

PERFORMANCE OF APTIMA HPV ASSAY IN REFERRAL POPULATION

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Background: The performance of the APTIMA HPV (AHPV) Assay, which detects E6/E7 mRNA from 14 high-risk (HR) HPV types, was compared to the Qiagen Hybrid Capture 2 (HC2) assay in a Referral sample set. AHPV/HC2 discordant results were resolved by testing with a reverse-transcription PCR (RT-PCR) sequencing assay specific for E6/E7 mRNA from 14 HR HPV types.

Methods: A RT-PCR sequencing method was developed to use residual PreservCyt liquid-based cytology (LBC) samples. In feasibility testing using referral samples, very good agreement between RT-PCR and AHPV assays was obtained (Kappa = 0.84; 95%CI: 0.66-1). A larger set of LBC Referral samples with available cytology (N=121) and histology (N=41) information was then tested with the AHPV, HC2 and RT-PCR assays.

Results: Compared to HC2, the AHPV assay recorded fewer positives in ASCUS, LSIL and HSIL samples, with positive agreements of 59% (95%CI: 43.3-73.7%), 62.2%(95%CI: 46.5-76.2%), and 94.1% (95%CI: 71.3-99.9%), respectively. Of the 36 HC2+/AHPV-discordants in these categories, 100% were negative in the RT-PCR assay. For the 33 samples with abnormal histology diagnosis (CIN1+), the AHPV assay had 96.6% positive agreement (95%CI: 82.5-99.9%) and 100% negative agreement (95%CI: 39.8-100%) with HC2. For the one HC2+/AHPV- sample identified (= CIN1), RT-PCR was negative. Both AHPV and HC2 assays detected 100% of CIN2+ samples (n=19).

Conclusion: Use of RT-PCR sequencing to evaluate discordant results between the RNA-based AHPV assay and the DNA-based HC2 assay confirms the accuracy of the lower reactive rate of AHPV in low-grade cytology- and histology-diagnosed Referral samples. Compared to HC2, these results support an equivalent sensitivity and an improved specificity of the AHPV assay for detecting HPV-induced cervical disease.