本期企劃

實驗室開發檢測的監管爭議、訴訟風險與臨床溝通責任

Navigating the Regulatory Uncertainties, Legal Risks, and Clinical Communication Duties of Laboratory Developed Tests (LDTs)

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摘 要

實驗室開發檢測在精準醫療、罕見疾病診斷與個人化健康服務中扮演關鍵角色。然而，隨著其技術複雜度與應用規模迅速擴大，實驗室開發檢測的監管框架與法律責任也日益受到關注。本文首先回顧美國與臺灣對LDTs的監管發展與政策變遷，聚焦於2024年美國食品藥物管理署頒布實驗室開發檢測監管最終規則及2025年德州聯邦法院的判決對監管權限的否決，揭示當前制度面臨的法律挑戰與執法邊界問題。此外，進一步分析Quest / Athena Diagnostics與Maldonado v. GeneDx, Inc.實際案例，探討患者因檢測錯誤而提起訴訟的風險來源與責任歸屬。最後，本文強調臨床溝通

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關鍵詞：知情同意（informed consent）、產前篩檢（prenatal screening test）、實驗室自行研發檢驗方法（laboratory developed test, LDT）

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與知情同意程序的完整性對於降低法律風險、保障病患權益與重建醫療信任關係至關重要。

Laboratory Developed Tests (LDTs) play a pivotal role in precision medicine, rare disease diagnosis, and personalized healthcare services. However, as their technological complexity and scope of application rapidly expand, the regulatory framework and legal liability associated with LDTs have garnered increasing attention. This article first reviews the regulatory development and policy evolution of LDTs in the United States and Taiwan, focusing on the Food and Drug Administration's (FDA) promulgation of the final rule for LDTs regulation in 2024 and the 2025 federal court ruling in Texas that rejected the agency's regulatory authority, thereby revealing the legal challenges and enforcement boundary issues confronting the current system. Through cases including Quest/Athena Diagnostics and Maldonado v. GeneDx, Inc., we explore liability attribution when testing errors lead to patient litigation. The analysis reveals that amid regulatory uncertainty, robust clinical communication and informed consent procedures are vital for mitigating legal risks and protecting patient rights.

壹、LDTs的角色與臺灣監管制度現況

實驗室開發檢測（laboratory developed tests, LDTs）作為臨床實驗室自行研發、製造並應用的診斷工具，在現代醫療扮演重要的角色。COVID-19全球大流行初期，由各國學術醫療機構、公共衛生實驗室及私人檢驗單位，基於其既有的分子診斷技術平臺，迅速建立SARS-CoV-2核酸檢測方法，更推動