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A Study on Immunological and Molecular Genetic Test Methods of Bacterial Sexually Transmitted Diseases Reagents (Development of Evaluation Guidelines of Test Method for IDV for Sexually Transmitted Infection)

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Abstract: *Chlamydia trachomatis* is usually isolated only from humans and is often infected together with other sexually transmitted diseases(STD). *C. trachomatis* is a serious disease which infects 500 million people per year globally and causes blindness in 7 to 9 million people per year due to continuous infection. Thus, it is urgent to develop (draft) guidelines on the test methods for performance evaluation of medical devices for in vitro diagnosis of bacterial STD(*C. trachomatis*) based on molecular diagnosis. In this study, in reference to the U.S. FDA Guidance, has derived essential methods for testing performance which are applicable to medical device for in vitro diagnosis of bacterial STD which are used in the field of molecular diagnosis. Because of the establish of the test method for performance evaluation of medical devices, it could provide consistent performance evaluation standards for the approval and examination of products, promote the improvement of the quality and safety of products. This will contribute to the development of the quality and safety of products. This will contribute to the development of medical device for in vitro diagnosis in Korea.

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