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Commentary

Near-point-of-care molecular HPV diagnostics: Pathways to scalable cervical-cancer screening in low- and middle-income countries

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Introduction

Cervical cancer remains a leading cause of preventable death among women. Around 660,000 new cases and 350,000 deaths were reported in 2022. Most of these cases and deaths occurred in low- and middle-income countries [1]. Persistent infection with oncogenic human papillomavirus (HPV) genotypes is an important cause of almost all cervical cancers [2]. The most prevalent types among various subtypes are 16 and 18. Despite advances in HPV vaccination and molecular screening, persistent implementation gaps in laboratory access, supply-chain logistics and workforce capacity continue to impede their scale-up in the Global South [3–5].

High-throughput centralized molecular systems, including the Roche Cobas® 4800/6800 [6], Abbott RealTime High Risk HPV assay [7], and BD Onclarity™ platform [8], are FDA-approved and widely validated as reference standards in high-income countries. However, their dependence on sophisticated instrumentation, continuous power supply, and skilled personnel limit their scalability in primary-care and rural settings across LMICs.

These assays provide robust multiplex genotyping with high analytical precision but depend on complex instrumentation, controlled laboratory environments, continuous power, and skilled operators, conditions rarely met in primary-care settings across LMICs. These limitations have created an urgent need for technologies that combine molecular accuracy with operational simplicity. Consequently, a technological gap persists between laboratory excellence and population coverage. The global shift toward near-point-of-care (near-POC) molecular diagnostics, which are compact, automated systems capable of integrated amplification and detection, offers a breakthrough opportunity to decentralize screening and achieve same-day test-and-treat outcomes. Platforms such as careHPV™, Xpert® HPV, and portable micro-PCR systems (e.g., Truenat®) have demonstrated laboratory-comparable accuracy while operating with minimal infrastructure and simplified workflows. Emerging assays targeting the E6/E7 oncogenes further enhance diagnostic specificity and adaptability to decentralized settings [9–12].

This article provides insights on the translational feasibility of near-POC molecular HPV testing in LMICs, analyzing their analytical performance, operational readiness and implementation potential under the WHO 90-70-90 cervical-cancer elimination framework [3]. It highlights how innovations such as portable PCR platforms, stabilized reagents and self-sampling workflows are bridging the gap between laboratory accuracy and real-world accessibility.

Evolution of Molecular HPV Testing

HPV diagnostic technology has evolved from early hybridization assays to fully automated, real-time amplification platforms. The first FDA-approved assay, Hybrid Capture 2 (HC2; Qiagen),

enabled pooled detection of 13–14 high-risk HPV types but lacked genotyping capability [13]. Subsequent PCR-based assays such as Roche Cobas 4800/6800, Abbott RealTime HPV, and BD Onclarity™ introduced type-specific detection and automated workflows validated under the VALGENT and Meijer criteria [6–8,14]. While such high-throughput platforms remain standard in high-income countries, their infrastructure demands have limited use in LMIC programs, prompting development of simplified, portable molecular formats. Despite their reliability, these laboratory-based systems require sophisticated infrastructure and cold-chain logistics, limiting accessibility in resource-poor regions [15]. To overcome these constraints, developers have engineered simplified, portable molecular assays that preserve analytical rigor while reducing operational demands [16].

The first decentralized advance, careHPV™, developed by Qiagen in collaboration with PATH and the Bill & Melinda Gates Foundation, uses signal-amplified hybrid-capture chemistry to detect 14 high-risk HPV genotypes [17]. Field evaluations in China, India, and Africa demonstrated 84–90% sensitivity for CIN2+ lesions at a fraction of centralized testing costs [18]. Although not a true molecular platform, *careHPV* established the feasibility of low-infrastructure HPV screening in resource-constrained settings.

Next-generation cartridge-based molecular systems, including *Cepheid Xpert® HPV* [10], *Truenat® HPV* (Molbio Diagnostics, India) and the indigenous *Load-and-Go HPV* molecular platform developed by Mylab Discovery Solutions (India), integrate nucleic-acid extraction, amplification, and detection within closed, self-contained cartridges [19]. Multi-site validation studies across Africa and India demonstrate sensitivities >90% and specificities >85% for CIN2+ detection, comparable to centralized Cobas 4800 assays [20].

Concurrently, emerging isothermal amplification, CRISPR–Cas, and microfluidic lab-on-chip technologies are being adapted for rapid HPV testing [21–23]. Early prototypes achieve detection limits <100 copies per reaction within 40 minutes, underscoring convergence between molecular precision and true point-of-care accessibility [24]. Collectively, these advances mark a paradigm shift from centralized laboratories to field-deployable molecular HPV diagnostics, aligning with global cervical-cancer elimination strategies [25].

Analytical and Clinical Performance of Near-POC Molecular HPV Platforms

Near-point-of-care (near-POC) molecular platforms aim to preserve laboratory PCR accuracy while enabling decentralized screening. A true near-POC assay integrates sample preparation, nucleic-acid amplification and detection in a self-contained cartridge or chip, lowering contamination risk and operator dependence. This section synthesizes analytical validity, reproducibility, and field-level clinical performance for near-POC/POC assays relevant to low- and middle-income country (LMIC) implementation.

Analytical validity and reproducibility. Analytical limits of detection (LoD) for near-POC PCR and isothermal assays are typically in the order of 10^2–10^3 copies/test, comparable with laboratory PCR platforms when optimized for clinically relevant genotypes. Internal process controls, lyophilized reagents, and sealed cartridges underpin robustness to temperature and handling variability. Validation frameworks based on Meijer criteria and VALGENT principles emphasize clinical sensitivity for CIN2+ as the principal endpoint and require high intra- and inter-run concordance; decentralized systems that have undergone rigorous validation report concordance and κ values typically >90% and >0.7, respectively [14,25].

CareHPV™ (Qiagen)

As the earliest low-infrastructure screening tool, careHPV uses signal-amplified hybrid-capture to detect 14 high-risk types and has shown 84–90% sensitivity and 80–85% specificity for CIN2+ in field studies [9,18]. A pooled meta-analysis of POC assays reported similar pooled sensitivity (88.1%) and specificity (83.7%) for clinician-collected samples [26], supporting careHPV's role as a semi-molecular benchmark.

Xpert® HPV (Cepheid)

The cartridge-based Xpert® assay performs fully automated PCR and reports grouped genotypes (16, 18/45, other HR). Field studies in LMICs have demonstrated ≈91–94% sensitivity and ≈85–88% specificity for CIN2+, with excellent reproducibility and stable performance on self- and clinician-collected samples [10,20].

Truenat® HPV (Molbio Diagnostics)

Truenat® HPV is a micro-PCR platform derived from Molbio's existing tuberculosis and SARS-CoV-2 diagnostic systems. It utilizes lyophilized reagents, a portable analyzer, and battery-capable operation, permitting deployment in primary or district health facilities. The currently marketed version detects four high-risk HPV genotypes [16,18,31,45]. Field studies have reported analytical limits of detection near 10^2 copies/test with >95% agreement against standard reference PCR assays, demonstrating suitability for decentralized testing. While clinical detection rates are high, CIN2+ sensitivity and specificity estimates from large prospective screening cohorts are not yet available.

Mylab PathoDetect / Load-and-Go HPV 16/18

Mylab's cartridge-based HPV system targets viral E6/E7 oncogenes, allowing direct detection of transcriptionally active infections linked with progressive cervical lesions. The assay employs lyophilized closed-cartridge chemistry suited for near-POC workflows and does not require cold-chain handling. Initial clinical studies, including those referenced in Dakhave *et al.* (2024), demonstrate high analytical accuracy and strong concordance with reference molecular platforms in limited trial settings, although CIN2+-linked clinical performance data are not yet available.

Further, both Truenat® and Mylab platforms have completed national analytical validation under the DBT–BIRAC i-HPV initiative, reportedly using IARC reference materials and multicentric study sites. While initial outcomes indicate successful qualification for programmatic rollout, full performance metrics including CIN2+ sensitivity, specificity, sample panel characteristics, and study design are not yet available.

Other LMIC-relevant POC/isothermal platforms

Recent studies evaluate several alternative near-POC technologies that are already used or tested in resource-constrained settings:

- AmpFire / Atila (isothermal multiplex): an isothermal amplification system with simplified instrumentation and

rapid results; field and laboratory comparisons report good analytic performance and potential for high throughput in decentralized workflows [27].

- Sentis (isothermal / LAMP-based): evaluated for concordance with lab PCR on clinician- and self-collected samples; early evidence supports high agreement with established assays, particularly for high-risk genotypes [28].
- OncoE6/PreTect family (E6/E7 protein/mRNA detection): protein or mRNA-based triage tests (e.g., OncoE6 lateral flow, PreTect HPV-Proofer mRNA) show high specificity though lower sensitivity in some studies; useful as triage tools following broad DNA screening [29,30].
- Refer **Table 1** for comparative details of HPV tests.

Emerging CRISPR and microfluidic approaches

CRISPR-Cas biosensors and microfluidic lab-on-chip devices demonstrate analytical LoD <100 copies/reaction and time-to-result <40 min in laboratory evaluations; these approaches are rapidly moving toward field prototypes and disposable cartridges [21–24]. Their combination of low power, minimal reagent cold-chain, and smartphone-readout potential make them promising candidates for next-generation POC screening.

Collectively, validated near-POC molecular platforms (Xpert, Truenat, Mylab) now demonstrate laboratory-grade clinical sensitivity in decentralized settings when validated by standardized frameworks, while isothermal, CRISPR and protein/mRNA triage assays provide complementary tradeoffs between sensitivity, specificity and operational simplicity. Implementation should therefore prioritize (a) assays with independent field validation against histology/Cobas-type reference standards, (b) robust EQA participation, and (c) integration into screening algorithms that account for self-sampling performance and triage needs [10,11,20, 26] (**Table 1**).

Table 1. Comparative characteristics and validation performance of current and emerging HPV molecular diagnostic platforms.

Platform / Assay	Developer	Detection method	Target (gene/ protein)	Time to result	LoD (approx.)	Sensitivity (CIN2+)	Specificity (CIN2+)	Validation Notes	Reference
Hybrid Capture 2 (HC2)	Qiagen	Signal-amplified hybrid capture	Pooled HR DNA (L1)	~4 h	n/a	80–85%	80–90%	Classic centralized comparator; CIN2+ lesion-based data.	13
Cobas 4800/6800	Roche	Automated real-time PCR	L1 (HPV16/18 + pooled HR)	~3 h	≈200 copies	92–95%	84–88%	Screening/referral studies with histology endpoints.	6
Abbott Real Time HR-HPV	Abbott	Automated real-time PCR	L1	~3 h	≈200 copies	~95–98% (range)	90–93%	Screening/cohort validation with CIN2+ endpoints.	7
BD Onclarity HPV	BD	Automated PCR, genotype resolution	L1 (type-specific)	~3 h	≈100 copies	93–95%	85–90%	VALGENT-3 validation; CIN2+ data available.	8
careHPV™	Qiagen + PATH	Hybrid capture (semi-molecular)	L1 (14 HR types)	2–3 h	n/a	84–90%	80–85%	Large field studies and pooled analyses with CIN2+ endpoints.	9,18,26
Xpert® HPV	Cepheid	Cartridge PCR (sample-to-answer)	L1 (grouped: 16; 18/45; others)	~60 min	≈200 copies	91–94%	85–88%	Multiple field studies with CIN2+ endpoints; validated on self-samples.	10,20
Truenat® HPV	Molbio (India)	Portable micro-PCR (chip)	L1 (4 HR)	45–70 min	10^2–10^3	Limited CIN2+ data; field concordance reported	Limited CIN2+ data	Manufacturer/field reports and small validation studies; peer-reviewed lesion-level data limited — see ICMR/ BIRAC program notes for 8 HR HPV	11
Load-and-Go (Mylab)	Mylab Discovery Solutions (India)	Cartridge PCR; fully automated	E6/E7 (HPV-16/18)	45–60 min	≈50 IU/mL (reported)	No CIN2+ lesion data — analytic/ HPV-type agreement only	No CIN2+ lesion data — high HPV-16/18 specificity reported	Analytical and small clinical agreement studies (HPV-16/18); ICMR/ BIRAC validation status reported (programmatic for 7 HR HPV).	19

Platform / Assay	Developer	Detection method	Target (gene/ protein)	Time to result	LoD (approx.)	Sensitivity (CIN2+)	Specificity (CIN2+)	Validation Notes	Reference
AmpFire® HPV	Atila Biosystems	Isothermal multiplex amplification	L1 (multiple HR types)	~60 min	10^2–10^3	No large CIN2+ cohort data; PPA/ NPA vs Xpert reported	No large CIN2+ cohort data	Field evaluation in the HIV-positive cohort showed high PPA/NPA vs Xpert; lesion-level CIN2+ data limited.	27
OncoE6 Rapid Test	Arbor Vita	Lateral-flow immuno-chromatography	E6 protein (HPV-16/18 ±45)	20–30 min	protein-based	40–70% (triage)	90–98%	High specificity triage tool; not a primary screening test.	29
PreTect HPV-Proofer (mRNA)	PreTect / NorChip	NASBA mRNA detection	E6/E7 mRNA (type-specific)	~90 min	n/a	60–80% (triage)	90–95%	Useful molecular triage after DNA screening; CIN2+ triage data exist.	30
CRISPR-based HPV assays	Academic / start-ups	Isothermal + CRISPR-Cas biosensing	L1 or E6/ E7	<40 min	<100 copies	>90% (lab)	Not standardized	Lab prototypes show strong analytic sensitivity; clinical lesion-level validation pending.	23
Microfluidic lab-on-chip	Academic	Integrated chip PCR / isothermal	L1 / E6/E7	<40 min	<100 copies	>90% (lab)	Not standardized	Prototype performance promising; field CIN2+ data pending.	24

*OncoE6 and some mRNA tests sacrifice sensitivity for higher specificity — useful as triage after a high-sensitivity primary screen. Values above are representative ranges from the cited literature and prototypes; replace with exact figures for journal tables if space allows.

Translational Feasibility and Implementation Pathways in Low- and Middle-Income Countries

The successful translation of near-point-of-care (near-POC) molecular HPV diagnostics into large-scale cervical-cancer screening relies on the interplay of technical readiness and operational integration. These dimensions determine whether an analytically validated assay can perform reliably and sustainably under LMIC field conditions.

Technical and operational readiness

The robustness and workflow simplicity are the principal enablers of feasibility in resource-limited settings. Platforms employing dry or lyophilized reagents, as used by Truenat® and Mylab systems, or self-contained cartridges such as Xpert® HPV, eliminate cold-chain dependence and enable operation at ambient temperatures up to 40°C [11,18,31]. Battery-operated analyzers and cloud-based connectivity permit data upload and remote quality monitoring across dispersed networks [32,33].

The sample flexibility is equally important. Studies from Kenya, Papua New Guinea, Uganda, and Guatemala demonstrate that self-collected vaginal samples tested by near-POC platforms (e.g., Xpert® HPV, careHPV™) show high concordance with clinician-collected specimens often ≥90%. This supports broader community-based screening strategies [19,25,31]. Self-sampling has shown lower access barriers and enables community outreach without sacrificing diagnostic integrity [25].

Most validated near-POC molecular platforms meet or exceed the WHO performance thresholds, with sensitivity ≥90% and specificity ≥85% for detecting CIN2+. However, several challenges still exist. These include the need for strong external quality assessment (EQA) systems, standardized operator training, and regular maintenance for decentralized devices [14,26,32]. WHO guidance on laboratory quality management for POC testing provides an operational checklist to address these gaps and should be incorporated into national roll-outs [32].

In addition to analytical accuracy and operational robustness, regulatory acceptance of HPV assays requires demonstration of non-inferior clinical performance compared with a recognized reference test under standardized evaluation conditions. International guidance including the Meijer criteria and VALGENT framework recommends that HPV tests show ≥90% sensitivity and ≥98% specificity relative to established molecular platforms and be evaluated using well-characterized specimen panels or multicenter implementation cohorts [14,39]. Many near-POC assays in LMICs have not yet undergone full VALGENT-style evaluation, and future adoption plans should integrate external quality assurance, panel-based verification, and multi-site reproducibility studies to ensure sustainable national deployment [31,32]. Such structured validation pathways bridge laboratory innovation with regulatory confidence, enabling ministries of health to adopt near-POC HPV platforms without compromising population-level screening accuracy.

Integration into global screening frameworks

The WHO 90-70-90 cervical cancer elimination goals have catalyzed a policy shift toward molecular-first screening in many LMICs [3]. Countries including Kenya, Uganda, South Africa, Mexico, Peru, and India have piloted or implemented near-POC

assays frequently pairing molecular screening with visual triage or same-day treatment pathways to reduce loss to follow-up and accelerate linkage to care [27–29,36]. Early program reports indicate decentralized molecular hubs can deliver results and triage decisions within working-day timeframes, improving patient notification and retention compared with multi-visit cytology models [27,29,36].

Regional initiatives supported by FIND, PATH, PAHO and national institutes are actively evaluating decentralized molecular solutions and digital registration systems to integrate screening data into national cancer registries and referral networks [31,33,34]. Field pilot evaluations demonstrate that decentralization, when coupled with digital traceability and EQA, can scale while maintaining quality and supporting monitoring and evaluation needs [31,33,35].

Economic and programmatic feasibility

Cost-effectiveness analyses from sub-Saharan Africa and Latin America indicate near-POC screening is economically attractive at per-test costs in the USD 8–12 range, largely because of single-visit management and reduced loss to follow-up [28,36]. Scalability is further enhanced when analyzers are leveraged as multi-disease platforms (tuberculosis, HIV, SARS-CoV-2), improving utilization rates and amortizing capital investments across programs [24,28].

Enhancing regional manufacturing capacity and reagent stabilization through WHO and regional manufacturing partnerships reduces import dependencies and improves long-term affordability and supply security [38]. Several LMIC manufacturers and national programs are now developing locally validated assays and production lines to strengthen diagnostic sovereignty [38].

Future directions and implementation research

Priority implementation research areas include:

- Multicenter prospective comparisons of near-POC versus centralized testing across LMICs to inform policy and procurement [37].
- Digital-registry integration for automated recall and treatment linkage and to support quality monitoring [33].
- Algorithms that combine broad L1-based screening with E6/E7-targeted triage to balance sensitivity and specificity [18,39,40].
- Operational evaluations of next-generation CRISPR and microfluidic platforms for truly disposable, ultra-rapid testing [20–24].

Collectively, these strategies will determine how rapidly health systems in LMICs can translate laboratory innovation into population-level prevention and progress toward WHO elimination targets [3,32].

Conclusions and Future Outlook

Molecular HPV testing has fundamentally improved cervical-cancer screening through higher sensitivity and objective detection, but its historical dependence on centralized laboratories has limited population impact in many low- and middle-income countries. The rise of near-point-of-care (near-POC) molecular platforms such as careHPV™, Xpert® HPV, Truenat® and emerging LMIC-origin systems including Mylab's E6/E7-targeted assay signals a shift toward decentralization of high-performance screening.

Across diverse implementation studies, these platforms demonstrate ≥90% sensitivity for CIN2+ with minimal infrastructure, short turnaround times and compatibility with self-collected samples. Such attributes support single-visit "test-and-treat" models that reduce loss to follow-up and substantially improve real-world screening effectiveness. The growing inclusion of dry chemistry, closed-cartridge workflows, digital connectivity and battery-based operation has strengthened operational feasibility in primary care centers, mobile clinics and community screening sites.

A key priority moving forward is validation and regulatory harmonization. Platforms entering national programs must demonstrate performance under accepted frameworks such as WHO prequalification, Meijer criteria, and the VALGENT evaluation process. For emerging LMIC-developed systems, including those still completing ICMR or international validation pathways, successful demonstration of analytical rigor and operational stability will be critical before large-scale adoption.

Economic sustainability will depend on pooled procurement, regional manufacturing capacity, and multipurpose analyzers already used for tuberculosis, HIV, and COVID-19, approaches that have already reduced cost barriers in several regions. Future research should refine screening algorithms pairing sensitive L1-based detection with E6/E7 or methylation-based triage to improve specificity and reduce overtreatment in younger populations.

In conclusion, near-POC molecular diagnostics represent a pivotal development in advancing equitable cervical-cancer prevention. With continued investment in validation standards, implementation science, and health-system integration, these platforms, including new national innovations, can become core components of population-based HPV screening, accelerating progress toward the WHO 90-70-90 elimination targets.

Declarations

Conflicts of interest

None.

Author contributions

MD: Conceptualization, manuscript drafting, critical revision and final approval of the submitted version. AK: Critical review and editing of the manuscript.

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