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Precision, Innovation, and Legacy in Laboratory Medicine



ISO 15189 Accreditation for Medical Laboratories: Insights and Practical Experience from Taiwan

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The development of Taiwan's medical laboratory accreditation system began in 2000, led by the Chinese National Laboratory Accreditation Body (CNLA, now Taiwan Accreditation Foundation, TAF), the Central Office of the Ministry of Health and various experts. In 2001, the first batch of medical laboratories was accredited under ISO 17025, a standard for testing laboratories.

ISO 15189, specifically for medical laboratories, was published in 2003, and TAF completed the Chinese version in 2004, marking the beginning of ISO 15189 accreditation in Taiwan. The standard has since undergone three revisions (ISO 15189:2007, ISO 15189:2012, and ISO 15189:2022). As of February 2025, 268 accredited medical laboratories in Taiwan operate within hospitals, clinics, diagnostic centers, foundations, and government institutions.

The adoption of ISO 15189 has strengthened clinical laboratory quality through standardized procedures, internal and external quality controls (IQC, EQA), metrological traceability, and comprehensive quality management systems. Government agencies now integrate accreditation into hospital evaluations, infectious disease testing, and national screening programs.

With over 20 years of promoting ISO 15189, Taiwan has established a common quality language among laboratories of varying sizes, enhancing the reliability of test reports and playing a crucial role in the global recognition of Taiwan's healthcare performance.

