
P-24; PERFORMANCE CHARACTERISTICS OF THE APTIMA® HPV ASSAY FOR DETECTION OF HIGH RISK HPV TYPES IN SUREPATH LIQUID-BASED CERVICAL CYTOLOGY SPECIMENS

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Background: Testing for high risk HPV in cervical specimens is useful for determining the need for follow-up in women with ASCUS cytology on Pap smear and for identifying women >30 years who can safely defer Pap smears to 3-year intervals. Collection of cervical specimens in liquid-based media (LBC) followed by automated slide preparation and staining has become routine for Pap smears in the U.S. The APTIMA HPV assay (AHPV, Gen-Probe Incorporated) is a new assay designed to detect high risk HPV mRNAs in PreservCyt LBC specimens (Cytoc Corporation).

Objectives: The goal of this study was to determine the performance of AHPV in SurePath (Becton Dickinson) LBC specimens compared to hc2 (Digene) and Pap smear LBC results.

Materials and Methods: Specimens from selected sites with a high prevalence of high risk HPV were randomly selected for inclusion. 1 ml of residual specimen was transferred to AHPV specimen transport medium (STM) within 48 hours of collection. Specimens were tested with the AHPV assay on a TIGRIS® DTS® System within 48 hours of transfer to STM. hc2 testing was performed as per laboratory-verified protocol. Samples from 263 subjects were tested; a complete data set (AHPV and hc2) was available for 259 subjects.

Results: Overall agreement of the AHPV assay with hc2 was 89%, with 93% negative agreement and 82% positive agreement. Both assays performed similarly compared to cytology. Agreement between AHPV and hc2 was reasonable and comparable to previous studies using Cytoc LBC.

Conclusions: AHPV and hc2 performed similarly compared to cytology. Further study and discrepant analysis are required to resolve

differences in high risk HPV detection between AHPV and hc2. The ability to detect high risk HPV types in SurePath LBC and the extent of agreement between hc2 and AHPV was promising.