

Detection of HPV mRNA In Cytology specimens with the APTIMA® HPV Assay

Authors: Clad, A.¹, Reuschenbach, M.², Rahmsdorf, J.¹, Grote, R.¹, and von Knebel Doeberitz, M.²

Organization: ¹Universitaets-Frauenklinik, Freiburg, Germany; ²Institut für Pathologie, Abteilung Angewandte Tumorbilogie, Universitaet Heidelberg, Germany

Background: The APTIMA HPV Assay (AHPV, Gen-Probe Incorporated) is a new, qualitative nucleic acid amplification test designed to detect the E6/E7 mRNA of 14 high-risk HPV types in women undergoing cervical cancer screening.

Objectives: Evaluate the ability to detect high-risk HPV mRNA and DNA in disease positive (CIN2+) specimens stored for up to 3 years at room temperature.

Methods: 298 clinical specimens were collected from patients with abnormal cytology and at follow-up visits after LEEP conization or laser vaporization. Conventional and liquid based cytology (LBC), colposcopy, and histology were performed. Samples were subsequently stored in the original liquid based cytology (LBC) vials at room temperature for up to 3 years. Detection of high risk HPV DNA was determined with the Hybrid Capture 2 HPV DNA Test (HC2, Qiagen Incorporated). AHPV results were compared to HC2, conventional cytology and histology results. 122 of the samples were CIN3 or worse (10 cervical carcinomas) in a punch biopsy or cone tissue, 60 CIN2, 36 CIN1 and 80 disease negative.

Results: Sensitivity/specificity for detection of CIN2+ were: AHPV 90,1%/78,4%, HC2 91,2%/62,9%, conventional cytology (\geq ASCUS) 85,2%/73,3%. Sensitivity/specificity for detection of CIN3+ were: AHPV 97.5%/60,2%, HC2 96,7%/48,3%, conventional cytology (\geq ASCUS) 94.3%/59,7%.

Conclusions: These results indicate that the AHPV Assay is able to detect high-risk HPV mRNA in retrospective LBC specimens stored at room temperature for up to three years with strong correlation to disease. The AHPV assay was as sensitive as the HC2 assay, but clearly more specific. The AHPV was not only more sensitive than conventional cytology, but also more specific.