

## Laboratory Developed Test Regulation in Asia

SOOBIN CHAE

Medical Technologist

Expertise in Next Generation Sequencing (NGS) analysis, human genetic testing, and quality control processes. Adept at managing end-to-end workflows for genetic testing and ensuring compliance with clinical and regulatory standards.

Clinical Laboratory Technologist ( Molecular Genetics Department )

2020/09 – Present

1. Next Generation Sequencing (NGS): Perform and manage NGS workflows, including DNA/RNA extraction, library preparation, sequencing, and data analysis for diagnostic purposes such as hereditary cancer and somatic mutation.
2. Human Genetic Testing: Conduct a variety of human genetic tests, including Real-time PCR, Sanger sequencing, and Clonality analysis, MLPA, HLA high resolution sequencing, ensuring high accuracy and reliability of results.
3. Laboratory Quality Assurance: Develop, optimize, and document protocols while maintaining compliance with international standards such as LMF(Laboratory Medicine Foundation) and CLIA. Perform regular quality control checks to uphold clinical testing reliability.
4. Laboratory-Developed Tests (LDTs): Perform laboratory-developed tests by using reagents from various manufacturers and conducting in-house validations to ensure the accuracy and reliability of results.

