

**STANDARD M10****Versatile Point-of-Care MDx Platform**

This product is used with SD BIOSENSOR's M10 Console & Module.



## STANDARD **M10**

# SARS-CoV-2

*All-in-one platform that can detect SARS-CoV-2 ORF1ab gene and E gene simultaneously.*

### Molecular Multi-Respiratory infections Point-of-Care Test

- Presence of **SARS-CoV-2**
- Simultaneous detection of **ORF1ab gene and E gene**
- 100% of sensitivity and specificity
- More accurate, simpler and faster clinical decision making near-the-patient

### All-in-one Cartridge Sample-in Result-out

- Real-Time PCR
- **NA extraction + amplification**
- Multiplex assay up to **12-plex**
- Including internal control
- Lyophilized reagents for stability
- Room temperature storage

### Versatile Point-of-Care MDx Platform

- Small footprint
- Random assessable
- Scalable
- 1 minute hands-on prep
- **30-60 minutes** of testing time
- Minimized maintenance requirements

## SPECIFICATONS

<b>Cat no.</b>	11COV10A
<b>Method</b>	<b>All-in-one Cartridge</b> Viral RNA Extraction : Column Method RNA Amplification : RT-PCR
<b>Target gene</b>	<b>ORF1ab gene, E gene</b> Internal Control (IC)
<b>Sample type</b>	Nasopharyngeal swab (VTM / UTM) 600 $\mu$ l
<b>Limit of Detection (LoD)</b>	ORF1ab gene – 6.63x10 <sup>-4</sup> TCID <sub>50</sub> /ml E gene – 6.63x10 <sup>-4</sup> TCID <sub>50</sub> /ml
<b>Testing time</b>	<b>30 - 60 minutes</b>
<b>Storage temp.</b>	2~28°C
<b>Test / Kit</b>	10 Tests



STANDARD™ M10 SARS-CoV-2

## CLINICAL PERFORMANCE

The performance of STANDARD M10 SARS-CoV-2 was evaluated using retrospective nasopharyngeal swab specimens in transport medium. Specifically, 120 negative nasopharyngeal specimens and 109 positive specimens were collected from patients with symptoms of respiratory infection. Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) were determined by comparing the results of the STANDARD M10 SARS-CoV-2 relative to the results of a SARS-CoV-2 FDA EUA RT-PCR test.

		US FDA EUA approved RT-PCR reagent		
		Positive	Negative	Total
STANDARD M10 SARS-CoV-2	Positive	109	0	109
	Negative	0	120	120
	Total	109	120	229
<b>Sensitivity</b>		<b>100%</b> (109/109, 95% CI: 96.67% - 100%)		
<b>Specificity</b>		<b>100%</b> (120/120, 95% CI: 96.97% - 100%)		

## TEST PROCEDURE

### 1 Sample ID Scan



### 2 Cartridge Scan



### 3 Sample Transfer



### 4 Cartridge Loading



## ORDERING INFORMATION

### Instrument

Cat. No.	Product	Contents
11M1011	STANDARD M10 Console	1 M10 Console (Operational module)
11M1012	STANDARD M10 Module	1 M10 Module (Analytical module)

### Cartridge

Cat. No.	Product	Pathogens
11COV10A	STANDARD M10 SARS-CoV-2	SARS-CoV-2 (ORF1ab gene, E gene)
11FLU10A	STANDARD M10 Flu/RSV/SARS-CoV-2	Influenza A, Influenza B, RSV, SARS-CoV-2 (ORF1ab gene, N gene)