COMBINED HPV GENOTYPING AND CELL-BASED E6, E7 mRNA (HPV ONCOTECT) DETECTION IN CERVICAL CYTOLOGY SPECIMENS PERFORMED ON A MOLECULAR HYBRID PLATFORM (MOHP) MAXIMIZES SENSIIVITY AND POSITIVE PREDICTIVE VALUE

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Backgroung: Current cervical cancer screening relies on cervical cytologic diagnosis combined with high risk HPV DNA (HR HPV) detection. This screening algorithm identifies women at risk for developing cervical cancer with high sensitivity and high negative predictive value. The positive predictive value (PPV) of HR HPV DNA detection for biopsy proven pre-cancerous lesions, however, is low (15%–25%).

Objectives: In this study, we sought to combine HPV tests with high sensitivity and high positive predictive value to develop a cervical cancer screening test bundle with optimal clinical performance that can be run on the same compact instrument.

Materials and Methods: We collected 100 cytologically normal samples in ThinPrep PreservCyt liquid and 20 samples in ThinPrep PreservCyt liquid of women with biopsy proven CIN 2 or above. All samples were analyzed using Hybrid Capture 2 (HC2, Qiagen, Germantown, MD, USA), bead-based HPV Genotyping (Qiagen, Germantown, MD, USA), and HPV OncoTect (Invirion Diagnostics,

Oakbrook Il, USA) for cell-based E6, E7 mRNA expression. Analysis of bead-based HPV Genotyping and HPV OncoTect were performed on the same MoHP (Invirion Diagnostics, Oakbrook Il, USA).

Results: HPV Genotyping had a 95% sensitivity for CIN 2 or above and HPV OncoTect had a 90% PPV for CIN 2 or above. By comparison, HC2 had a 90% sensitivity for CIN 2 or above and a PPV of 50%. Of the 18 cytologically normal samples that were positive by HC2, five were negative by genotyping and four were HPV type 70 a non-high risk genotype.

Conclusions: In summary, HPV genotyping and HPV OncoTect can be performed on the same, compact, cost-effective instrument and provide superior performance for cervical cancer screening compared to HPV DNA alone.