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BACKGROUND

HPV detection is a global health priority. High-risk HPV (HR-HPV) is a leading cause of cervical cancer, while low-risk HPV (LR-HPV) is associated with benign lesions such as genital warts. Reliable HPV testing requires standardized laboratory performance, and External Quality Assessment Programs (EQAP) play a vital role in ensuring accuracy and harmonization.

AIM

To compare laboratory performance in an EQAP for HR-HPV and LR-HPV molecular detection by PCR/qPCR, organized by a provider accredited to ABNT NBR ISO/IEC 17043:2011.

METHODS

Liquid samples from cervical brushing or cell lysate were utilized in the EQAP. Between 2020 and 2024, laboratories received two quarterly samples to evaluate accuracy (AC), sensitivity (SE), and specificity (SP). These performance metrics were assessed and compared between the High-risk and Low-risk HPV PCR/qPCR using chi-square tests and odds ratios. HR-HPV and LR-HPV AC trends over time were analyzed using the Mann-Kendall test.

RESULTS

69 laboratories (median 18 laboratories/round, range 5–51; 692 datasets) participated in the HR-HPV evaluation, and 34 laboratories (median 12 laboratories/round, range 2–26; 386 datasets) in the LR-HPV evaluation. HR-HPV results were 97.98% (678/692) AC, 97.79% (620/634) SE, and 100% (58/58) SP, while LR-HPV achieved 94.82% (366/386) AC, 93.84% (259/276) SE, and 97.27% (107/110) SP. Significant differences in SE (OR=2.91, 95%CI: 1.41–5.98, p=0.0048) and AC (OR=2.62, 95%CI: 1.32–5.19, p=0.0077) favored HR-HPV, while SP was comparable (OR=3.81, 95%CI: 0.19–75.02, p=0.5116) (Table 1). No significant trends in AC were observed over time for High-risk HPV testing (τ =0.046, p=0.795) or Low-risk HPV testing (τ =0.3, p=0.098).

CONCLUSIONS

Both evaluations demonstrated strong performance, with HR-HPV showing better sensitivity and accuracy, while specificity was similar. No significant trends in accuracy were observed over time, indicating stability with no changes over time. Detecting LR-HPV remains crucial for managing lesions, enabling cost-effective treatment, reducing transmission, and supporting public health strategies. This study highlights that LR-HPV PCR/qPCR assays have room for improvement to meet HR-HPV standards, emphasizing the need for ongoing refinement and quality assessments.

Table 1: Performance of participation in the HR-HPV program versus the LR-HPV program:

	HR-HPV	LR-HPV	Statistics
Labs total	69	34	-
Labs per round	18	12	Range: 5–51 and 2–26, respectively
Samples	692	386	-
AC	97.98%	94.82%	OR=2.62, 95% CI: 1.32-5.19, p=0.0077
SE	97.79%	93.84%	OR=2.91, 95% CI: 1.41-5.98, p=0.0048
SP	100%	97.27%	OR=3.81, 95% CI: 0.19-75.02, p=0.5116

Legend: Odds ratio (OR); Confidence Interval (CI)

DISCLOSURE

The authors confirm that they don't have any conflict of interest to declare.

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