

## ME Spring Seminar 04

# Development, Evaluation, and Regulatory Approval of In Vitro Diagnostic Medical Devices



**Prof. Tae Yeul Kim**

Laboratory Medicine and Genetics  
Samsung Medical Center



This lecture provides an overview of diagnostic testing methods used in hospitals for patient diagnosis, focusing particularly on the development, evaluation, and clinical application of these methods. Diagnostic tests can be categorized into three types: tests approved by the Ministry of Food and Drug Safety (MFDS), modified versions of approved assays, and laboratory-developed tests (LDTs). All of these can be either reimbursed or non-reimbursed depending on regulatory and clinical considerations.

In vitro diagnostic (IVD) devices classified as Class III or higher require MFDS approval, which mandates clinical performance studies using patient specimens at designated institutions. Approval is granted only when the device meets the required performance standards. However, the approval process has become increasingly stringent, resulting in fewer newly approved assays and the discontinuation of many previously approved IVDs after MFDS reevaluation. Consequently, the number of available diagnostic products—particularly those developed domestically—has been steadily declining.

At the same time, there remains an unmet clinical need for essential diagnostic tools in rare or low-demand indications that are not commercially viable for companies to pursue. To address these gaps, our research team collaborates with IVD manufacturers through government-funded and private-sector projects to develop new diagnostic methods. While our team can conduct assay development independently, obtaining regulatory approval, manufacturing, distribution, and quality control require industry involvement.

In areas where commercial participation is limited, modified assays or laboratory-developed tests are implemented to provide necessary diagnostic services to patients. This lecture will illustrate the overall process—from assay development to clinical application—through real-world case examples.

**Bldg.110 #N105**

**16:00 - 17:15**

**Wednesday, April 8**



Host:

Prof. Kang Soo Lee (kangsoolee@unist.ac.kr)