

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

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

**IVDR**

STANDARD **M10**

Flu/RSV/SARS-CoV-2

All-in-one platform that can detect Influenza A, Influenza B, RSV, SARS-CoV-2 simultaneously.

Reliable Molecular Test for Multiple Respiratory Pathogens

- Detection of **Flu A, Flu B, RSV, SARS-CoV-2**
- Diagnosis of co-infection respiratory tract at the same time
- 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 access
- Scalable configuration
- 1 minute hands-on prep
- **30-60 minutes** of testing time
- Minimized maintenance requirements

SPECIFICATONS

Cat no.	11FLU10A
Method	All-in-one Cartridge Viral RNA Extraction : Column Method RNA Amplification : RT-PCR
Target pathogen	Influenza A, Influenza B, RSV, SARS-CoV-2 (ORF1ab gene, N gene)
Sample type	Nasopharyngeal swab (VTM / UTM) 300 μ l
Limit of detection	Flu A - 399 copies/mL Flu B - 399 copies/mL RSV - 795 copies/mL SARS-CoV-2 - 795 copies/mL
Testing time	30-60 minutes
Storage temp.	2~28°C
Test / Kit	10 Tests



STANDARD™ M10
Flu/RSV/SARS-CoV-2

TEST PROCEDURE

1 Sample ID Scan



2 Cartridge Scan



3 Sample Transfer



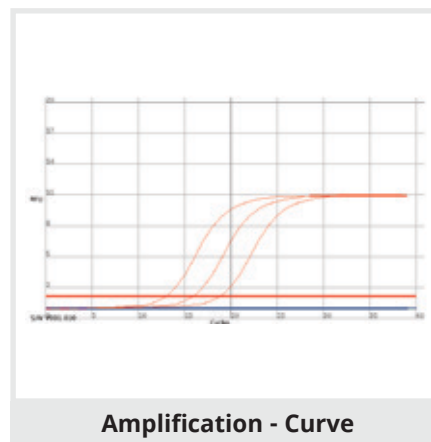
4 Cartridge Loading



RESULT EXAMPLE

Summary	Amplification	Details
Test Information		
Assay Name	Flu/RSV/SARS-CoV-2	
Patient ID		
Sample ID	1	
Test Type	Specimen	
Start Time	2023/02/04 10:12:08	
End Time	2023/02/04 10:12:22	
User	admin	
Result		
Pathogen		
Flu A	Not	
Flu B	Not	
RSV	Not	
SARS-CoV-2	Not	

Summary



Summary	Amplification	Details
Assay Name	Flu/RSV/SARS-CoV-2	
User	admin	
Patient ID		
Sample ID	1	
Sample Type	UTM	
Cartridge Lot No.	MNC00323001	
(New) Lot No.	BCB54LAC	
Cartridge Exp	2023/10/19	
Module S/N	MA3DC02EA0092	
Start Time	2023/02/04 10:12:08	
End Time	2023/02/04 10:12:22	

Details

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
11FLU10A	STANDARD M10 Flu/RSV/SARS-CoV-2	Influenza A, Influenza B, RSV, SARS-CoV-2 (ORF1ab gene, N gene)
11COV10A	STANDARD M10 SARS-CoV-2	SARS-CoV-2 (ORF1ab gene, E gene)