

Clinical Performance of the Microarray based Sexually Transmitted Disease Diagnostic Kit : STDetect Chip

Yong Kwan Lim¹, Jee-Hye Choi¹, Ae Ja Park¹, Jongwon Kim², Jihyung Lee², Ah Reum Park², In Young Kim², Shin Ae Lee²

¹Department of Laboratory Medicine, College of Medicine, Chung-Ang University, South Korea

²Department of Molecular Diagnostics, LabGenomics Co., South Korea

Background: The STDetect Chip, based on the microarray technology, is designed to detect 10 pathogens of sexually transmitted disease (STD); *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, *Ureaplasma urealyticum*, *Mycoplasma genitalium*, *M. hominis*, *Trichomonas vaginalis*, *Gardnerella vaginalis*, *Candida albicans*, Herpes simplex virus(HSV) 1 and 2. We had planned to evaluate this STDetect chip in two phases; first phase for commercial laboratory and second phase for university hospital. In this study, we expect to evaluate the clinical performance of the new assay with comparing commercially available STD detection kits.

Methods: In 2015, total 300 samples (161 swabs from women and 139 urines from men) were tested by STDetect chip and Anyplex II STI-7 (Seegen, Korea) as the comparing diagnostic kit. The second phase is in progress from the Chung-Ang University hospital, and total 750 samples will be evaluated with two STD assays and additional PCR test (Seeplex HSV2, Seegen) to detect HSV-2 infection

Results: In first clinical evaluation, only 6 pathogens were compared because of different inclusivity between two assays. Among 300 samples, 277 samples showed consistent results, and the sensitivities and specificities were 90.5% ~ 98.8% and 95.6% ~ 99.6%, respectively. The second phase has been completed about 60%, and expected to be finished at August, 2016. Results from two evaluations would show the clinical performance of the STDetect chip compared to PCR assays.

Conclusions: We expect that the multi-target STDetect chip could be one of the most useful assays in the diagnosis of STD in clinical situations.