €	✓ Simultaneous detection of MTBC and drug-resistance against rifampicin and isoniazid ✓ Simple sputum pre-treatment process / Result in 80 minutes
	MTB / NTM C €	✓ Simultaneous detection of MTBC and non-tuberculous mycobacteria (NTM) ✓ Simple sputum pre-treatment process / Result in 72 minutes
 Sexual Health	HPV (16/18/High risk) C €	✓ Separate detection of HPV high risk types HPV 16, HPV 18, other HPV high risk (31,33,35,39,45,51,52,56,58,59,66,68)
	STI Panel* (CT/NG/UU/MG/TV/MH/HSV1/HSV2)	✓ Simultaneous detection of STI pathogens
 Arbovirus	Arbovirus Panel C € (Dengue virus / Zika virus / Chikungunya virus / Yellow fever virus / West Nile virus)	✓ Simultaneous detection of DENV1~4, ZIKV, CHIKV, YFV and WNV
 Gastrointestinal Infections	<i>C. difficile</i> C €	✓ Detection of toxin B genet ( <i>tcdB</i> ) ✓ Simple stool pre-treatment process

It includes upcoming products. \*Marked products are scheduled to be released.

## Features

- Fully automated and integrated system
- User friendly GUI with animated guide
- Seamless connectivity with HIS/LIS
- Memory up to 5,000 with Ct values & amplification curves
- 10.1" touch screen
- Customized configuration up to 8 modules
- Minimized maintenance requirements
- Intuitive status indicator
- Small footprint

### Innovative substitute for all molecular diagnostic equipment

STANDARD M10 can be used anywhere diagnostics are needed, from clinics to large laboratories.



University hospital laboratory



Emergency room



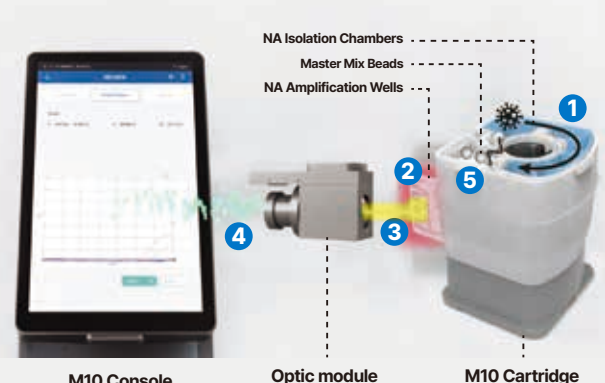
Testing site



Clinics

# All-in-one Cartridge NA extraction + amplification

## Multiplex assay up to 12-Plex including IC



### Technologies applied to STANDARD M10

- 1 Patented NA extraction process for PCR efficiency (Lysis-binding-washing-elution)
- 2 Precise temperature control of thermal block
- 3 Multi-well cartridge, multi-channel optic module enables multiplex assay without interference
- 4 Reliable data analysis algorithm
- 5 Lyophilized reagents for improved stability

The diagram shows the M10 Console, Optic module, and M10 Cartridge. The workflow steps are numbered 1 to 5, corresponding to the technologies listed.

- ✓ Fast 'Sample-in Result-out' workflow
- ✓ Reduced risk of cross-contamination

- ✓ Reliable and intuitive result interpretation
- ✓ Room temperature storage

### TEST PROCEDURE



1 Scan the sample ID.



2 Scan the cartridge code.



3 Apply the sample & close the cartridge.

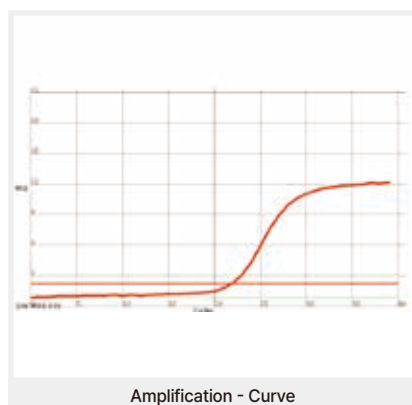


4 Insert the cartridge.

### Result Example

Summary	
<b>Test Information</b>	
Assay Name	SARS-CoV-2
Patient ID	
Sample ID	1
Test Type	Substrates
Start Time	2023/03/04 10:17:30
End Time	2023/03/04 12:17:44
Run	Success
<b>Result</b>	
Pathogen	IC Valid
QA/QC	Pass
IC	Pass

Summary



Details	
Assay Name	SARS-CoV-2
Test	IC Valid
Patient ID	
Sample ID	1
Sample Type	Substrates
Cartridge Lot No.	W180012000
Flow ID No.	W180012000
Cartridge Exp.	2023/03/18
Module ID	W180012000
Start Time	2023/03/04 10:17:30
End Time	2023/03/04 12:17:44

















Details

## ■ Ordering Information

### Instrument

Products	Contents	Cat. no.
STANDARD M10	1 M10 Console + 1 M10 Module	11M1010
STANDARD M10 Console	1 M10 Console	11M1011
STANDARD M10 Module	1 M10 Module	11M1012
STANDARD M10 Calibration Kit	Calibration Cartridge 2T/Kit	11CAL10H

### Cartridge

Products	Pathogens	Cat. no.
STANDARD M10 SARS-CoV-2   MFDS Approved	SARS-CoV-2 (ORF1ab gene, E gene)	11COV10A
STANDARD M10 SARS-CoV-2 Turbo  	SARS-CoV-2 (ORF1ab gene, N gene)	11COV20A
STANDARD M10 Flu/RSV/SARS-CoV-2   MFDS Approved	Flu A, Flu B, RSV, SARS-CoV-2 (ORF1ab gene, N gene)	11FLU10A
STANDARD M10 MDR-TB  	TB (IS6110, IS1081), Rifampicin ( <i>rpoB</i> ), Isoniazid ( <i>katG</i> , <i>inhA</i> )	11MTB10A
STANDARD M10 MTB/NTM  	TB (IS6110), NTM (ITS)	11MTB20A
STANDARD M10 HPV  	E6/E7 gene, HPV16,18, high risk(31,33,35,39,45,51,52,56,58,59,66,68)	11HPV10A
STANDARD M10 Arbovirus Panel  	DENV1~4, ZIKV, CHIKV, YFV, WNV	11ARB10A
STANDARD M10 <i>C. difficile</i>  	<i>Clostridioides difficile</i> ( <i>tcdB</i> )	11CDC10A
STANDARD M10 STI Panel*	CT, NG, UU, MG, MH, TV, HSV1, HSV2	-

It includes upcoming products. \*Marked products are scheduled to be released.

## ■ Specifications

Description	Details
Power Requirements	AC100~240V, 50/60Hz
Operation Conditions	Temperature 10 ~ 40°C (50-104°F) Humidity Condition 30-75% R.H.
Test method	LAMP and Real time PCR
System Operator	Console
Instrument module Coupling	Up to 8 modules with Console
Memory	5,000
External Interface	LAN, USB (x4)
LIS/HIS	HL7, LAW profile
Size	M10 Console : 17 x 23 x 39 cm M10 Module : 14 x 33 x 32 cm
Weight	M10 Console : 2kg M10 Module : 7kg