P–14; **EVALUATION OF APTIMA® HPV ASSAY PERFORMANCE WITH SPECIMENS COLLECTED IN AN ALTERNATIVE SPECIMEN TRANSPORT MEDIA**

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Background: The APTIMA HPV Assay (AHPV) is a qualitative nucleic acid test designed to detect the E6/E7 mRNA of 14 high-risk HPV types in liquid based cytology (LBC) specimens. In this study the performance of the assay was evaluated in specimens collected in Digene Specimen Transport Media (DG-STM).

Objectives: A method for processing DG-STM specimens compatible with the AHPV assay was developed. Its analytical sensitivity, as compared to LBC, was evaluated using HPV *in vitro* transcripts and HPV infected SiHa cells.

Materials and Methods: To evaluate clinical performance, DG-STM specimens (n=483), collected primarily from patients undergoing routine screening, were tested in both the AHPV assay and the hc2 HPV DNA Test or hc2 HR HPV DNA Test (hc2). AHPV assay performance was compared to hc2 as well as cytology for a subset of the specimens (n=98).

Results: DG-STM samples diluted into GP-STM at very low volumes or diluted in PBS and then GP-STM yield comparable analytical sensitivity to LBC samples diluted in GP-STM. Overall agreement of the AHPV assay with hc2 from the testing of the clinical specimens was 93%, with 99% negative agreement and 47% positive agreement. Cytology results were available for 28 of the 31 samples that were discordant between the AHPV and hc2 tests. Twenty-three were within normal limits, 3 were ASCUS, 1 was LSIL and 1 was HSIL.

Conclusions: These results demonstrate that specimens collected in Digene STM may be tested in the APTIMA HPV Assay. Additional evaluations are required to fully assess clinical performance of the APTIMA HPV Assay in this sample type.