Laws and regulations related to LDT (Laboratory Developed Test) in Japan

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When we perform the laboratory testing for diagnostic purposes in Japanese clinical laboratory, it is necessary to perform as follows: 1. Use a measuring device approved as a medical device, 2. Laboratories that meet the requirements for sufficient standards, 3. Use methods approved for clinical diagnostics. On the other hand, there is no system to confirm the performance, quality, and safety of LDT, and the way of thinking about LDT has not been decided even among medical professionals.

For example, in the case of genetic testing for intractable diseases, which includes many rare genetic diseases, the number of samples per test is small, and there are no companies developing in vitro diagnostics or medical devices because there is no expectation of recouping development costs. In addition, because the current insurance points for individual genetic tests are not commensurate with the cost of performing the tests, there are very few registered healthcare laboratories that develop and market LDTs, and the number of genetic testing laboratories in Japan is extremely small.

Japanese Committee for Clinical Laboratory Standards (JCCLS), Laboratory Standards Society in Japan published a guidance document for gene-related testing on the premise of obtaining certification by the ISO15189.JCCLS-ISO15189 and CAP-LAP indirectly assure the quality of laboratories themselves by conducting proficiency testing or inspections of laboratories based on checklists and requirements, and by accrediting laboratories and institutions. However, these checklists and requirements do not cover specific verification items and procedures that should be performed at the time of development of individual LDT test items.

This seems to be a major factor that makes it difficult to identify the quality of individual LDTs. In order to promote the use of LDTs while ensuring performance, quality, and safety, it is necessary to examine the framework and scope of application that are suitable for Japanese health insurance system and medical fee system, while refer to advantages and disadvantages of other countries that are leading the way, and deepening the understanding of the related parties.