

STANDARD *M10*

Versatile Point-of-Care Molecular Diagnostic Platform

STANDARD M10 is a Point-of-Care Molecular Diagnostic Platform designed to deliver more accurate results, provide simpler workflows, and enable faster clinical decision-making near-the-patient.



Respiratory
Infections



Sexual
Health



Tuberculosis



Healthcare Associated
Infections



Gastrointestinal
Infections



Vector Borne
Disease



Drug Susceptibility
Test

All-in-one Cartridge: NA Extraction / Amplification

Assay Menu

Categories	Products	Advantages
 Respiratory Infections	SARS-CoV-2	• Dual target gene detection (ORF1ab / E gene)
	Flu/RSV/SARS-CoV-2 C €	• Multiplex detection of respiratory pathogens in a sample
	Flu/RSV/SARS-CoV-2 Fast C € 0123	• Multiplex detection of respiratory pathogens in 36 minutes
 Sexual Health	STI Panel C € 0123 UK CA	• Simultaneous detection of 8 major STI pathogens - CT/NG/MG/UU/TV/MH/HSV1/HSV2
	CT/NG UK CA	• Simultaneous detection of <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i>
	HPV C €	• Detection of HPV high risk types HPV 16/18/other high risk (31,33,35,39,45,51,52,56,58,59,66,68)
	Hr-HPV UK CA	• Detection of HPV high risk types HPV 16/18/other high risk
 Tuberculosis	MDR-TB C €	• Simultaneous detection of MTBC and drug-resistance against rifampicin and isoniazid
	MTB-RIF/INH UK CA	• Simultaneous detection of MTBC and drug-resistance against rifampicin and isoniazid using melting curve analysis
	MTB/NTM C €	• Differentiation of MTBC from non-tuberculous mycobacteria (NTM)
	MTB/NTM v2.0 UK CA	• Differentiation of MTBC from non-tuberculous mycobacteria (NTM)
 Healthcare Associated Infections (HAIs)	CARBA UK CA	• Identification of broader carbapenemase genes - KPC, NDM, VIM, OXA-48, IMP, GES
	MRSA/SA UK CA	• Covers all <i>SCCmec</i> types from I to XV
	vanA/vanB UK CA	• Detection of vancomycin-resistance (vanA/vanB) genes
 Gastrointestinal Infections	<i>C. difficile</i> C €	• Detection of toxin B gene (<i>tcdB</i>)
	<i>C. difficile</i> BT* C €	• Presumptive differentiation of hypervirulent <i>C. difficile</i> (027 ribotype) from common strains.
 Vector Borne Disease	Arbovirus Panel C €	• Simultaneous detection of DENV 1 ~ 4, ZIKV, CHIKV, YFV and WNV
	DENV 1~4 UK CA	• Differentiation of Dengue virus 1~4 serotypes
 Others	MPX/OPX	• Detection of Mpox and orthopoxviruses with Mpox clade I/II differentiation

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

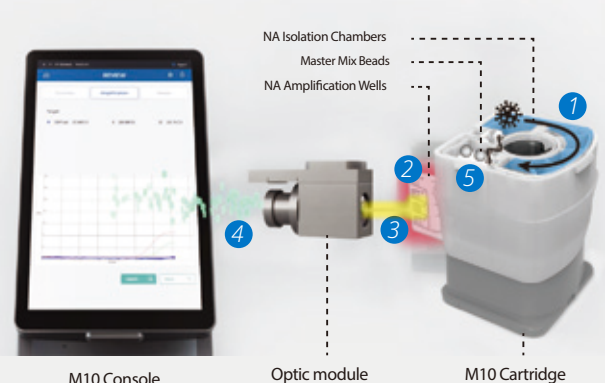


Testing site



Clinics

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

- Fast 'Sample-in Result-out' workflow
- Reliable and intuitive result interpretation
- Reduced risk of cross-contamination
- 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
Amplification
Details

Test Information

Assay Name	SARS-CoV-2
Patient ID	
Sample ID	1
Test Type	Specimen
Start Time	2025/3/12 15:40:39
End Time	2025/3/12 15:40:53
User	admin

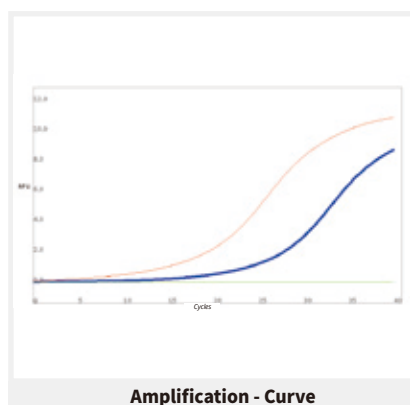
Result

Pathogen: V IC Valid

ORF1ab: + 10.23 Ct

E: - N/A

Summary



Summary
Amplification
Details

Assay Name	SARS-CoV-2
User	admin
Patient ID	
Sample ID	1
Sample Type	UTM
Cartridge Lot No.	MMCO0123009
(New) Lot No.	BC83763AC
Cartridge Exp	2023/05/18
Module S/N	NA3BC02EAA0062
Start Time	2023/2/24 12:17:30
End Time	2023/2/24 12:17:44

Details

Ordering Information

Instrument

Products	Contents	Cat. no.
STANDARD M10 Console	M10 Console, D-sub cable, AC cable	11M1011
STANDARD M10 Module	M10 Module, Gender, Bracket, AC cable, AC cover	11M1012
STANDARD M10 Calibration Kit	Calibration Cartridge 2T/Kit	11CAL10H

Cartridge

Categories	Products	Target	Cat. no.
Respiratory Infections	SARS-CoV-2 C €	SARS-CoV-2 (ORF1ab gene, E gene)	11COV10A
	Flu/RSV/SARS-CoV-2 C €	Flu A, Flu B, RSV, SARS-CoV-2 (ORF1ab gene, N gene)	11FLU10A
	Flu/RSV/SARS-CoV-2 Fast C € 0123	Flu A, Flu B, RSV, SARS-CoV-2 (ORF1ab/E gene, N gene)	11FLU30A
Sexual Health	STI Panel C € 0123 UK CA	CT, NG, MG, UU, TV, MH, HSV1, HSV2	11STI10A
	CT/NG UK CA	<i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i>	11CTN10A
	HPV C €	E6/E7 gene, HPV 16/18/ other high risk (31,33,35,39,45,51,52,56,58,59,66,68)	11HPV10A
	Hr-HPV UK CA	E6/E7 gene, HPV 16/18/ other high risk (31,33,35,39,45,51,52,56,58,59,66,68)	11HPV20A
Tuberculosis	MDR-TB C €	TB (IS6110, IS1081), Rifampicin (<i>rpoB</i>), Isoniazid (<i>katG</i> , <i>inhA</i>)	11MTB10A
	MTB-RIF/INH UK CA	TB (IS6110, IS1081), Rifampicin (<i>rpoB</i>), Isoniazid (<i>katG</i> , <i>inhA</i>)	11MTB30A
	MTB/NTM C €	TB (IS6110), NTM (ITS)	11MTB20A
	MTB/NTM v2.0 UK CA	TB (IS6110, IS1081), NTM (16S rRNA/23S rRNA/ITS)	11MTB40A
Healthcare Associated Infections (HAIs)	CARBA UK CA	KPC, NDM, VIM, OXA-48, IMP, GES	11CAR10A
	MRSA/SA UK CA	<i>SCCmec</i> , <i>mecA/mecC</i> , and <i>spa</i> gene	11MSS10A
	vanA/vanB UK CA	<i>vanA</i> , <i>vanB</i> gene	11VAN10A
Gastrointestinal Infections	<i>C. difficile</i> C €	Toxin B gene (<i>tcdB</i>)	11CDC10A
	<i>C. difficile</i> BT* UK CA	<i>tcdB</i> gene, <i>tcdC</i> deletion at nt 117, and <i>cdtA</i>	11CDC20A
Vector Borne Disease	Arbovirus Panel C €	Dengue virus 1~4, Zika virus, Chikungunya virus, Yellow fever virus, West Nile virus	11ARB10A
	DENV 1~4 UK CA	Dengue virus 1~4	11DEN10A
Others	MPX/OPX UK CA	Mpox virus (G2R), orthopoxvirus (E9L)	11MPX20A

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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	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
Size	M10 Console : 17 x 23 x 39 cm M10 Module : 14 x 33 x 32 cm
Weight	M10 Console : 2kg M10 Module : 7kg