

RESULTS OF THE FRENCH APTIMA HPV SCREENING EVALUATION (FASE STUDY)

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Background: The APTIMA HPV assay (AHPV, Gen-Probe Incorporated) detects E6/E7 mRNA from 14 high-risk types. The FASE study evaluated the use of the AHPV assay in France undergoing screening for cervical cancer.

Objectives: To assess the performance of the AHPV assay in comparison with the HC2 assay (Qiagen) for detection of HR HPV and detection of high-grade CIN in conjunction with liquid-based cytology (LBC).

Methods: This was a regional, cross-sectional cervical cancer screening study of 5000 women (age 20-65 years) for detection of CIN. Women cytologically abnormal or positive for either HPV test were sent for colposcopic evaluation. Biopsy specimens were taken from women with abnormal colposcopy or normal colposcopy following a positive screening test.

Results: Fewer specimens tested positive with the AHPV assay compared with the HC2 especially in women with less than CIN1 where there were almost twice as many HC2 positives compared to AHPV. Clinical performance results from 1528 women to date show that in a disease positive population (CIN2+), the sensitivity of the AHPV assay was 87.4% compared to HC2 sensitivity of 95.8%. The clinical specificity of the AHPV assay was significantly higher than the HC2 assay at 72.4% compared to 52.4% in the HC2 assay. Sensitivity in a CIN3 population was 100% for both assays, specificity was 69.1% for AHPV and 49.7% for HC2.

Conclusions: The results to date show that the AHPV assay had statistically equivalent sensitivity, but higher specificity than the HC2 assay for detection of CIN2+. The AHPV assay may provide improved clinical utility in comparison to HPV DNA testing.