We compared the clinical performance of the PapillomCheck® assay with the high-risk HPV GP5+/6+-PCR method, followed by enzyme immunoassay readout (GP5+/6+-PCR-EIA) on cervical samples originating from women of a population-based cervical screening cohort tested by combined co-testing and GP5+/6+-PCR-EIA (POBASCAM trial). A random sample of 1,437 controls (defined as women with normal cytology (age 40-60 years) without evidence of ≥CIN2 within up to 8 years), and 192 cases (women aged 30-60 years with ≥CIN3 detected within up to 3 years of follow-up) were subjected to PapillomCheck® analysis. When all 17 (probably) hrHPV types were taken into account PapillomCheck® had a clinical specificity for ≥CIN2 of 95.8% (95%CI: 92.8-98.8) and a clinical specificity for ≥CIN2 of 95.3% (95%CI: 91.6-98.3). After restricting PapillomCheck® analysis to the 14 hrHPV types targeted by GP5+/6+-PCR-EIA the clinical sensitivity for ≥CIN3 of 96.4% (95%CI: 93.9-98.9) and 97.7% (95%CI: 96.9-98.5), respectively, for GP5+/6+-PCR-EIA. When including all 17 (probably) hrHPV types non-inferiority against that of PapillomCheck® assay is clinically compatible to the GP5+/6+-PCR-EIA assay.
BACKGROUND: Cervical screening detects precancerous lesions and routine screening could be improved by testing for Human Papillomavirus (HPV), the virus that causes cervical cancer. HPV infection is common and the benefit of HPV testing would be a prerequisite for the use of genotyping assays in cervical cancer screening algorithms. Recently, a commercially available HPV DNA chip, the Papillomavirus Microarray (Papillomavirus), has been developed. The objective of this study was to evaluate its clinical performance compared with HPV detection assays currently employed in cervical cancer screening programmes.

METHODS: Two hundred and thirty six women referred for colposcopy and histology. Papillomavirus microarray test results were compared with a panel of six other HPV detection tests: Hybrid Capture II (HCII), Linear Array (LA), SPF10 PCR, HC2, QIAGEN and Roche. For comparison, 91 (67.4%) showed absolute agreement between the assays (concordant genotype-specific results), 34 (25.1%) showed discordant results, and the remaining 10 (7.4%) samples did not show any similarity between the tests (discordant results). The majority of the discrepant results confirmed a possibly high rate of false positive results of HC2-HR test in the 1-5 RLU/CO grey zone. The study shows that the Papillomavirus test gives comparable results to the Linear Array test (Roche Diagnostics). Cervical specimens collected in PreservCyt (Cytyc) solution and obtained from women who presented abnormal cytological findings were tested primarily by the Hybrid Capture 2 High-Risk assay (HC2-HR) and the Linear Array test (LA). The remaining samples were tested by other HPV detection assays using a clinical cut-off of CIN2+.

RESULTS: Of the 236 samples available, 135 (57%) showed absolute agreement between the Papillomavirus and the LA tests (concordant results). In conclusion, it is demonstrated that both the linear array and the linear array HPV genotyping test (Roche Diagnostics) allows accurate HPV typing and genotyping, without additional costs compared to current screening programmes. This study confirms that HPV detection by Papillomavirus is comparable to the currently used clinic genetic tests.

Comparison of the clinical performance of carcinogenic HPV typing of the Linear Array and Papillomavirus HPV-screening assay.

Human Papillomavirus negative but dyskaryotic cervical cytology: re-analysis of molecular testing.

Papillomavirus negative but dyskaryotic cervical cytology: re-analysis of molecular testing.

Evaluation of the novel Papillomavirus® HPV genotyping test with Comparison With Two Other Genotyping Systems and the H2C Test. A total of 144 samples were selected according to the signal intensity obtained with the HC2-HR test, expressed as RLU/CO value, and divided into 4 groups as follows: (i) LRU200 (negative HC2-HR result, 34 samples), (ii) LRU50-200 (negative HC2-HR result, 30 samples), (iii) LRU50-200 (positive HC2-HR result, 40 samples), and (iv) LRU50-200 (positive HC2-HR result, 40 samples). The concordance levels between the HC2-HR and each of the genotyping assays was similar (86% and 87%), and the study agreement between these assays was considered as "good". The detailed analysis of the discrepant results confirmed a possible high rate of false positive results of HC2-HR test in the 1-5 RLU grey zone. Cytological scoring of the primary smears was identical for both HPV typing assays (Papillomavirus and LA). The study concludes that HPV negative but dyskaryotic cervical cytology cannot be explained only by a conflicting genotype result, suggesting the need for an additional molecular test.

Analytical evaluation of the Papillomavirus® test, a new commercial DNA chip for detection and genotyping of human papillomaviruses.

Background: Recently, a commercially available HPV DNA chip, the Papillomavirus, has been developed for the use in viral HPV typing. The Papillomavirus test is a POC-based test using a new commercial primer set for HPV detection designed to use an HPV amplicon which is amplified on the Papillomavirus® test DNA chip, and 47% with LA), and HPV31 was the second most detected type (13% with Papillomavirus). Of the 135 samples available, HPV16 was detected 78.4% (n=40/51). HR HPV detection by Papillomavirus® test seemed to be more sensitive to detect HPV type 53 whereas Papillomavirus® test and the Linear Array test have a good clinical sensitivity to detect HPV types in CIN2+ patients. These assays allow, in the same experiment, to detect and determine the virus type. HPV typing using Human Papillomavirus (HPV) screening tests and, respectively, HPV16, HPV18, HPV31, HPV33, HPV39, HPV45, HPV52, and HPV58, and 66 and 59. The majority of discrepant results confirmed a possibly high rate of false positive results of HC2-HR test in the 1-5 RLU grey zone. Cytological scoring of the primary smears was identical for both HPV typing assays (Papillomavirus and LA). The study concludes that HPV negative but dyskaryotic cervical cytology cannot be explained only by a conflicting genotype result, suggesting the need for an additional molecular test.

Comparison of the clinical performance of carcinogenic HPV typing of the Linear Array and Papillomavirus HPV-screening assay.