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Performance of the Abbott RealTime High Risk HPV Assay with SurePath Liquid Based Cytology Specimens from Women with Low Grade Cytological Abnormalities

Authors : Alexandra Sargent, Sarah Ferris, Ioannis Theofanous

Abstract : The Abbott RealTime High Risk HPV test (RealTime HPV) is one of five assays clinically validated and approved by the English NHS Cervical Screening Programme (CSP) for HPV triage of low grade dyskaryosis and test-of-cure of treated Cervical Intraepithelial Neoplasia. The assay is a highly automated multiplex real-time PCR test for detecting 14 high risk (hr) HPV types, with simultaneous differentiation of HPV 16 and HPV 18 versus non-HPV 16/18 hrHPV. An endogenous internal control ensures sample cellularity, controls extraction efficiency and PCR inhibition. The original cervical specimen collected in SurePath (SP) liquid-based cytology (LBC) medium (BD Diagnostics) and the SP post-gradient cell pellets (SPG) after cytological processing are both CE marked for testing with the RealTime HPV test. During the 2011 NHSCSP validation of new tests only the original aliquot of SP LBC medium was investigated. Residual sample volume left after cytology slide preparation is low and may not always have sufficient volume for repeat HPV testing or for testing of other biomarkers that may be implemented in testing algorithms in the future. The SPG samples, however, have sufficient volumes to carry out additional testing and necessary laboratory validation procedures. This study investigates the correlation of RealTime HPV results of cervical specimens collected in SP LBC medium from women with low grade cytological abnormalities observed with matched pairs of original SP LBC medium and SP post-gradient cell pellets (SPG) after cytology processing. Matched pairs of SP and SPG samples from 750 women with borderline (N = 392) and mild (N = 351) cytology were available for this study. Both specimen types were processed and parallel tested for the presence of hrHPV with RealTime HPV according to the manufacturer´s instructions. HrHPV detection rates and concordance between test results from matched SP and SPGCP pairs were calculated. A total of 743 matched pairs with valid test results on both sample types were available for analysis. An overall-agreement of hrHPV test results of 97.5% (k: 0.95) was found with matched SP/SPG pairs and slightly lower concordance (96.9%; k: 0.94) was observed on 392 pairs from women with borderline cytology compared to 351 pairs from women with mild cytology (98.0%; k: 0.95). Partial typing results were highly concordant in matched SP/SPG pairs for HPV 16 (99.1%), HPV 18 (99.7%) and non-HPV16/18 hrHPV (97.0%), respectively. 19 matched pairs were found with discrepant results: 9 from women with borderline cytology and 4 from women with mild cytology were negative on SPG and positive on SP; 3 from women with borderline cytology and 3 from women with mild cytology were negative on SP and positive on SPG. Excellent correlation of hrHPV DNA test results was found between matched pairs of SP original fluid and post-gradient cell pellets from women with low grade cytological abnormalities tested with the Abbott RealTime High-Risk HPV assay, demonstrating robust performance of the test with both specimen types and reassuring the utility of the assay for cytology triage with both specimen types.

Keywords : Abbott realtime test, HPV, SurePath liquid based cytology, surepath post-gradient cell pellet
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