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Intra- and interlaboratory reproducibility of the RIATOL qPCR HPV genotyping assay

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Abstract

The implementation of cervical screening based on human papillomavirus (HPV) continues to progress rapidly across countries. Evidence has shown that assays detecting high-risk human papillomavirus (hrHPV) deoxyribonucleic acid (DNA) are more effective than cytology-based screening. Validation of new hrHPV DNA assays requires both noninferior clinical accuracy compared to a standard comparator for cervical precancer and good reproducibility. This study builds upon previous diagnostic accuracy assessments of the RIATOL HPV genotyping qPCR assay and aims to evaluate the international validation criteria for reproducibility. The intra- and interreproducibility of the RIATOL-qPCR assay were assessed using 550 remnant cervical cell material from the cytology archive of the National Reference Center for HPV in Belgium. Specimens were collected in the context of cervical cancer screening and tested in two different laboratories. The international reproducibility criteria include the lower bound of 95% confidence interval of the intra- and interlaboratory agreement regarding the detection of hrHPV DNA exceeding 87% with kappa ≥0.50. The RIATOL-qPCR assay demonstrated excellent intralaboratory reproducibility, achieving an overall agreement of 98.2 (95% CI 96.6-99.1%) and a kappa of 0.96. Interlaboratory testing showed an overall agreement of 98.5 (95% CI 97.1-99.4%) with a kappa of 0.97. The RIATOL-qPCR assay fulfills the third criterion for HPV test reproducibility requirement for use in cervical cancer screening.

Keywords: HPV genotyping; RIATOL; cervical cancer; human papillomavirus; test validation.

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