Research on the Reform and Practice of Medical Laboratory Personnel Training Mode Under the Guidance of Laboratory Developed Tests (LDTs)

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Abstract: With the rapid development of precision medicine, Laboratory Developed Tests (LDTs) have become critical for clinical diagnosis and translational research. China's LDTs sector faces dual challenges: improved regulation and a shortage of high-quality interdisciplinary talents. Based on domestic and foreign regulatory and quality management requirements, this paper identifies key problems in medical laboratory personnel training: overemphasis on theory over practice, overemphasis on verification over research and development (R&D), and weak regulatory awareness. Guided by Outcome-Based Education (OBE), Project-Based Group Study (PBGS), and the"isomorphism and equivalence"concept, this study proposes an integrated training model featuring medicine-science-engineering intersection and industry-university-research collaboration. By reconstructing the curriculum, strengthening whole-process quality management training, and establishing a diversified evaluation mechanism, we aim to cultivate innovative, quality-conscious and compliant medical laboratory professionals to meet the demands of the LDTs era.
***Keywords*:** Laboratory Developed Tests (LDTs); medical laboratory science; personnel training; OBE; quality management

1. Introduction

Laboratory Developed Tests (LDTs) are in vitro diagnostic tests independently developed, validated and used in clinical laboratories. Supported by high-throughput technologies such as mass spectrometry and next-generation sequencing, LDTs are widely applied in rare disease diagnosis, precision tumor therapy and pharmacogenomics. However, their technical complexity and non-standardized features impose high requirements on professional competence.

In China, LDTs are moving toward standardized supervision through national pilot programs. Nevertheless, the current medical laboratory education focuses on commercial kit operation rather than LDTs-oriented R&D, methodological verification and regulatory compliance. Cultivating high-quality talents for LDTs has become an urgent task for educational reform.

2. Analysis of LDTs Development Status and Talent Demand Characteristics

2.1 Regulatory Trends and Quality Challenges of LDTs

LDTs differ from commercial in vitro diagnostic reagents by their self-developed and self-used nature. The United States adopts CLIA'88 as the core regulatory framework; the final LDTs supervision rule issued by the FDA in 2024 was judged ultra vires, and the CMS-CLIA joint regulatory model is still in effect. The EU adopted the IVDR Regulation in 2017, fully implemented on May 26, 2022, which incorporates homemade reagents into medical device supervision, with a transition period for in-house reagents in medical institutions, some extended to 2028. China has not fully liberalized LDTs. The revised Regulations on the Supervision and Administration of Medical Devices implemented on June 1, 2021 provides legal support for pilot programs. The National Medical Products Administration and the National Health Commission have jointly carried out pilot projects, and pilot schemes in Shanghai and other regions require the establishment of a full-process quality system. Such a regulatory trend requires practitioners to master experimental operations and possess solid quality management capabilities. LDTs face challenges including complex technical platforms. Laboratories must follow standardized procedures. Taking liquid chromatography-tandem mass spectrometry as an example, its quality management covers all essential elements, and the complexity of methodological verification far exceeds that of conventional IVD verification[4].

2.2 Post Competency and Talent Shortage

The development of LDTs relies on interdisciplinary professionals with medical, scientific and engineering backgrounds, who should be equipped with research and development innovation, full-process quality control capabilities, as well as regulatory and ethical literacy. Students trained under the current education system are mostly proficient in standardized operations, lacking the ability to solve complex engineering problems and respond to unexpected quality issues, making it difficult to meet the high-level, innovative and challenging requirements of LDTs positions[3].

3. Analysis of Deficiencies in the Current Medical Laboratory Personnel Training Model

Based on the theory of isomorphism and equivalence, specialty construction should be structurally consistent and value-aligned with industrial structure and talent demands. Compared with LDTs job requirements, the current training model has the following mismatches.

3.1 Structural Mismatch Between Curriculum System and Industrial Demand

Traditional curricula are mostly divided into subspecialties such as biochemistry, immunology and microbiology, with contents mainly based on the principles of mature commercial kits. Cutting-edge technologies involved in LDTs, such as mass spectrometry sample preparation, bioinformatics analysis and reagent raw material screening, are rarely covered. Traditional teaching leaves students “knowing what but not why”, resulting in the need for retraining after employment[6].

3.2 Rhythm Mismatch Between Practical Teaching and Research and Development Process

The essence of LDTs is a closed loop of research and development, verification and application. However, existing experimental teaching is mostly confirmatory, where students obtain results through step-by-step operation, lacking in-depth training in methodological performance evaluation (e.g., interference test, recovery test). This model fails to cultivate students’ scientific thinking and problem-solving abilities for unknown issues.

3.3 Value Mismatch Between Quality Awareness and Regulatory Requirements

Quality management requirements for LDTs are higher than those for routine tests. Students lack systematic learning of ISO 15189, CAP accreditation standards and special regulations for LDTs during their studies, leading to weak awareness in formulating standard operating procedures, handling deviations and managing risks in practice.

4. Construction Path of LDTs-Oriented Medical Laboratory Personnel Training Model

To address the above deficiencies, the Outcome-Based Education (OBE) concept should be introduced, and the talent training system should be reconstructed by learning from Project-Based Group Study (PBGS) and industry-education integration.

4.1 Concept Reconstruction: Oriented by OBE and Isomorphism-Equivalence

Guided by OBE, interdisciplinary talents are cultivated with industrial demand as the output orientation. The goal is to enable students to master solid medical laboratory theories, understand LDTs research and development processes, and be competent for relevant positions. In terms of cross-border integration, disciplinary boundaries are broken to integrate multidisciplinary knowledge and form an adaptable knowledge system.

4.2 Curriculum Reconstruction: Establishing a Modular Curriculum System

Specialized technical courses for LDTs are added, such as Clinical Mass Spectrometry, focusing on raw material screening and other key contents. Methodological verification teaching is strengthened, and practical training proportion is increased to help students recognize the differences between LDTs and IVD verification. Regulatory and ethical education is integrated, with relevant courses offered to interpret policies and cultivate compliance awareness.

4.3 Model Innovation: Implementing PBGS and Integrated Theory-Practice Teaching

Drawing on the PBGS model and situational teaching method, LDTs research and development is transformed into teaching projects to drive students to complete the whole process[8]. Integrated theory-practice teaching eliminates the separation between theoretical learning and experimental operation. Clinical application scenarios are simulated, and role-playing is arranged to enhance students’ communication, collaboration and clinical thinking abilities[7].

4.4 Faculty Development: Building an Interdisciplinary “Double-Qualified” Teaching Team

LDTs teaching requires instructors proficient in clinical laboratory science, reagent development and regulations.

To integrate enterprise resources into education, research and development engineers from in vitro diagnostic enterprises and technical directors from third-party laboratories are employed as part-time instructors to share practical LDTs development experience.

To enhance professional competence, full-time teachers are selected to work in LDTs pilot hospitals or IVD enterprises, participating in real LDTs development and verification projects to improve engineering practice capabilities.

4.5 Evaluation Reform: Establishing a Whole-Process and Multidimensional Assessment Mechanism

The traditional "one-exam-fits-all" model is broken, and an evaluation system based on post competency is established[5].

Process evaluation focuses on students' performance in projects, including the scientificity of experimental design, standardization of operation, rigor of data analysis and teamwork capability.

Outcome evaluation is product-oriented, assessing the quality of LDTs performance verification reports, SOP documents and original records submitted by students, which must meet clinical laboratory accreditation standards.

5. Conclusion

LDTs represent an inevitable trend in the development of precision medicine and mark a key shift of laboratory medicine from "serving clinics" to "leading clinics". Faced with technological breakthroughs and regulatory pressures brought by LDTs, medical laboratory education must take the initiative to reform. Relying on the OBE concept, promoting industry-education integration, optimizing curriculum design, and strengthening methodological verification and regulatory education can cultivate interdisciplinary talents with research and development thinking, quality awareness and innovation capacity[2]. This approach not only alleviates the current shortage of LDTs professionals but also provides solid talent support for the high-quality development of laboratory medicine in China[1].

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