

STANDARD M10**Versatile Point-of-Care
Molecular Diagnostic
Platform**

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



STANDARD **M10**

HPV

Simultaneous detection of HPV DNA with genotyping 16, 18, and 12 other high risk HPV.


IVDR

Detects more than 99% of types of HPV that causes cervical cancer

- Presence of DNA with high risk genotyping **16, 18, and 12 others** (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68)

More accurate and sensitive Molecular Multi-HPV Test

- Limit of detection :
HPV 16 - 51 cells/mL
HPV 18 - 21 cells/mL

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 Molecular Diagnostic Platform

- Small footprint
- Random access
- Scalable configuration
- Simple pretreatment process
- **64 minutes** of testing time

SPECIFICATIONS

Cat no.	11HPV10A
Method	All-in-one Cartridge Bacterial DNA Extraction: Column Method Nucleic Acid Amplification: PCR
Target gene	DNA E6/E7 gene of High risk HPV16,18 12 Others (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68) Internal Control (IC)
Sample type	Cervical swab, 1.4mL (VTM,UTM)
Limit of Detection (LoD)	HPV 16 – 51 cells/mL HPV 18 – 21 cells/mL 12 other HPV high risks – 54 ~ 158 copies/reaction (1 copies/reaction = 50 copies/mL)
Testing time	64 minutes
Storage temp.	2 ~ 28°C
Test / Kit	10 Tests



STANDARD™ M10 HPV

M10 HPV FOLLOWS WHO'S HPV DIAGNOSTIC GUIDE (DNA BASED PCR TEST)

Recommended use of HPV DNA vs HPV mRNA NAATs

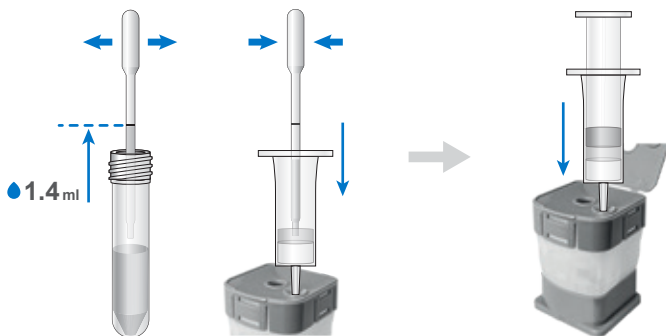
HPV DNA NAATs	HPV mRNA NAATs
Recommended* as the preferred primary screening test in both "screen-and-treat" and "screen, triage and treat" strategies to prevent cervical cancer in the general population, starting at age 30	Suggested* as an alternative primary screening test in both "screen-and-treat" and "screen, triage and treat" strategies to prevent cervical cancer in the general population, starting at age 30
Recommended* as the preferred primary screening test and suggested* for use within a "screen, triage and treat" strategy to prevent cervical cancer in women living with HIV, starting at age 25	No recommendation for use in women living with HIV because no applicable evidence was identified
5- to 10-year screening intervals suggested* in the general population, and 3-5 years in women living with HIV	5-year screening intervals suggested* in the general population
Samples taken by health-care provider or self-collected	Samples taken by health-care provider ONLY * "Recommended" = strong recommendation; "suggested" = conditional recommendation.

*Source: Human papillomavirus (HPV) nucleic acid amplification tests (NAATs) to screen for cervical pre-cancer lesions and prevent cervical cancer, 16 March 2022 | WHO Policy brief

TEST PROCEDURE

0 Specimen preparation

1. Prepare the specimen in VTM or UTM and take a sample using dropper
2. Put the sample into cartridge



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
11HPV10A	STANDARD M10 HPV	High risk HPV 16, 18, and others (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68)