

COMPARISON OF THREE HIGH-RISK HPV (HR-HPV) TESTS ON ASC SAMPLES WITH FOLLOW-UP

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Background: HR-HPV testing might help qualifying the ASC-US diagnosis in determining which women should be referred for colposcopy and which could be returned to the screening programme.

Objectives: To evaluate the performance of CINtec® p16INK4a Cytology (p16, mtm laboratories), APTIMA HPV (AHPV, Gen-Probe Incorporated) and Linear Array (LA, Roche Molecular Diagnostics) on samples diagnosed ASC-US and ASC-H.

Methods: Residual ThinPrep® specimens (Hologic) were collected from consecutive ASC-US and ASC-H samples from the population based screening programme in the Region of Funen, Denmark, and follow-up results were registered. The p16 staining and the LA tests were conducted in our department and the AHPV tests were performed by Gen-Probe (San Diego). The clinical sensitivity and specificity were calculated with histological CIN2+ as endpoint.

Results: A total of 195 ASC samples including 78 ASC-US (40 %), 99 ASC-H (51 %) and 18 ASC-US in two consecutive cytology specimens (9 %) were tested with the three HR-HPV tests. Follow-up results were available for 182 (93 %) of the women. A follow-up result of CIN2+ was found in 10 % of ASC-US, 31 % of ASC-H and 24 % of ASC-US twice. For p16, AHPV and LA the clinical sensitivity was 92.1 %, 95.1 % and 97.6 % with 3, 2 and 1 false negative diagnoses respectively. The clinical specificity for p16, AHPV and LA was 54.5 %, 34.0 % and 26.2 % with 56, 93 and 104 false positive diagnoses respectively.

Conclusions: In our experience the perfect HR-HPV test for ASC triage does not exist yet, but the results are promising. For clinical use the level of the sensitivity and specificity must be as high as possible in order to avoid false diagnoses. The choice of HR-HPV test is highly dependent on the clinical significance, financial possibilities and local laboratory capacity and expertise.