## P-13; HPV mRNA DETECTION IN LIQUID BASED CYTOLOGY SPECIMENS STORED UPTO THREE YEARS AT ROOM TEMPERATURE WITH THE APTIMA® HPV ASSAY

Andreas Clad<sup>1</sup>, Miriam Reuschenbach<sup>2</sup>, Janina Rahmsdorf<sup>1</sup>, Janel Dockter<sup>3</sup>, Astrid Schroder<sup>3</sup>, Cristina Giachetti<sup>3</sup>, Magnus von Knebel Doberitz<sup>2</sup>

<sup>1</sup>Universitäts-Frauenklinik, Freiburg, Germany

<sup>2</sup>Institut für Pathologie, Abteilung Angewandte Tumorbiologie, Universität Heidelberg, Heidelberg, Germany

<sup>3</sup>Gen-Probe Incorporated, San Diego, United States

**Background:** The APTIMA HPV Assay (AHPV, Gen-Probe Incorporated) 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 a set of Cytyc LBC specimens stored for up to 3 years at room temperature and the results compared to histology.

**Materials and Methods:** More than 400 clinical specimens were collected from patients with abnormal cytology over the course of more than 2 years (Universitäts-Frauenklinik, Freiburg). Cytology, both conventional and liquid based, as well as histology results were evaluated. Subsequently, samples were stored at room temperature for up to 3 years and a subset (n=47) recently tested for HPV mRNA in the AHPV assay. AHPV results were compared to histology results.

**Results:** The AHPV assay yielded a positive result in all 10 CIN 3 and cervical carcinoma specimens. All 6 CIN 2–3 specimens, 6 of 8 CIN 2 specimens, and 3 of 4 CIN 1–2 specimens were positive in the AHPV assay. Of the 19 CIN1 and normal specimens, 15 were negative in the AHPV assay.

Conclusions: The results from this subset of specimens tested to date indicates that the APTIMA HPV assay is able to detect HPV high-risk mRNA in retrospective LBC specimens stored at room temperature for up to three years with strong correlation to disease. Testing of additional specimens from this sample set will be completed as well as HPV DNA testing.