P–12; **ANALYTICAL PERFORMANCE CHARACTERISTICS OF THE CE-MARKED INVADER® HPV HR MOLECULAR ASSAY**

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Background: The Invader® HPV HR Molecular Assay is an isothermal signal amplification technology designed to detect high-risk (HR) HPV types in cervical cytology samples. This assay also utilizes an internal control, the human histone 2 gene (HIST2H2BE) to assure sample sufficiency. Studies were undertaken to determine the analytical sensitivity, specificity, and accuracy of this assay in detecting 14 HR HPV types associated with cervical cancer.

Methods: DNA extraction was performed using the Agencourt® GENfind™ v.1 kit. Analytical sensitivity was determined by testing dilutions of purified HPV DNAs of known copy number. Cross-reactivity was evaluated by testing low-risk HPV types and a panel of microorganisms. Accuracy for clinical specimens was established by testing 192 PreservCyt® cervical cytology samples with results compared to those obtained with PCR/sequencing. Reproducibility was determined in a multi-center study using a panel of 16 PreservCyt® samples containing cervical cells or cultured cells. This testing was performed at 3 external laboratories on 5 non-consecutive days.

Results: Established sensitivities varied depending on each of the 14 HR HPV types tested, with sensitivities ranging from 1,250–5,000 copies of HPV DNA/reaction. Of 192 clinical samples tested, clear Invader® and sequencing results were available for 188/192. An overall 91.5% agreement (172/188; 95% CI=86.6–95.1) was observed between methods, with a positive and negative agreement of 94.4% and 87.5%, respectively (95% CI=88.3-97.9 and 78.2-93.8). No cross-reactivity was observed to common low-risk HPV types or the tested microorganisms. The reproducibility study demonstrated that between-day (within site) percent agreement across all 3 sites was 99.3% (1-sided 95% confidence lower limit=97.6%). Between-site percent agreement was 99.3% (1-sided 95% confidence lower limit=98.7%).

Conclusions: The Invader® HPV HR Molecular Assay is a sensitive, specific, highly accurate, and consistently reproducible method for identifying HR HPV in PreservCyt® liquid cytology specimens. These characteristics make it suitable for use for cervical cancer screening programs.