ZEESAN Biotech
致善生物

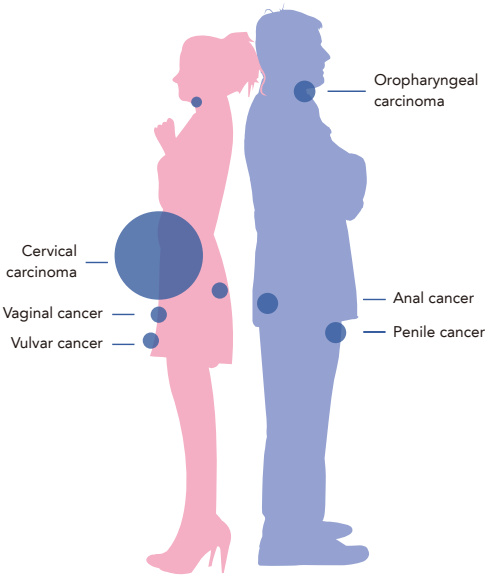
A Comprehensive Solution for HPV Genotyping

Distinguish 14 types of HPV in a single tube

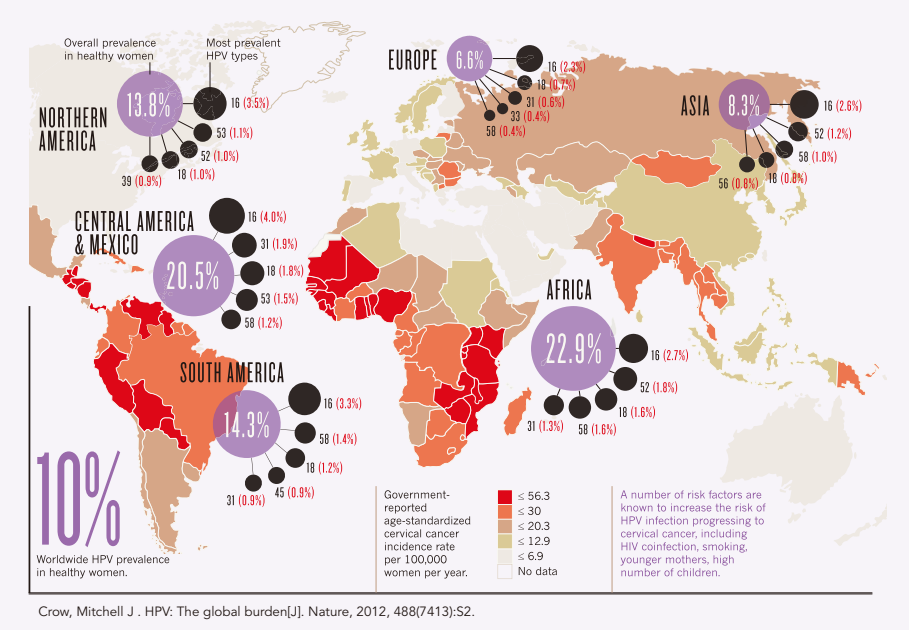
14 high-risk HPV genotypes

14 low-risk HPV genotypes

HPV is the most common sexually transmitted infections(STI). There were about 43 million HPV infections in 2018, many of them were found in their late teens and early 20s. There are many different types of HPV. Some types can cause health problems, including genital warts and cancers.



Overall HPV prevalence and percentage of each genotype in different regions



Crow, Mitchell J . HPV: The global burden[J]. Nature, 2012, 488(7413):S2.

HPV Product Advantages

Single-tube for 14 high-risk or 14 low-risk HPV genotyping

94 samples in 2.5 hours

Patented technology
MMCA®

Automated
Result interpretation

Reagent Information

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, 81
Reagent type	Pre-loaded freeze-dry reagent
Sample size	25 μL
Time to result	2.5 hours
LoD	500 copies/reaction
Specificity	98.63%
Reference gene	GAPDH
Result	Automated interpretation

HPV Genotying Detection Workflow

Option 1 MeltPro® HPV Genotyping Detection Workflow

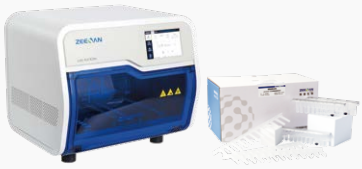
Automated High Throughput Extraction Solutions (96 samples)

Lab-Aid 896 Nucleic Acid Extraction System

process up to **96** samples in a single run, in batches of **12**

Automated Medium Throughput Extraction (24 samples)

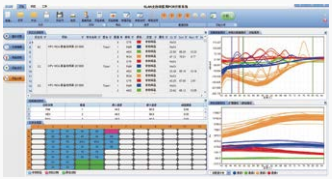
Lab-Aid 824s Nucleic Acid Extraction System

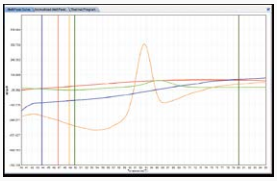


process **1-24** samples in a single run

Multicolor Melting Curve Analysis (MMCA®)

Sample Report (e.g. HPV 16 positive)





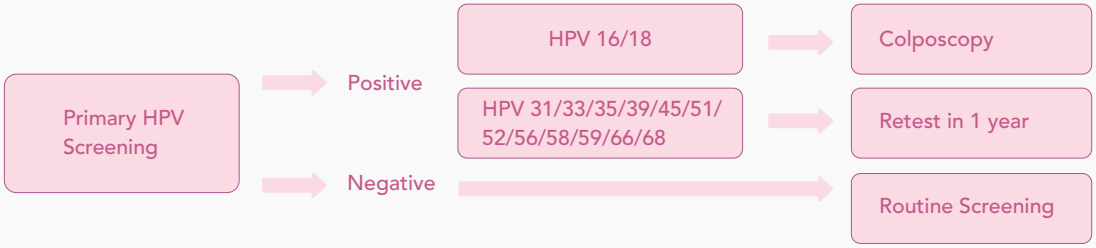
Option 2 Integrated Detection Platform

01 Sample Loading

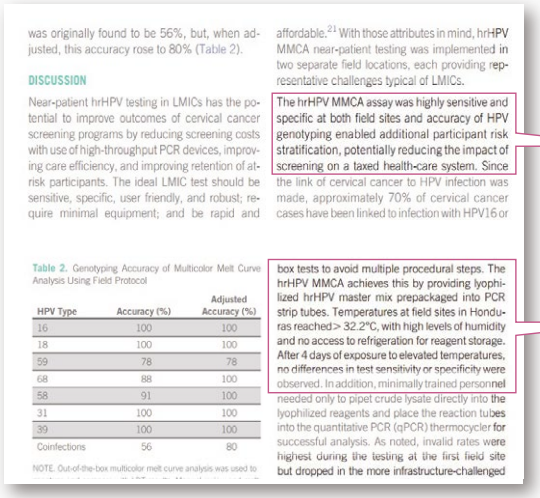
02 Sanity 2.0 System

WHO guideline for screening and treatment of cervical pre-cancer lesions for cervical cancer prevention

Screening for 14 types of high-risk HPV



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

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

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

MeltPro® HPV 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 **MeltPro® HPV**.

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.

Products Information

Cat.No.	Product name	Specification / Model
604106	Lab-Aid 824 HPV DNA Extraction Kit	48 Tests/Kit
610104	HPV DNA Extraction Kit (Lab-Aid 896)	96 Tests/Kit
608112	HPV DNA Extraction Kit (Sanity 2.0)	24 Tests/Kit
801170	High Risk HPV Genotyping Kit (Sanity 2.0)	24 Tests/Kit
801011	MeltPro® High Risk HPV Genotyping Assay (MMCA)	48 Tests/Kit
801013	MeltPro® Low Risk HPV Genotyping Assay	48 Tests/Kit
505101	Sanity 2.0 System	Sanity® 2.0
502602	Real-Time PCR System (SLAN-48P)	SLAN® 48P
502601	Real-Time PCR System (SLAN-96P)	SLAN® 96P
502603	Real-Time PCR System (SLAN-96S)	SLAN® 96S
501101	Lab-Aid 824s Nucleic Acid Extraction System	Lab-Aid® 824s
501110	Nucleic Acid Extraction System (Lab-Aid 896)	Lab-Aid® 896

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

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