

2025

**The 8th AAMLS &
The 16th APFMLS**

2025 8th Congress of Asia Association of Medical Laboratory Scientists
in conjunction with 16th Asia-Pacific Forum of Medical Laboratory Sciences

Precision, Innovation, and Legacy in Laboratory Medicine



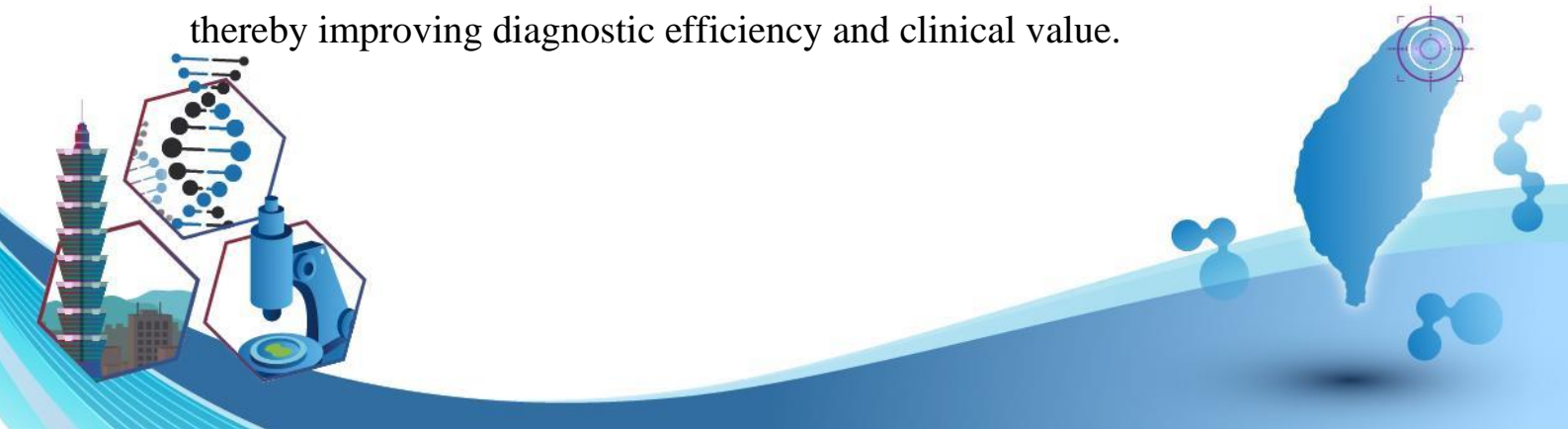
How Taiwan's LDT Regulations and Reimbursement Shape the Future of Precision Medicine

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Taiwan's Laboratory Developed Tests (LDTs) are driving innovation in precision medicine, playing a crucial role in cancer genetic testing, genetic disorder diagnosis, and infectious disease detection. As advanced diagnostic tools, LDTs must be conducted in certified medical laboratories that meet strict quality standards to ensure accuracy and reliability. To safeguard patient safety and testing quality, healthcare institutions must obtain approval from the Ministry of Health and Welfare (MOHW) before implementing LDTs, and they must undergo continuous monitoring to ensure compliance with regulations and clinical applicability.

Since 2024, the National Health Insurance (NHI) program has officially included Next-Generation Sequencing (NGS) LDTs in its reimbursement system, significantly improving patient access to precision diagnostics and targeted therapies, and expanding the clinical application of genetic testing technologies. However, LDTs still face challenges, such as sample processing, data analysis, and clinical implementation efficiency. To address these challenges, Taiwanese laboratories are actively adopting automation, AI-driven analysis, and diversified testing strategies, such as multi-gene panel testing and high-throughput NGS platforms while integrating liquid biopsy with traditional tissue analysis. These technological breakthroughs are reshaping clinical workflows, enabling faster, more accurate, and more comprehensive genetic variant analysis, thereby improving diagnostic efficiency and clinical value.



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Through policy innovation and technological advancement, Taiwan's LDT ecosystem is continuously enhancing diagnostic accuracy and clinical impact. Medical laboratory scientists play a key role in this transformation, ensuring quality control, method validation, and data reliability, maintaining high standards for LDTs, and providing optimal healthcare services for patients.

This presentation will explore Taiwan's LDT regulatory framework, NHI reimbursement policies, and quality management strategies, while analyzing approaches to advancing LDTs, aligning with international standards, and shaping the future of precision medicine from Taiwan's perspective.

