A Comprehensive Solution for HPV Genotyping

Distinguish 28 types of HPV in a single reaction
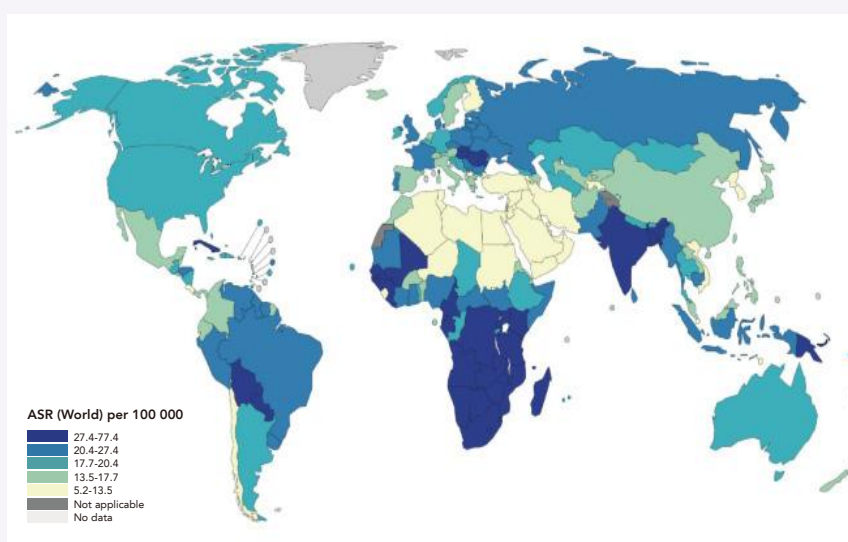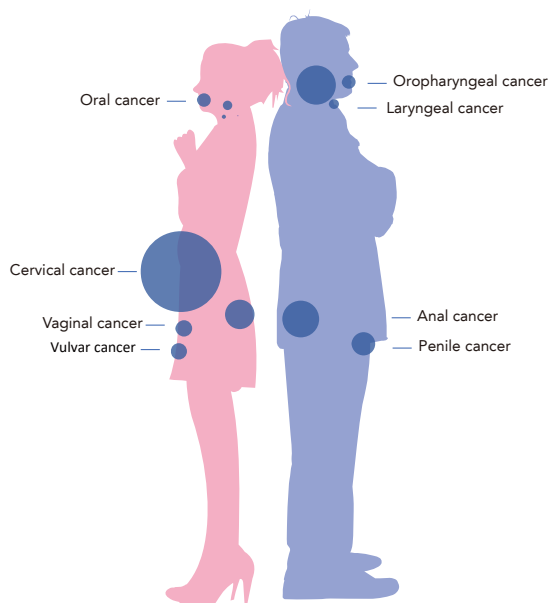
14 HPV screening

14 high-risk HPV genotypes

14 low-risk HPV genotypes

CE IVD

HPV is the most common sexually transmitted infection (STI). In 2022, approximately 831,204 cancer cases (11.4% in men, 88.6% in women) and 422,935 deaths (10.4% in men, 89.6% in women) were attributed to HPV infection, with cervical cancer accounting for the largest proportion (75.6% of cases).
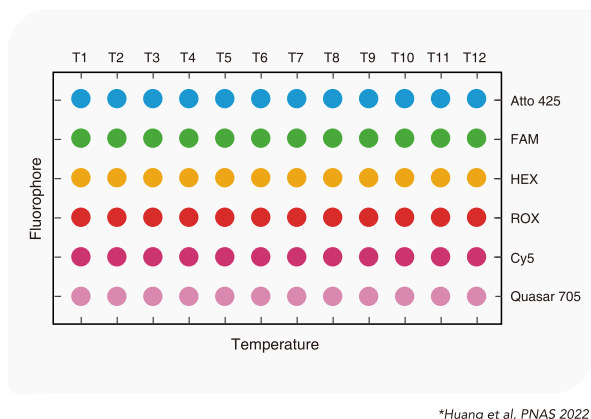
Age-standardized incidence rate of eight HPV-related cancers by geographic region.

Oral cancer
Oropharyngeal cancer
Laryngeal cancer
Cervical cancer
Vaginal cancer
Vulvar cancer
Anal cancer
Penile cancer

ASR (World) per 100 000
- 27.4-77.4
- 20.4-27.4
- 17.7-20.4
- 13.5-17.7
- 5.2-13.5
- Not applicable
- No data

Zhang, J., Ke, Y., Chen, C., et al. HPV cancer burden by anatomical site, country, and region in 2022[J]. Scientific Report, (2025) 15: 21048

Technology

Patented **M**ulticolor **M**elting **C**urve **A**nalysis (**MMCA**®) and **MeltArray** maximize the number of targets per channel, delivering high-level multiplex detection in a single reaction while saving samples and time.
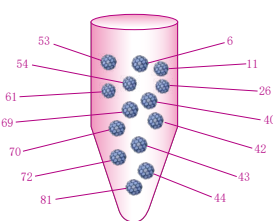

T1 T2 T3 T4 T5 T6 T7 T8 T9 T10 T11 T12

Atto 425
FAM
HEX
ROX
Cy5
Quasar 705

Fluorophore

Temperature

Huang et al, PNAS 2022

MeltArray 2D Label = Fluorescence Channels + Melting Curve

1 test, 28 HPV genotypes

14 High-Risk HPV

51 16
52 18
56 31
58 33
59 35
66 39
68 45

14 Low-Risk HPV

53 6
54 11
61 26
69 40
70 42
72 43
81 44
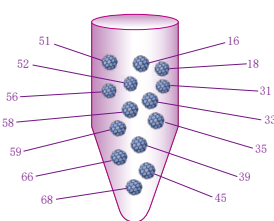
Advantages

28 HPV genotypes identified in a single reaction

94 samples in **2.5** hours

Unique **MMCA®/ MeltArray** multiplex PCR to save precious samples

Automated workflow from sample to result

Specifications

Items	Information
Types	14 High-Risk HPV: 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68
	14 Low-Risk HPV: 6, 11, 26, 40, 42, 43, 44, 53, 54, 61, 69, 70, 72,
Reagent type	Pre-loaded lyophilized reagent
Sample size	25 μL
Detection specificity	>99%
LoD	500 copies/reaction
Reference gene	*GAPDH*
Internal control	Positive and negative control are included

HPV Genotyping Detection Workflow

Option 1 → **Integrated Workflow**

Sanity 2.0s All-in-One Platform

- Sample-in, result-out
- Minimal hands-on time
- Pre-loaded reagents
- Small footprint

(Flexible loading of 1-4 samples)

Option 2 → **High-Throughput Detection Workflow**

Automated Nucleic Acid Extraction
(Up to 96 samples)
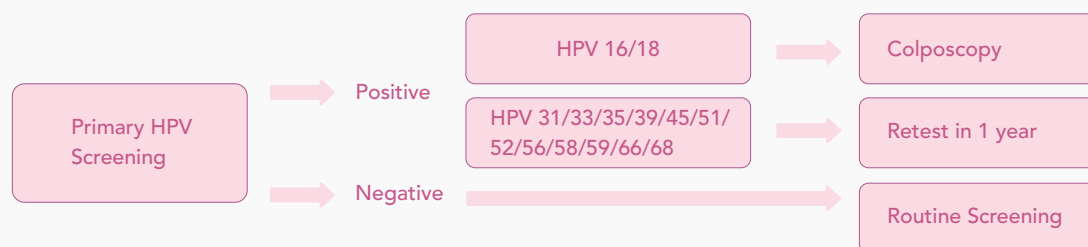
qPCR Detection
(Up to 94 samples)

Data Interpretation

Screening for 14 types of high-risk HPV

Primary HPV Screening → Positive

HPV 16/18 → Colposcopy

HPV 31/33/35/39/45/51/52/56/58/59/66/68 → Retest in 1 year

Primary HPV Screening → Negative → Routine Screening

Verification of experimental results

was originally found to be 56%, but, when adjusted, this accuracy rose to 80% (Table 2).

DISCUSSION

Near-patient hrHPV testing in LMICs has the potential to improve outcomes of cervical cancer screening programs by reducing screening costs with use of high-throughput PCR devices, improving care efficiency, and improving retention of at-risk participants. The ideal LMIC test should be sensitive, specific, user friendly, and robust; require minimal equipment; and be rapid and affordable.[21] With those attributes in mind, hrHPV MMCA near-patient testing was implemented in two separate field locations, each providing representative challenges typical of LMICs.

The hrHPV MMCA assay was highly sensitive and specific at both field sites and accuracy of HPV genotyping enabled additional participant risk stratification, potentially reducing the impact of screening on a taxed health-care system. Since the link of cervical cancer to HPV infection was made, approximately 70% of cervical cancer cases have been linked to infection with HPV16 or

box tests to avoid multiple procedural steps. The hrHPV MMCA achieves this by providing lyophilized hrHPV master mix prepackaged into PCR strip tubes. Temperatures at field sites in Honduras reached > 32.2°C, with high levels of humidity and no access to refrigeration for reagent storage. After 4 days of exposure to elevated temperatures, no differences in test sensitivity or specificity were observed. In addition, minimally trained personnel needed only to pipet crude lysate directly into the lyophilized reagents and place the reaction tubes into the quantitative PCR (qPCR) thermocycler for successful analysis. As noted, invalid rates were highest during the testing at the first field site but dropped in the more infrastructure-challenged

Table 2. Genotyping Accuracy of Multicolor Melt Curve Analysis Using Field Protocol

HPV Type	Accuracy (%)	Adjusted Accuracy (%)
16	100	100
18	100	100
59	78	78
68	88	100
58	91	100
31	100	100
39	100	100
Coinfections	56	80

NOTE: Out-of-the-box multicolor melt curve analysis was used to

Zeesan HPV Assay offers high sensitivity and specificity, which reduces the risk of progression to cervical precancer / cancer due to undefined genotypes.

Experimental results shows the high stability of **Zeesan HPV Assay**.

Turner S A , Deharvengt S J , Lyons K D , et al. Implementation of Multicolor Melt Curve Analysis for High-Risk Human Papilloma Virus Detection in Low- and Middle-Income Countries: A Pilot Study for Expanded Cervical Cancer Screening in Honduras[J]. Journal of Global Oncology, 2018(4):1-8.

Product Information

Cat.No.	Product name	Size	Compatible Platform
608112	HPV DNA Extraction Kit (Sanity 2.0)	24 Tests/Kit	Sanity 2.0s System
801170	High Risk HPV Genotyping Kit (Sanity 2.0)	24 Tests/Kit	
801946	MeltArray High Risk HPV Genotyping Assay (Sanity)	24 Tests/Kit	
801916	Low Risk HPV Genotyping Kit (Sanity 2.0)	24 Tests/Kit	
604106	Lab-Aid 824 HPV DNA Extraction Kit	48 Tests/Kit	824s/896 Extraction System + SLAN Real-time PCR System
610104	HPV DNA Extraction Kit (Lab-Aid 896)	96 Tests/Kit	
801011	MeltPro® High Risk HPV Genotyping Assay (MMCA)	48 Tests/Kit	
801943	MeltArray High Risk HPV Genotyping Assay	48 Tests/Kit	
801013	MeltPro® Low Risk HPV Genotyping Assay	48 Tests/Kit	

For more information, please visit http://www.zeesandx.com