

# MassARRAY spectrometry is more sensitive than PreTect HPV-Proofer and consensus PCR for type-specific detection of high-risk oncogenic human papillomavirus genotypes in cervical cancer.

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## Abstract

Type-specific detection of human papillomavirus (HPV) is indicated for better risk stratification and clinical management of women testing positive for HPV and for epidemiologic surveillance. MassARRAY spectrometry (MassARRAY; Sequenom) is a novel method for type-specific detection of 15 high-risk oncogenic HPV types: HPV-16, -18, -31, -33, -35, -39, -45, -51, -52, -56, -58, -59, -66, -68, and -73. PreTect HPV-Proofer (Proofer; Norchip) is a type-specific assay that detects E6/E7 mRNA from five high-risk oncogenic HPV types: HPV-16, -18, -31, -33, and -45. The performance of these tests for type-specific identification of HPV was assessed with cervical specimens from 192 cases of cervical cancer in comparison with consensus MY09/MY11 PCR followed by nucleotide sequencing (consensus PCR). The overall HPV detection rates were 94.8% (95% confidence interval [CI], 91.7, 97.9), 83.3% (95% CI, 78.1, 88.5), and 86.5% (95% CI, 81.7, 91.3) for MassARRAY, Proofer, and consensus PCR, respectively. All tests were negative in six (3.1%) of the 192 cases. Considering only the specimens that contained at least one of the five types targeted by Proofer, the detection rates were 96.6%, 91.4%, and 86.9% for MassARRAY, Proofer, and consensus PCR, respectively. MassARRAY detected multiple infections in 14.1%, Proofer detected multiple infections in 3.6%, and consensus PCR failed to detect any multiple infections. The agreement was highest at 86.0% (kappa = 0.76) between MassARRAY and Proofer and lowest at 81.8% (kappa = 0.69) between Proofer and consensus PCR. In conclusion, MassARRAY is a highly sensitive and accurate method for type-specific detection of oncogenic HPV in cervical cancer, with Proofer showing impressive performance.

