

Evaluation of novel assays for the detection of human papilloma virus in self-collected samples for cervical cancer screening

Q. Chen¹, H. Du¹.², R. Zhang³, J.H. Zhao⁴, Q.C. Hu¹.², C. Wang¹.², G.X. Wang¹.², J.L. Tang¹.² and R.F. Wu¹.²

¹Peking University Shenzhen Hospital, Shenzhen, China ²Shenzhen Key Laboratory on Technology for Early Diagnosis of Major Gynecological Diseases, Shenzhen, China ³Jiangsu BioPerfectus Technologies, Jiangsu, China ⁴Human Assisted Reproduction Center, Shanxi Women & Children's Hospital, China

Corresponding author: R.F. Wu E-mail: wuruifang 1@163.com

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ABSTRACT. The aim of this study was to evaluate the performance of three new high-risk human papillomavirus (HPV) assays for primary cervical cancer screening, by using self-collected samples, and to identify an HPV assay that could overcome the major obstacles faced during large-scale population-based screening. Two hundred and ten women showing abnormal cervical cytology (and referred for a colposcopy) were recruited in this study. Self-collected samples obtained from all women were tested with the Cobas, Seq, and BioPerfectus Multiplex Real Time HPV assays; simultaneously, clinician-collected samples (from the same women) were tested with the gold-standard Cobas HPV assay. The results of all the assays were consistent. The sensitivity, positive predictive value, and negative predictive value for cervical intraepithelial neoplasia 2+ (CIN2+) and CIN3+ were comparable

between the self-collected samples tested with the three new assays and the clinician-collected samples tested with the Cobas HPV assay (P > 0.05). The single-genotype HPV load per sample did not differ significantly between the self- and clinician-collected samples (P = 0.195). In conclusion, the results of this study demonstrated the applicability of the three new HPV assays for primary cervical cancer screening based on self-collection.

Key words: Cervical cancer; Human papillomavirus; Screening; Cervical intraepithelial neoplasia