

# STANDARD M10

Versatile Point-of-Care MDx Platform

The STANDARD M10 is a novel Point-of-Care molecular diagnostic (MDx) system that enables simple, fast and accurate diagnosis of infectious disease drug resistance and genetic testing. Its scalable modular configuration is suitable for any healthcare settings from near-patient to a large laboratory. Standard M10 all-in-one cartridge enables 'Sample-in Result-out' process with minimum hands-on time which minimizes human error and contamination.



### Simple and Fast

- Result out in 20\* -30 mins

### Multiplex

- Maximum 12 targets including internal control

### Various Menus

- QL: SARS-CoV-2, Respiratory, TB, Arbovirus
- Viral Load: HIV-1, HBV, HCV and more

### Modular and Scalable

- Scalable configuration for customized throughput

- User friendly GUI with animated guide
- Seamless connectivity with HIS/LIS
- Memory up to 5,000 with Ct values and amplification curves
- 10.1" touch screen
- Alternative operating system to PC (Window) or Tablet (Android)
- Minimized maintenance requirements
- Intuitive status indicator
- Small footprint
- Customized configuration up to 8 modules
- Positive early call in 20 minutes. Negative results in 30 minutes

### All-in-one Cartridge NA extraction + amplification Multiplex assay up to 12-Plex including IC



- Reliable result by accumulated technologies
- One minute hands-on prep
- Multiplex using FAM/HEX/Cy5
- Room temperature storage

### Easy way for the better performance



1. Scan the sample ID.



2. Scan the cartridge code.



3. Apply the sample & close the cartridge.



4. Insert the cartridge.

### SPECIFICATION

Power Requirements	AC100~240V, 50/60Hz
Operation Conditions	Temperature 10-40°C (50-104°F) Humidity Condition 20-80%
Test Method	LAMP and Real time PCR
System Operator	Console, Desk-top(Window), Tablet(Android)
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 PCD-01 profile support
Size	M10 Console : 17 x 23 x 39 cm M10 Module : 14 x 33 x 32 cm
Weight	M10 Console : 2kg M10 Module : 7kg

## ASSAY MENU

Category	Product	Pack Size	Cat. No.
Respiratory Disease	Standard™ M10 SARS-CoV-2	10 Tests	11COV10A
	Standard™ SARS-CoV-2 Turbo	10 Tests	11COV30A
	Standard™ M10 Flu/RSV/SARS-CoV-2	10 Tests	11FLU10A
Tuberculosis	Standard™ M10 MDR-TB	10 Tests	11MTB10A
	Standard™ M10 MDR/NTM	10 Tests	11HPV20A
Sexual Health	Standard™ M10 HPV	10 Tests	11HPV10A
Gastrointestinal Disease	Standard™ M10 C.difficile	10 Tests	11CDC10A
Gastrointestinal Disease	Standard™ M10 C.difficile	10 Tests	11CDC10A

## ETC

Category	Product	Pack Size	Cat. No.
Standard™ M10 Calibration Kit	Calibration Cartridge	2 Tests	11CAL10H
Standard™ M10 Calibration Kit	Positive 5 vials/ Negative 5 vials	10 each	11COVC10J

# STANDARD M10 SARS-CoV-2

STANDARD™ M10 SARS-CoV-2 qualitatively detects SARS-CoV-2 virus infection by extracting and amplifying the nucleic acids from nasopharyngeal swab or oropharyngeal swab samples. Reverse transcription real-time polymerase chain reaction (Real-time RT-PCR) is used on the amplification and detection of SARS-CoV-2.

**Test Type** Professional use only  
**Specimen Type** Nasopharyngeal Swab  
**Storage Conditions** 2~28°C



### Advantages

- All-in-one cartridge (NA extraction + amplification)
- Sensitivity of 100% and specificity of 100% (Ref.no: SDB-CS-MNCOV03)
- Result in 20-60 minutes (NA extraction + amplification)
- One minute hands-on preparation
- Multiplex using FAM/HEX/Cy5
- Room temperature storage

### SPECIFICATION

Test Method	All-in-one Cartridge. Nucleic acid extraction/isolation: Column Method / Nucleic acid amplification : RT-PCR
Detection or Analysis Gene	ORF1ab gene, E gene / Internal Control (IC)
Limit of Detection	ORF1ab gene – 6.63 x10 <sup>-4</sup> TCID <sub>50</sub> /ml / E gene – 6.63 x10 <sup>-4</sup> TCID <sub>50</sub> /ml
Sensitivity	100% (109/109, 95% CI: 96.67% - 100%)
Specificity	100% (120/120, 95% CI: 96.97% - 100%)
Test Time	20-60 mins
Storage Temperature	2~28°C
Test/Kit	10 Tests/kit

### TEST PERFORMANCE

Product	Clinical Sensitivity	Clinical Specificity	Limit of Detection
RT-PCR	100% (109/109, 95% CI: 96.67% - 100%)	100% (120/120, 95% CI: 96.67% - 100%)	-ORF 1ab (RdRp) gene - 6.63x10 <sup>-04</sup> TCID <sub>50</sub> /ml -E gene- 6.63x10 <sup>-04</sup> TCID <sub>50</sub> /ml

### ORDERING INFORMATION

REFERENCE	PACK SIZE	CAT. NO.
STANDARD M10 SARS-CoV-2	10 Tests	11COV10A

## STANDARD M10

# SARS-CoV-2 Lamp (Turbo)

STANDARD™ M10 SARS-CoV-2 Turbo is a real-time RT-LAMP test intended for use with STANDARD M10 system for the qualitative detection of SARS-CoV-2 nucleic acids in human nasopharyngeal swab

**Test Type** Professional use only  
**Specimen Type** Nasopharyngeal Swab  
**Storage Conditions** 2~28°C

### Advantages

- All-in-one cartridge (NA extraction + amplification)
- Fast results in 30 minutes
- One minute hands-on preparation
- Multi-target: ORF1ab and N gene
- Room temperature storage



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## STANDARD M10

# FLU/RSV/SARS-CoV-2

STANDARD™ M10 FLU/RSV/SARS-CoV-2 is a multiplex real-time RT-PCR test intended to use with STANDARD M10 system for the qualitative detection of Influenza A, Influenza B, RSV and SARS-CoV-2 nucleic acids in human nasopharyngeal swab.

**Test Type** Professional use only  
**Specimen Type** Nasopharyngeal Swab  
**Storage Conditions** 2~28°C

### Advantages

- All-in-one cartridge (NA extraction + amplification)
- Simultaneous detection and differentiation of Flu A, Flu B, RSV and SARS-CoV-2
- Real-time RT-PCR result in one hour
- One minute hands-on preparation
- Room temperature storage



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## STANDARD M10

# MDR-TB

STANDARD™ M10 MDR-TB is a multiplex real-time PCR test intended for use with STANDARD M10 system for the qualitative detection of Mycobacterium tuberculosis nucleic acids and drug-resistance against rifampicin (RIF) and isoniazid (INH) in human normal sputum or sputum sediment sample.

**Test Type** Professional use only  
**Specimen Type** Pretreated normal sputum, sputum sediment sample  
**Storage Conditions** 2~28°C

### Advantages

- All-in-one cartridge (NA extraction + amplification)
- Simultaneous detection of M.tuberculosis and drug-resistance against rifampicin (RIF) and isoniazid (INH)
- Fast result in 75 minutes
- Simple sputum pretreatment process
- Room temperature storage



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## STANDARD M10 MTB/NTM

STANDARD™ M10 MDR MTB/NTM is a multiplex real-time PCR test intended for use with STANDARD M10 system for the qualitative detection of Mycobacterium Tuberculosis and non-tuberculosis mycobacterial (NTM) nucleic acids in human normal sputum or sputum sediment sample.

**Test Type** Professional use only  
**Specimen Type** Pretreated normal sputum, sputum sediment sample  
**Storage Conditions** 2~28°C

### Advantages

- All-in-one cartridge (NA extraction + amplification)
- Simultaneous detection of M.tuberculosis and NTM
- Fast result in 77 minutes
- Simple sputum pretreatment process
- Room temperature storage



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## STANDARD M10 HPV

STANDARD™ M10 HPV is real-time PCR test intended for use with STANDARD M10 system for the qualitative detection of Human Papillomavirus (HPV) nucleic acids in human cervical swab sample.

**Test Type** Professional use only  
**Specimen Type** Cervical Swab  
**Storage Conditions** 2~28°C

### Advantages

- All-in-one cartridge (NA extraction + amplification)
- Separate detection of HPV high risk types HPV16, HPV 18, HPV HR (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68)
- One minute on hand preparation
- Room temperature storage



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## STANDARD M10 C.difficile

STANDARD™ M10 C.difficile is a Real-Time PCR test intended for use with STANDARD M10 system for the qualitative detection of Clostridioides difficile nucleic acids in unformed (watery or soft) stool sample.

**Test Type** Professional use only  
**Specimen Type** Unformed stool  
**Storage Conditions** 2~28°C

### Advantages

- All-in-one cartridge (NA extraction + amplification)
- Detection of Toxin B gene (tcd B)
- Simple stool pretreatment process
- Room temperature storage



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