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Clinical performance of the novel full-genotyping OncoPredict HPV Quantitative Typing assay using the VALGENT framework

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Abstract

Clinical validation of human papillomavirus (HPV) assays according to international criteria is prerequisite for their implementation in cervical cancer screening. OncoPredict HPV Quantitative Typing (QT) assay (Hiantis Srl, Milan, Italy) is a novel full-genotyping multiplex real-time PCR quantitative assay targeting E6/E7 genes, allowing individual viral load determination of 12 high-risk (HR) HPV types. Quality controls for sample adequacy, efficiency of nucleic acid extraction and PCR inhibition are included in the assay. Clinical performance of OncoPredict HPV QT test was assessed as part of the "Validation of HPV Genotyping Tests" (VALGENT-2) framework, consisting of 1300 cervical liquid-based cytology (LBC) samples of women aged between 20 and 60 years who had originally attended for routine cervical screening in Scotland. The clinical accuracy of the OncoPredict HPV QT (index test) for the detection of CIN2+ was assessed relative to the GP5+/6+ Enzyme ImmunoAssay (GP5+/6+ EIA) (comparator test), using noninferiority criteria. Intra- and interlaboratory reproducibility of the assay was assessed on a subpopulation, comprising 526 samples. The relative sensitivity and specificity for OncoPredict HPV QT vs GP5+/6+-PCR-EIA were 1.01 (95% CI: 0.99-1.03) and 1.03 (95% CI: 1.0-1.06) respectively. The P-values for noninferiority were ≤0.001. The intra- and inter-laboratory reproducibility demonstrated a high concordance (>98.7%) with kappas for individual types ranging from 0.66 to 1.00. OncoPredict HPV QT fulfills the international validation criteria for the use of HPV tests in cervical cancer screening.

Keywords: OncoPredict HPV quantitative typing (QT); VALGENT framework; cervical cancer prevention; clinical performance study; full-genotyping HPV viral load.

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