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Comparative analysis of SD biosensor standard™ M10 HPV and seegene anyplex™ II HPV HR for detecting high-risk human papillomavirus: a concordance study

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Abstract

Background Cervical cancer, primarily caused by persistent high-risk human papillomavirus (hrHPV) infections, is a significant health burden, particularly in low-resource settings such as Sarawak, Malaysia. Effective prevention depends on effective vaccination and early hrHPV detection. This study compares the performance of the point-of-care test (POCT) SD Biosensor Standard™ M10 HPV and laboratory-based Seegene Anyplex™ II HPV HR assay, focusing on their ability to detect and genotype hrHPV in self-collected high vaginal swab samples.

Methods A total of 151 archived self-sampled high vaginal swabs from the Sarawak Urban and Rural Action for Cervical Cancer Elimination Programme (*Program SUARA*) were analyzed. hrHPV detection and genotyping were performed using Anyplex, which identifies 14 hrHPV genotypes, and M10, which detects HPV16, HPV18, and other hrHPV categorized into six genogroups. Agreement between the assays was evaluated using Cohen's Kappa (κ), McNemar's test, and overall agreement percentages. Statistical significance was determined with p-values, and discordant results were further analyzed for potential diagnostic implications.

Results The overall agreement between M10 and Anyplex for hrHPV detection was 92.05% (κ = 0.84, 95% CI 0.75–0.93), indicating almost perfect agreement. M10 demonstrated comparable sensitivity for detecting HPV16, HPV18, and other hrHPV genotypes, achieving 96.91% agreement (κ = 0.89, 95%CI 0.73-1.00) in hrHPV classification when discordant results were excluded. Genogrouping also showed almost perfect agreement (κ = 0.91, 95% CI 0.82–0.98). McNemar's test indicated no significant difference in hrHPV detection rates (*p* > 0.05), affirming their comparable performance in detecting clinically significant hrHPV infections.

Conclusion The SD Biosensor Standard™ M10 HPV POCT and the Seegene Anyplex™ II HPV HR assay demonstrated almost perfect agreement in hrHPV detection and classification, supporting their complementary roles in cervical cancer prevention. M10's rapid, field-deployable design makes it suitable for resource-limited settings, while Anyplex provides enhanced genotyping capability in laboratory environments, allowing informed vaccine strategy.

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Incorporating both assays into cervical cancer prevention programs can improve screening coverage and accessibility, particularly in underserved areas. These findings align with the World Health Organization's cervical cancer elimination goals, reinforcing the importance of adaptable diagnostic tools in diverse healthcare contexts.

Keywords Human papillomavirus, Cervical cancer, Point-of-care, Self-sampling, Standard M10 HPV, Anyplex

Background

Cervical cancer is predominantly driven by persistent infections with high-risk human papillomavirus (hrHPV) types, making it one of the most preventable cancers through comprehensive early screening and HPV vaccination. In Malaysia, cervical cancer ranks as the third most common cancer and is the second leading cause of cancer-related deaths among women [1]. In 2020, the age-standardized incidence rate of cervical cancer in Malaysia was 10.2 per 100,000 women, with Sarawak consistently recording the highest incidence at 12.1 per 100,000 [2]. These statistics underscore the urgency of improving vaccination coverage and screening, especially in regions with high incidence rates, as Malaysia works towards the World Health Organization's (WHO) Cervical Cancer Elimination Initiative goal of reducing cervical cancer incidence to fewer than 4 cases per 100,000 women [3].

Sarawak, Malaysia's largest region, faces significant healthcare access challenges, with more than half its population living in rural or hard-to-reach areas. These logistical barriers make reaching underserved populations essential for achieving cervical cancer elimination targets [2]. In response, Universiti Malaysia Sarawak (UNIMAS) in collaboration with Pink and Teal Empowher, a non-governmental organization and state government stakeholders and ministries, initiated HPV diagnostic efforts in 2018 with conventional Polymerase Chain Reaction (PCR) on clinician-collected cervical swabs [4]. In 2019, the programme expanded to include self-sampling and hrHPV detection using the careHPV system (Qiagen) [5], which was well-suited for low-resource settings [6]. However, the careHPV system lacked genotyping capability and internal control, limiting its effectiveness in providing a comprehensive profile of hrHPV genotype distribution in Sarawak. Furthermore, careHPV system was reported to be less sensitive when combined with self-sampling, especially among the older women [7].

To address these limitations, the careHPV system was replaced in 2023 with Seegene's Anyplex™ II HPV HR system (Anyplex), offering both genotyping and an internal control. Yet, while Anyplex improved diagnostic depth, it relies on laboratory-based batch processing, reducing its applicability for point-of-care testing—a critical feature for effective screen-and-treat strategies in remote areas. In late 2024, the Standard M10 cartridge-based HPV test was adopted, providing a portable, sample-to-result solution in approximately one hour. This system not only detects HPV16, HPV18, and other hrHPV genotypes (grouped as G1-G6) but also enables field-based testing, directly supporting the *Sarawak Urban and Rural Action* for Cervical Cancer Elimination Programme (*Program SUARA*) [8], which aims to extend advanced hrHPV diagnostics to underserved communities.

To our knowledge, no comparative study has evaluated M10's utility in detecting hrHPV. This study aims to evaluate the concordance between M10 HPV systems against Anyplex for hrHPV detection and genotyping in Sarawak. Through this comparison, we aim to identify optimal diagnostic strategies that enhance accessibility and accuracy in HPV testing, supporting Sarawak's broader cervical cancer prevention initiatives.

Materials and methods

Specimens

The minimum sample size was estimated using Open Epi Sample size calculator (https://www.openepi.com/) at 139 samples, based on an expected agreement rate of 90%, a ± 5% margin of error, and a 95% confidence level. To ensure robustness, the study included 151 samples, which exceeded the calculated requirement.

The 151 archived self-sampled high vaginal swabs (HVSs) were obtained from *Program SUARA* HPV Laboratory at the Faculty of Medicine and Health Sciences, Universiti Malaysia Sarawak, Kota Samarahan, Sarawak, Malaysia. The mean age of the participants was 34.35 years (SD = 7.84, 24–64), with a median age of 33 years.

These samples consisted of 72 hrHPV positive and 79 hrHPV negative samples previously confirmed via Anyplex™ II HPV HR Detection (Seegene, South Korea) were included in this study Anyplex can simultaneously detects, differentiate, and quantifies 14 high-risk HPV genotypes (HPV16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68) in a single reaction. The semiquantitative genotyping results were categorised into three levels corresponding to cyclic-Catcher Melting Temperature Analysis (CMTA) cycle 30 (+++), 40 (++), and 50 (+) [9]. The nucleic acid was extracted on a 48-well Genti™ Advanced Viral DNA/RNA Extraction kit (GenAll, South Korea), and detection was carried out on CFX96 DX Real-Time PCR Detection System (Bio-Rad, California, USA) (see Supplementary Material 1). These samples were anonymised and blinded to the operator. All tests were valid by the detection of the respective internal controls.

Table 1 Comparison of M10 (SD Biosensor) and anyplex (Seegene) for the detection of hrHPV

M10	Anyplex		TOTAL	Cohen Kappa (κ) (*95% CI*)	McNemar
	NEG	**POS**			
NEG	74	7	**81**	**0.84**	**0.77**
POS	5	65	**70**	*(0.75–0.93)*	*(p > 0.05)*
TOTAL	**79**	**72**	**151**		

Table 2 The comparison between M10 and anyplex in their ability to classify hrHPV into HPV16, 18 and Other

M10	Anyplex						TOTAL	Cohen's kappa (κ) (95% CI)	McNemar
	16	**18**	**16 and Other**	**16, 18**	**18 and Other**	**Other**			
16	1						**1**	**0.89**	**0.48**
18		5			1		**6**	*0.73-1.00*	*(p > 0.05)*
16 & Other			1				**1**		
16, 18 & Other				1			**1**		
18 and Other					1		**1**		
Other						55	**55**		
TOTAL	**1**	**5**	**1**	**1**	**2**	**55**	**65**		

POCT hrHPV

The samples were retested using the Standard M10 HPV system (SD Biosensor, South Korea) according to the manufacturer's instruction (see Supplementary Material 1) for the qualitative detection of HPV16, 18 and other hrHPV (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68). The other 12 hrHPV were semi-genotyped into six [6] groups, namely G1 (HPV51-species α-5), G2 (HPV33, 52, 58-species α-9), G3 (HPV31, 35- species α-9), G4 (45, 59 species α-7), G5 (HPV39, 68 species α-7), and G6 (HPV56, 66- species α-6) [10]. This assay will be referred to as M10 throughout this manuscript.

Data analyses

Firstly, we compared the performance of M10 [1] to detect hrHPV; [2] to differentiate hrHPV into HPV16, HPV18 and other hrHPV; and [3] genogrouping of other hrHPV to G1, G2, G3, G4, G5, G6 in comparison to the results obtained from Anyplex. All results were reclustered accordingly to allow for comparison. The flow of data and exclusion criteria is shown in Supplementary Material 2.

  All results were tabulated and statistical analyses such as Agreement, Cohen's Kappa (κ) and McNemar coefficients were carried out in SPSS Version 27. The interpretation of the Kappa (κ) coefficient was as follows: 0.81–1.00 indicated almost perfect agreement, 0.61–0.80 good agreement, 0.41–0.60 moderate agreement, 0.21–0.40 fair agreement, 0.00–0.20 minimal agreement, and less than 0.00 signified poor agreement between the assays [11].

Results

Detection of hrHPV

M10 and Anyplex have positive and negative agreement of 90.3% and 93.7%, respectively, which suggests that the results from both assays are in almost perfect agreement with one another (κ = 0.84, 95% CI: 0.75–0.93) and are largely consistent in their ability to detect hrHPV. McNemar's test value (0.77; *p* > 0.05) indicates no significant difference between the assays. Both assays have an overall agreement of 92.05% (Table 1).

Detection of HPV16, HPV18 and other hrHPV

We included 65 concordant samples in the calculation after excluding 7 discordant samples, the overall agreement between the assays was 96.91% (κ = 0.89, 95% CI: 0.73-1.00). McNemar's Test's (*p* > 0.05) shows no statistically significant difference in the discordance between the two tests. It shows that the performance of M10 and Anyplex was almost perfect in classifying hrHPV to HPV16, HPV18 and Others (Table 2).

Non-HPV16/18 genogrouping

We subsequently removed 8 samples that were only positive for HPV16 and 18 and had incomparable discordant results. Of the 57 non-HPV16/18 samples by M10 and Anyplex, we found the overall genogrouping agreement to be 82.5% (κ = 0.91, 95% CI: 0.82–0.98) with almost perfect agreement in comparison with Anyplex. The McNemar's Test (*p* > 0.05) suggests no significant difference between the two assays (Table 3).

Performance

The 7 discordant samples performed on M10 were monoinfections with CTMA + [(HPV16 (x2), 52 (x2), 58,

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Table 3 Comparison between M10 and anyplex in the classification of non-HPV16/18 hrHPV into G1, G2, G3, G4, G5 and G6

M10	Anyplex									TOTAL	Cohen Kappa (κ) 95% CI	McNemar
	G1	G2	G3	G4	G5	G6	G1, G5	G2, G5	G4, G5			
G1	9									9	0.91 0.82–0.98	1.0
G2		18								18		
G3			1							1		
G4				4						4		
G5					8					8		
G6						7				7		
G1, G2		2								2		
G1, G5					1		3			4		
G2, G4		1								1		
G2, G5								2		2		
G4, G5									1	1		
TOTAL	9	21	1	4	9	7	3	2	1	57		(p > 0.05)

39, 51)]. The discordance may be due to the lower sensitivity of M10 compared to Anyplex. It must be noted that 2 monoinfection samples contain HPV16. However, M10 detected 5 more positives that were not detected by Anyplex. These samples can be grouped into G2 (60%), G5 (20%) and G6 (20%) with the mean Ct value of 20.66 (95% CI, $p < 0.05$, Standard Deviation (SD) of 11.72, 9–33) is not close to the manufacturer-set negative cutoff value of Ct > 39. It is worth noting that two G2 samples as determined by M10 had the Ct < 9 and were missed by Anyplex. The actual HPV genotypes missed by Anyplex cannot be elucidated without further unbiased sequence analyses.

Discordances in classifying hrHPV into HPV16, HPV18, and other hrHPV have no clinical impact per our screen-and-treat strategy, as all hrHPV-positive women will be triaged for cervical examination. However, such distinctions may still be informative.

Discussion

Our study aimed to compare the performance of the point-of-care test Standard™ M10 HPV System (SD Biosensor, South Korea) (referred to as M10) against the Anyplex™ II HPV HR Detection (Seegene, South Korea) (referred to as Anyplex). Both assays are CE-IVD certified, and compliant with Malaysia's Medical Device Act (MDA). Since 2023, the *SUARA Program*'s laboratory at Universiti Malaysia Sarawak has adopted the Anyplex assay in combination with self-sampling, especially within remote rural settlements, employing a screen-and-treat strategy where feasible.

This screen-and-treat approach begins with community outreach for self-collected samples, which are then tested in batches using the Anyplex assay as a triaging tool. Individuals testing positive for high-risk HPV (hrHPV) are recalled for a secondary triage-and-treat stage, which includes colposcopy and thermocoagulation as necessary [12]. In contrast, for walk-in patients, a point-of-care test (POCT)-and-treat approach is more practical. M10 can address diagnostic gaps on-site, eliminating the need for repeating the two-stage process, and in return ensuring timely results and treatment.

Our findings revealed nearly perfect agreement between M10 and Anyplex, with an overall agreement of 92.05% (κ = 0.84). This performance is comparable to the Xpert HPV (Cepheid), another cartridge-based POCT, which demonstrated an agreement of 91.5% (κ = 0.844) against Anyplex28, a broader Seegene assay designed to detect additional low-risk HPV types [13]. When Anyplex28 and Xpert HPV were evaluated against the GP5+/6 + EIA comparator HPV assay, sensitivity and specificity were 98.3% and 93.6% for Anyplex28, and 94.1%, and 90.3% for Xpert HPV, respectively [14, 15]. These data suggest that cartridge-based POCTs may

exhibit slightly lower agreement compared to laboratory-based assays [15].

Each HPV DNA assay, however, has unique sensitivity and specificity profiles. For example, the Anyplex assay has been reported with sensitivities ranging from 92.5 to 98.3% and specificities from 81.7 to 94.1% for detecting cervical intraepithelial neoplasia grade 2 or worse (CIN2+) [16, 17, 18]. These performance metrics highlight the balance between sensitivity and specificity in correlating HPV positivity to cytological pathology [19]. While M10 demonstrated slightly lower positive agreement for hrHPV detection than Anyplex, its clinical utility as a triaging tool in resource-limited areas remains significant. By providing accessible and timely screening options, M10 has the potential to expand coverage and save lives. Notably, the careHPV system—though falling short of international standards when used with self-sampling [15] has been successfully implemented in low-resource settings in Cambodia and Tanzania [7, 20]. It is essential to recognize that HPV DNA-based testing represents a paradigm shift in cervical cancer screening, moving from pathology-based detection to identifying the etiological agent. Numerous studies affirm that HPV DNA testing is more sensitive than cytology in detecting precancerous lesions and cervical cancers [21, 22, 23] and any HPV DNA test is better than none.

The WHO's Cervical Cancer Elimination Initiative outlined a three-pronged strategy to eliminate cervical cancer as a public health threat: vaccination, screening, and treatment [3, 24]. The first prong aims to vaccinate 90% of girls under 15 with HPV vaccines. The second prong emphasises screening 70% of women for hrHPV by the age of 35 and again by 45 using validated HPV DNA tests. The third prong ensures that 90% of women diagnosed with precancer or cancer receive appropriate treatment. The use of POCT may ensure that hrHPV-positive women receive appropriate care and treatment within the same day. To address variability in sensitivity and specificity across assays, women testing negative for hrHPV may benefit from retesting within 3–5 years using a validated assay from the same or different manufacturer.

Limitations

Despite having a significant sample size, our samples can be expanded in a population study to improve the power. Our posthoc selection of positive and negative samples may introduce bias but allows a higher number of positive samples to be evaluated for the concordance study. This study focused solely on the concordance between two assays without correlating hrHPV detection with cytological or histopathological outcomes. Anyplex is a clinically validated assay that conforms to international standards for primary cervical cancer screening, the diagnostic implications of discordant cases remain uncertain

without follow-up cytology or colposcopy. While cotesting offers no additional benefit over stand-alone hrHPV DNA testing, it may result in higher colposcopy referrals due to false positives [23]. In our study, all volunteers positive for hrHPV by M10 but previously negative by Anyplex were recalled for cervical examinations. Future concordance studies integrating clinical follow-up would better assess the impact of using M10 in real-world screening program.

Conclusion

The Standard M10 (SD Biosensor, South Korea) and Anyplex II HPV HR (Seegene, South Korea) were found to be in almost perfect agreement to detect hrHPV in high vaginal swabs. No one assay can be regarded as superior or inferior as both have demonstrated their strength and weaknesses.

Abbreviations

CE-IVD	European Conformity-in vitro diagnostic
CIN	Cervical intraepithelial neoplasia
CI	Confidence level
Ct	Cycle threshold
CMTA	Cyclic-Catcher Melting Temperature Analysis
DNA	Deoxyribonucleic acid
HPV	Human papillomavirus
hr	High-risk
MDA	Medical Device Act
PCR	Polymerase chain reaction
POCT	Point-of-care-test
RNA	Ribonucleic acid
SUARA	Sarawak Urban and Rural Action for the Elimination of Cervical Cancer
UNIMAS	Universiti Malaysia Sarawak
WHO	World Health Organisation
κ	Kappa

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12879-025-10714-y.

Supplementary Material 1

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Declarations

Ethics approval and consent to participate
This study was conducted in accordance with the principles of the Declaration of Helsinki. Ethical approval was obtained from Universiti Malaysia Sarawak Medical Ethics Committee (UNIMAS/NC-21.02/03 – 02 Jld.3(17), and written informed consent was obtained from all participants prior to sample collection.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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References
1. Manan A, Nor Saleha IT, Abdullah NH, Asmah ZA, Wahab M. Malaysian National Cancer Registry Report 2007–2011 [Internet]. National Cancer Institute, Ministry of Health Malaysia. 2015 [cited 2019 Jun 24]. Available from: https://drive.google.com/file/d/1pCsJIw0ysFccCMFA0XqzfbYu1OFDRbO_/view
2. Tan CS, Hamzah ND, Ismail ZHF, Jerip AR, Kipli M. Self-sampling in Human Papillomavirus screening during and post-COVID-19 pandemic. Med J Malaysia [Internet]. 2021 [cited 2021 May 28];76(3):298–303. Available from: http://www.ncbi.nlm.nih.gov/pubmed/34031326
3. Cervical Cancer Elimination Initiative [Internet]. [cited 2024 Nov 8]. Available from: https://www.who.int/initiatives/cervical-cancer-elimination-initiative
4. Yi MS, Siang TC, Lwin S, Myint KT, Yee KT, Lwin N et al. Prevalence of Human Papilloma virus in women with Abnormal Cervical Smears from Sarawak, Malaysia. Res J Pharm Technol [Internet]. 2021 May 26 [cited 2021 Sep 1];14(5):2729–34. Available from: https://rjptonline.org/AbstractView.aspx?PID=2021-14-5-65
5. WHO prequalifies additional HPV test. expanding options as countries pursue cervical cancer elimination [Internet]. [cited 2024 Nov 8]. Available from: https://www.who.int/news/item/14-06-2023-who-prequalifies-additional-hpv-test-expanding-options-as-countries-pursue-cervical-cancer-elimination
6. Jerip RA, Kipli M, Hamzah ND, Tan CS. The prevalence of HrHPV among the isolated community in the Highland of Bario, Sarawak, East Malaysia. Res Sq. 2020;PREPRINT(v2).
7. Katanga J, Kjaer SK, Manongi R, Wu C, Sen, Iftner T, Waldstrom M et al. Performance of careHPV, hybrid capture 2 and visual inspection with acetic acid for detection of high-grade cervical lesion in Tanzania: A cross-sectional study. Chuang L, editor. PLoS One [Internet]. 2019 Jun 19 [cited 2020 Feb 21];14(6):e0218559. Available from: https://doi.org/10.1371/journal.pone.0218559
8. Launching of Program SUARA. Sarawak urban and rural action for cervical cancer prevention – UNIMAS Gazette [Internet]. [cited 2024 Nov 19]. Available from: https://gazette.unimas.my/2023/07/28/launching-of-program-suara-sarawak-urban-and-rural-action-for-cervical-cancer-prevention/
9. Kim YJ, Kwon MJ, Woo HY, Paik SY. Prevalence of human papillomavirus infection and genotype distribution determined by the cyclic-catcher melting temperature analysis in Korean medical checkup population. J Microbiol [Internet]. 2013 Oct [cited 2024 Nov 19];51(5):665–70. Available from: https://pubmed.ncbi.nlm.nih.gov/24037659/
10. SD BIOSENSOR| PRODUCTS [Internet]. [cited 2024 Nov 19]. Available from: https://www.sdbiosensor.com/product/product_view?product_no=23003
11. Landis JR, Koch GG. The measurement of observer agreement for categorical data. Biometrics. 1977;33(1):159.
12. WHO guideline for. Screening and treatment of cervical pre-cancer lesions for cervical cancer prevention. 2021;97.
13. Nassereddine H, Charpentier C, Bucau M, Joly V, Bienvenu L, Davitian C et al. Interest of cytology combined with Xpert® HPV and Anyplex® II HPV28 Detection human papillomavirus (HPV) typing: differential profiles of anal and cervical HPV lesions in HIV-infected patients on antiretroviral therapy. HIV Med [Internet]. 2018 Nov 1 [cited 2024 Nov 19];19(10):698–707. Available from: https://onlinelibrary.wiley.com/doi/full/https://doi.org/10.1111/hiv.12661
14. Cuschieri K, Geraets D, Cuzick J, Cadman L, Moore C, Broeck D, Vanden et al. Performance of a cartridge-based assay for detection of clinically significant human papillomavirus (hpv) infection: Lessons from Valgent (Validation of HPV Genotyping Tests). J Clin Microbiol [Internet]. 2016 Sep 1 [cited 2024 Nov 12];54(9):2337–42. Available from: https://doi.org/10.1128/jcm.00897-16
15. Arbyn M, Simon M, Peeters E, Xu L, Meijer CJLM, Berkhof J et al. 2020 list of human papillomavirus assays suitable for primary cervical cancer screening. Clinical Microbiology and Infection [Internet]. 2021 Aug 1 [cited 2024 Oct 31];27(8):1083–95. Available from: http://www.clinicalmicrobiologyandinfection.com/article/S1198743X21002196/fulltext
16. Jung S, Lee B, Kap;, Lee N, Kim Y, Oh EJ. Clinical validation of Anyplex II HPV HR detection test for cervical cancer screening in Korea. meridian.allenpress.comS Jung, B Lee, KN Lee, Y Kim, EJ OhArchives of Pathology & Laboratory Medicine, 2016•meridian.allenpress.com [Internet]. 2016 [cited 2024 Oct 31];140:276–80. Available from: https://meridian.allenpress.com/aplm/article-abstract/140/3/276/65056
17. Hesselink AT, Sahli R, Berkhof J, Snijders PJF, van der Salm ML, Agard D et al. Clinical validation of Anyplex™ II HPV HR Detection according to the guidelines for HPV test requirements for cervical cancer screening. J Clin Virol [Internet]. 2016 Mar 1 [cited 2024 Nov 11];76:36–9. Available from: https://pubmed.ncbi.nlm.nih.gov/26809131/
18. Oštrbenk A, Xu L, Arbyn M, Poljak M. Clinical and analytical evaluation of the anyplex II HPV HR detection assay within the VALGENT-3 framework. J Clin Microbiol. 2018;56(11).
19. Arbyn M, Ronco G, Anttila A, Chris CJL, Poljak M, Ogilvie G, et al. Evidence regarding human papillomavirus testing in secondary prevention of cervical Cancer. Vaccine. 2012;30(SUPPL5):F88–99.
20. Hang S, Haruyama R, Uy K, Fujita N, Kimura T, Koum K et al. Feasibility, accuracy and acceptability of self-sampled human papillomavirus testing using careHPV in Cambodia: a cross-sectional study. J Gynecol Oncol [Internet]. 2023 Jan 1 [cited 2024 Nov 19];35(1):e6. Available from: https://pmc.ncbi.nlm.nih.gov/articles/PMC10792213/
21. Thomsen LT, Kjær SK, Munk C, Ørnskov D, Waldstrøm M. Benefits and potential harms of human papillomavirus (HPV)-based cervical cancer screening: A real-world comparison of HPV testing versus cytology. Acta Obstet Gynecol Scand [Internet]. 2021 Mar 1 [cited 2024 Nov 19];100(3):394–402. Available from: https://onlinelibrary.wiley.com/doi/full/https://doi.org/10.1111/aogs.14121
22. Ali M, Sinha R, kumar A, Karim S, Irfan M, Kumar S et al. HPV DNA status and clinical history of patients are supplements for accurate reporting of the cytological Pap smear. Scientific Reports 2024 14:1 [Internet]. 2024 Jul 30 [cited 2024 Nov 19];14(1):1–8. Available from: https://www.nature.com/articles/s41598-024-68344-4
23. Liang LA, Einzmann T, Franzen A, Schwarzer K, Schauberger G, Schriefer D et al. Cervical cancer screening: Comparison of conventional pap smear test, liquid-based cytology, and human papillomavirus testing as stand-alone or cotesting strategies. Cancer Epidemiology Biomarkers and Prevention [Internet]. 2021 Mar 1 [cited 2024 Nov 20];30(3):474–84. Available from: https://doi.org/10.1158/1055-9965.EPI-20-1003
24. World Health Organization. Global strategy to accelerate the elimination of cervical cancer as a public health problem. World Health Organization [Internet]. 2020 [cited 2024 Nov 19];1–56. Available from: https://www.who.int/publications/i/item/9789240014107

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