

# STANDARD M

Molecular diagnostics



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## STANDARD M

### Molecular Diagnostics

STANDARD™ M is a molecular diagnostic brand including STANDARD M10, a point-of-care molecular diagnostic system, PCR reagents and other related products. STANDARD™ M10 is a versatile POC system designed for more accurate, simpler and faster clinical decision making near-the-patient using real-time PCR or real-time LAMP. STANDARD™ M10 is an automated system that integrates extraction and amplification of nucleic acids from various specimens and detection of target sequences. STANDARD™ M10 consists of STANDARD™ M10 Module and STANDARD™ M10 Console. The entire testing process is carried out inside STANDARD™ M10 Module, and STANDARD™ M10 Console controls the process, analyzes the result and manages the database using the software. The patented all-in-one STANDARD™ M10 cartridges hold the nucleic acid extraction reagents and real-time PCR/LAMP reagents. STANDARD™ M10 portfolio covers infectious disease diagnosis, drug resistance confirmation, and genetic testing.

# STANDARD M10

## Versatile Point-of-Care MDx Platform

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



**qPCR  
+  
LAMP  
in One System**



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.

### 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 development for all molecular diagnostic equipment

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



### Assay Menu

Category	Products	Tests / Kit	Cat. no.
Respiratory Disease	STANDARD™ M10 SARS-CoV-2	10T	11COV10A
	STANDARD™ M10 SARS-CoV-2 Turbo	10T	11COV20A
	STANDARD™ M10 Flu/RSV/SARS-CoV-2	10T	11FLU10A
Tuberculosis	STANDARD™ M10 MDR-TB	10T	11MTB10A
	STANDARD™ M10 MTB/NTM	10T	11MTB20A
Sexual Health	STANDARD™ M10 HPV	10T	11HPV10A
Gastrointestinal Disease	STANDARD™ M10 <i>C. difficile</i>	10T	11CDC10A
Arbovirus	STANDARD™ M10 Arbovirus Panel	10T	11ARB10A

### STANDARD M10 SARS-CoV-2

CE MFDS

Multiplex real-time RT-PCR test intended for use with STANDARD™ M10 system for the qualitative detection of nucleic acid from the SARS-CoV-2 ORF1ab(RdRp) gene and E gene in upper respiratory specimens (such as nasopharyngeal) collected from individuals suspected of COVID-19.

**Test type** Professional Use Only  
**Specimen type** Nasopharyngeal swab  
**Storage condition** 2 ~ 28°C



#### Test Performance

Reference	Clinical Sensitivity	Clinical Specificity	Limit of Detection (LoD)
RT-PCR	100% (109/109, 95% CI: 96.67% -100%)	100% (120/120, 95% CI: 96.67% -100%)	- ORF1ab (RdRp) gene- 6.63x10 <sup>4</sup> TCID <sub>50</sub> /ml - E gene- 6.63x10 <sup>4</sup> TCID <sub>50</sub> /ml

#### Ordering Information

Products	Tests / Kit	Cat. No.
STANDARD M10 SARS-CoV-2	10 Tests	11COV10A

### STANDARD M10 SARS-CoV-2 Turbo (LAMP)

CE

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 condition** 2 ~ 28°C



#### Advantage

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

#### Ordering Information

Products	Tests / Kit	Cat. No.
STANDARD M10 SARS-CoV-2 Turbo	10 Tests	11COV20A

### STANDARD M10 Flu/RSV/SARS-CoV-2

CE

STANDARD™ M10 Flu/RSV/SARS-CoV-2 is a multiplex real-time RT-PCR test intended for 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 condition** 2 ~ 28°C



#### Advantage

- 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 1 hour
- One minute hands-on preparation
- Room temperature storage

#### Ordering Information

Products	Tests / Kit	Cat. No.
STANDARD M10 Flu/RSV/SARS-CoV-2	10 Tests	11FLU10A

**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.

<b>Test type</b>	Professional Use Only
<b>Specimen type</b>	Pretreated normal sputum, sputum sediment sample
<b>Storage condition</b>	2 ~ 28°C

**Advantage**

- 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

**Ordering Information**

Products	Tests / Kit	Cat. No.
STANDARD M10 MDR-TB	10 Tests	11MTB10A

**STANDARD M10  
MTB/NTM**

STANDARD™ M10 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-tuberculous mycobacteria(NTM) nucleic acids in human normal sputum or sputum sediment sample.

<b>Test type</b>	Professional Use Only
<b>Specimen type</b>	Pretreated normal sputum, sputum sediment sample
<b>Storage condition</b>	2 ~ 28°C

**Advantage**

- 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

**Ordering Information**

Products	Tests / Kit	Cat. No.
STANDARD M10 MTB/NTM	10 Tests	11MTB20A

**STANDARD M10  
HPV**

STANDARD™ M10 HPV is a 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.

<b>Test type</b>	Professional Use Only
<b>Specimen type</b>	Cervical swab
<b>Storage condition</b>	2 ~ 28°C

**Advantage**

- All-in-one cartridge (NA extraction + amplification)
- Separate detection of HPV high risk types
- HPV 16, HPV 18, HPV HR (31,33,35,39,45,51,52,56,58,59,66,68)
- One minute hands-on preparation
- Room temperature storage

**Ordering Information**

Products	Tests / Kit	Cat. No.
STANDARD M10 HPV	10 Tests	11HPV10A

**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.

<b>Test type</b>	Professional Use Only
<b>Specimen type</b>	Unformed stool
<b>Storage condition</b>	2 ~ 28°C

**Advantage**

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

**Ordering Information**

Products	Tests / Kit	Cat. No.
STANDARD M10 <i>C. difficile</i>	10 Tests	11CDC10A



## STANDARD M10 Arbovirus Panel



STANDARD™ M10 Arbovirus Panel is a multiplex real-time RT-PCR test intended for use with STANDARD M10 system for the qualitative detection of Arbovirus; Dengue virus(DENV), Zika virus(ZIKV), Chikungunya virus(CHIKV), Yellow Fever virus(YFV) and West Nile virus(WNV) nucleic acids in human serum or plasma sample.

<b>Test type</b>	Professional Use Only
<b>Specimen type</b>	Serum, Plasma
<b>Storage condition</b>	2 ~ 28°C

### Advantage

- All-in-one cartridge (NA extraction + amplification)
- Simultaneous detection of DENV, ZIKV, CHIKV, YFV and WNV
- Serum / plasma sample
- Room temperature storage

### Ordering Information

Products	Tests / Kit	Cat. No.
STANDARD M10 Arbovirus Panel	10 Tests	11ARB10A



## STANDARD M SARS-CoV-2 Real-Time Detection Kit



STANDARD M SARS-CoV-2 Real-Time Detection kit is a real-time RT-PCR assay intended for the *in vitro* qualitative detection of severe acute respiratory syndrome coronavirus 2(SARS-CoV-2) RNA in human nasopharyngeal swab and oropharyngeal swab specimens.

<b>Test type</b>	Professional Use Only
<b>Specimen type</b>	Nasopharyngeal swab, Oropharyngeal swab
<b>Storage condition</b>	-25 ~ -15 °C

### Test Performance

Concentration (copies/ml)	ORF1ab gene	N gene	Limit of Detection (LoD)
4.0 × 10 <sup>6</sup> copies/ml	120/120 (100%)	120/120 (100%)	• ORF1ab gene ~ 1 copies/μl • N gene ~ 0.5 copies/μl
2.0 × 10 <sup>6</sup> copies/ml	120/120 (100%)	120/120 (100%)	
1.0 × 10 <sup>6</sup> copies/ml	119/120 (99%)	120/120 (100%)	
5.0 × 10 <sup>5</sup> copies/ml	108/120 (90%)	115/120 (95%)	
2.5 × 10 <sup>5</sup> copies/ml	78/120 (65%)	101/120 (84%)	

### Ordering Information

Products	Tests / Kit	Cat. No.
M SARS-CoV-2 Real-Time Detection Kit	100 Tests	11NCO30



## STANDARD M nCoV Real-Time Detection Kit



STANDARD M nCoV Real-Time Detection kit is used for identification and detection of SARS-CoV-2 ORF1ab (RdRp) gene and E gene in human nasopharyngeal swab, oropharyngeal swab and sputum specimens using reverse transcription(RT) real-time PCR.

<b>Test type</b>	Professional Use Only
<b>Specimen type</b>	Nasopharyngeal swab, Oropharyngeal swab, Sputum
<b>Storage condition</b>	-25 ~ -15 °C

### Test Performance

Reference	Clinical Sensitivity	Clinical Specificity	Limit of Detection (LoD)
RT-PCR	100% (120/120, 95% CI: 96.97% -100%)	100% (157/157, 95% CI:97.68% -100%)	• ORF1ab (RdRp) gene- 0.5 copies/μl • E gene-0.5 copies/μl

### Ordering Information

Products	Tests / Kit	Cat. No.
M nCoV Real-Time Detection kit	96 Tests	11NCO10



qPCR REAGENT - RESPIRATORY DISEASE

**STANDARD M**  
**SARS-CoV-2/Variant I Real-Time Detection Kit** 

STANDARD M SARS-CoV-2/Variant I Real-Time Detection Kit is a real-time RT-PCR assay intended for the in vitro qualitative detection and differentiation of SARS-CoV-2 RNA and the Omicron variant in human nasopharyngeal swab specimens.



**Test type** Professional Use Only  
**Specimen type** Nasopharyngeal swab  
**Storage condition** -25 ~ -15 °C

**Test Performance**

Concentration (copies/ml)	ORF1ab gene	N gene	S gene_ins214EPE	S gene_E484A	Limit of Detection (LoD)
4.0 × 10 <sup>5</sup> copies/ml	144/144 (100%)	144/144 (100%)	144/144 (100%)	144/144 (100%)	
2.0 × 10 <sup>5</sup> copies/ml	144/144 (100%)	144/144 (100%)	<b>141/144 (97.9%)</b>	<b>144/144 (100%)</b>	
1.0 × 10 <sup>5</sup> copies/ml	<b>144/144 (100%)</b>	<b>143/144 (99.3%)</b>	124/144 (86.1%)	134/144 (93.1%)	- SARS-CoV-2 Wild Type - 1 copies/µl - Omicron Variant - 2 copies/µl
5.0 × 10 <sup>4</sup> copies/ml	135/144 (93.8%)	134/144 (93.1%)	88/144 (61.1%)	125/144 (86.8%)	
2.5 × 10 <sup>4</sup> copies/ml	104/144 (72.2%)	120/144 (83.3%)	51/144 (35.4%)	95/144 (66.0%)	

**Ordering Information**

Products	Tests / Kit	Cat. No.
M SARS-CoV-2/Variant I Real-Time Detection Kit	100 Tests	11NC050



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