

# 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	
 <b>Respiratory Infections</b>	SARS-CoV-2	• Dual target gene detection (ORF1ab / E gene)	
	Flu/RSV/SARS-CoV-2	€ €	• Multiplex detection of respiratory pathogens in a sample
	Flu/RSV/SARS-CoV-2 Fast	€ € 0123	• Multiplex detection of respiratory pathogens in 36 minutes
 <b>Sexual Health</b>	STI Panel	€ € 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	€ €	• 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
 <b>Tuberculosis</b>	MDR-TB	€ €	• 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	€ €	• Differentiation of MTBC from non-tuberculous mycobacteria (NTM)
	MTB/NTM v2.0	UK CA	• Differentiation of MTBC from non-tuberculous mycobacteria (NTM)
 <b>Healthcare Associated Infections (HAIs)</b>	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
 <b>Gastrointestinal Infections</b>	<i>C. difficile</i>	€ €	• Detection of toxin B gene ( <i>tcdB</i> )
	<i>C. difficile</i> BT*		• Presumptive differentiation of hypervirulent <i>C. difficile</i> (027 ribotype) from common strains.
 <b>Vector Borne Disease</b>	Arbovirus Panel	€ €	• Simultaneous detection of DENV 1 ~ 4, ZIKV, CHIKV, YFV and WNV
	DENV 1~4	UK CA	• Differentiation of Dengue virus 1~4 serotypes
 <b>Others</b>	MPX/OPX		• Detection of Mpx and orthopoxviruses with Mpx 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

The diagram illustrates the M10 assay system components and workflow steps:

- M10 Console:** A tablet displaying a graph of the assay results.
- Optic module:** A component that receives data from the M10 Cartridge.
- M10 Cartridge:** A multi-well cartridge containing NA Isolation Chambers, Master Mix Beads, and NA Amplification Wells.

**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
- 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.

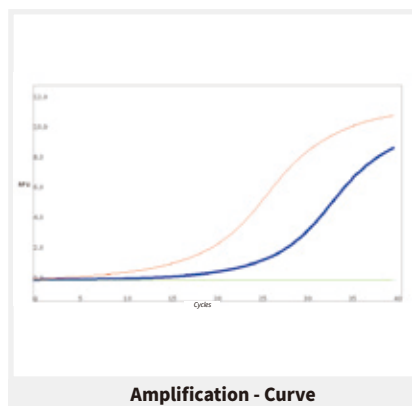


4 Insert the cartridge.

## Result Example

Summary	Amplification	Details
<b>Test Information</b>		
Assay Name	SARS-CoV-2	
Patient ID		
Sample ID	1	
Test Type	Specimen	
Start Time	2025/3/12 15:49:39	
End Time	2025/3/12 15:49:53	
User	admin	
<b>Result</b>		
Pathogen	IC Valid	
ORF1ab	30.23 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.	MMCD09123009	
(Well) Lot No.	8C837xSAC	
Cartridge Exp	2028/03/18	
Module S/N	MA36C02EA0092	
Start Time	2025/02/24 12:17:30	
End Time	2025/02/24 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, inhA</i> )	11MTB10A
	MTB-RIF/INH UK CA	TB (IS6110, IS1081), Rifampicin ( <i>rpoB</i> ), Isoniazid ( <i>katG, 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, mecA/mecC, and spa</i> gene	11MSS10A
	vanA/vanB UK CA	<i>vanA, vanB</i> gene	11VAN10A
Gastrointestinal Infections	<i>C. difficile</i> C €	Toxin B gene ( <i>tcdB</i> )	11CDC10A
	<i>C. difficile</i> BT* C €	<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 C €	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

eurobio **teco**

Switzerland / Headquarters  
**TECOmedical AG**  
 Gewerbestrasse 10  
 4450 Sissach  
 Phone: +41 61 985 81 00  
 Fax: +41 61 985 81 09  
 Mail: info@tecomedical.com

Austria  
**TECOmedical AG**  
 Hotline: 0800 20 40 66  
 Fax: 0800 20 40 55  
 Mail: info@tecomedical.com

