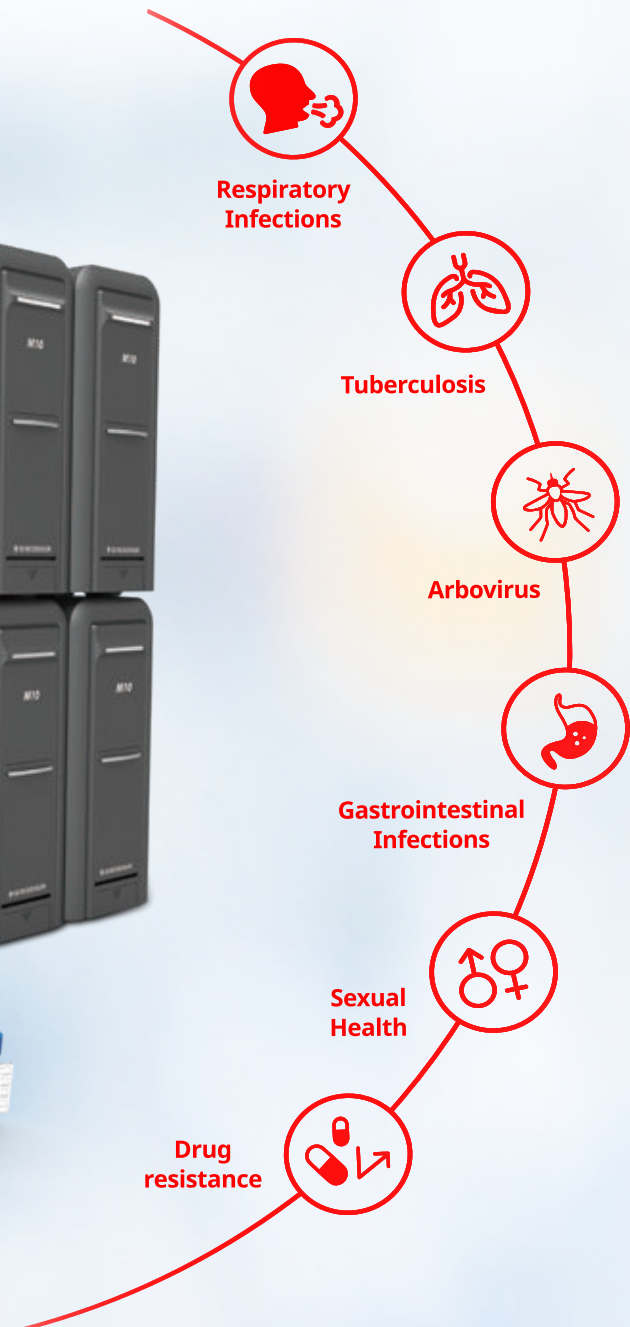


STANDARD *M10*







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 € €	✓ Multiplexed detection of respiratory pathogens in a sample
	SARS-CoV-2 € € MFDS	✓ Sensitive result with real-time RT-PCR
	SARS-CoV-2 Turbo	✓ Fast result with patented isothermal amplification technology, IB-DFO
 Tuberculosis	MDR-TB € €	✓ Simultaneous detection of TB and drug-resistance against rifampicin and isoniazid ✓ Simple sputum pre-treatment process / Result in 75 minutes
	MTB / NTM € €	✓ Simultaneous detection of TB and non-tuberculous mycobacteria (NTM) ✓ Simple sputum pre-treatment process / Result in 75 minutes
	XDR-TB*	✓ Simultaneous detection of TB and drug-resistance to the most common first and second line drug
 Sexual Health	HPV (16/18/High risk) € €	✓ 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 € € (Dengue virus / Zika virus/ Chikungunya virus / Yellow fever virus / West Nile virus)	✓ Simultaneous detection of DENV, ZIKV, CHIKV, YFV and WNV
 Gastrointestinal Infections	<i>C. difficile</i> € €	✓ Detection of toxin B genet (<i>tcdB</i>) ✓ Simple stool pre-treatment process
 Drug resistance	MDR-TB € €	✓ Simultaneous detection of TB and drug-resistance against rifampicin and isoniazid ✓ Simple sputum pre-treatment process / Result in 75 minutes

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

Features

- 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
- Alternative operating system to PC (Window)
- 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



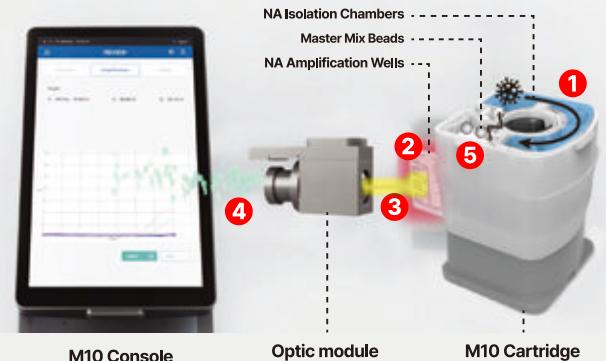
Clinics

All-in-one Cartridge NA extraction + amplification

Multiplex assay up to 12-Plex including IC

- ✓ Simple 'Sample-in Result-out' workflow
- ✓ Result in 30-60 minutes

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



The diagram illustrates the M10 workflow components and steps:

- M10 Console:** A tablet displaying a graph.
- Optic module:** A component that receives data from the console.
- M10 Cartridge:** A cartridge with internal components labeled: NA Isolation Chambers, Master Mix Beads, and NA Amplification Wells.

Numbered steps in the diagram:

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

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

TEST PROCEDURE



1 Scan the sample ID.



2 Scan the cartridge code.



3 Apply the sample & close the cartridge.

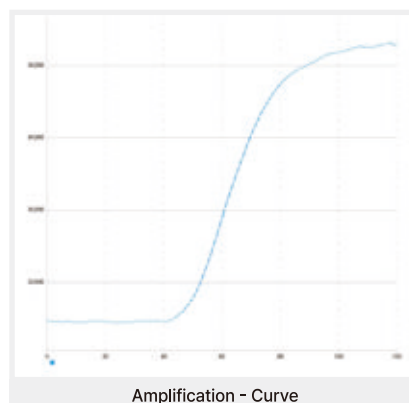


4 Insert the cartridge.

Result Example

Summary	Amplification	Details
Test Information		
Assay Name	SARS-CoV-2	
Patient ID		
Sample ID	LSH TEST	
Test Type	Specimen	
Run Started	2023/05/14 10:48:49	
Run ended	2023/05/14 11:45:55	
User	admin	
Result		
ORF1ab	Valid	0.99
E	Valid	0.99
IC	Valid	28.67

Summary



Details	
Operator ID	Labuser1
Cartridge S/N	122705480206
Cartridge Expiration Date	2026/04/12
Module S/N	21020314105902
Test Status	Completed
Error Code	
Test Start Date and Time	2023/05/14 10:48:49
Test End Date and Time	2023/05/14 11:45:55
Test Execution Time	30 min 15sec
Assay Name	Assay A0
Test ID	234233
Test Result	Positive
Detecting Pathogen	HF A, HF B
Undetected Pathogen	Dbov,HEV,Adenov,spici

Details

■ Ordering Information

Instrument

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

Cartridge

Products	Pathogens	Cat. no.
STANDARD M10 SARS-CoV-2 CE MFDS	SARS-CoV-2 (ORF1ab gene, E gene)	11COV10A
STANDARD M10 SARS-CoV-2 Turbo CE	SARS-CoV-2 (ORF1ab gene, N gene)	11COV20A
STANDARD M10 Flu/RSV/SARS-CoV-2 CE	Flu A, Flu B, RSV, SARS-CoV-2 (ORF1ab gene, N gene)	11FLU10A
STANDARD M10 MDR-TB CE	TB (IS6110, IS1081), Rifampicin (<i>rpoB</i>), Isoniazid (<i>katG, inhA</i>)	11MTB10A
STANDARD M10 MTB/NTM CE	TB (IS6110), NTM (ITS)	11MTB20A
STANDARD M10 HPV CE	E6/E7 gene, HPV16,18, high risk(31,33,35,39,45,51,52,56,58,59,66,68)	11HPV10A
STANDARD M10 Arbovirus Panel CE	DENV, ZIKV, CHIKV, YFV, WNV	11ARB10A
STANDARD M10 <i>C. difficile</i> CE	<i>Clostridioides difficile</i> (<i>tcdB</i>)	11CDC10A
STANDARD M10 STI*	CT, NG, UU, MG, MH, TV, HSV1, HSV2	-
STANDARD M10 HIV-1 VL*	HIV-1 viral load	-
STANDARD M10 HCV VL*	Hepatitis C viral load	-
STANDARD M10 HBV VL*	Hepatitis B viral load	-

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

■ Specifications

Description	Details
Power Requirements	AC100~240V, 50/60Hz
Operation Conditions	Temperature 15-40°C (59-104°F) Humidity Condition 20-80%
Test method	LAMP and Real time PCR
System Operator	Console, Desk-top (Window)
Instrument module Coupling	Up to 8 modules with Console or Tablet Up to 16 modules with Desktop
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



LEF-M10-EN Rev.08

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