醫事綜探

以機器人系統進行PCR檢測：醫學自動化的法規支持

Deploying Robotic System in the PCR Testing: The Regulatory Basis for the Medicine in the Era of Automation

陳怡君 Yi-Chun Chen*　黃浥昕 Yi-Hsin Huang**

摘　要

自新冠肺炎疫情爆發後，在各國檢驗能量備受考驗下，不同國家以各種相應措施試圖改善檢測的困境，並試圖加快檢驗速度、加大檢驗數量。我國以專案方式授權國外輸入檢驗試劑及輔導國內製造；美國則以緊急使用授權開放進口並放寬審查；日本廠商在機場、體育場館等人群聚集處導入機器人系統加速檢驗，並降低醫療人員採檢時的感染風險，機器人的自動預處理更可自動對陽性樣本進行基因解析，快速掌握變異株的感染狀況並檢測出新的變異株；荷蘭研究所則是導入號稱是迄今最快、最精確的機器人檢測系統。

*亞歷桑那大學法學研究生（Graduate Student, James E. Roger College of Law, The University of Arizona）
**職能治療師（Occupational Therapist）
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Since the outbreak of COVID-19, the public health agencies have been seriously challenged by the pandemic; countries tried to accelerate the quality and quantity of PCR test and tried to improve the storage of testing reagent with different solutions. In Taiwan, TFDA authorized case-by-case on the importation of test reagent for the emergency use and assisted the domestically produced test reagent. In Japan, the robot manufacturer developed an automated PCR viral testing robot system in crowded places, such as airports and stadiums to speed up the test and ceased the infection risk when the health professionals collected the sample. There was also an automated system for the analysis of the novel coronavirus, which the pre-process could automatically conduct the gene analysis to the positive sample, monitor the infection status of the sample and detect new variants. In the Netherlands, the research institute developed a pioneering automated test robot, which claimed to be the fastest and most accurate robotic test system.

自2020年第一波疫情爆發後，各國檢驗能量備受考驗，對於是否進行普篩，不同國家的公衛政策與方針大相逕庭，而醫療公衛單位是否能夠負擔如此巨大的檢驗量則成為眾人矚目的焦點。在進行PCR檢測時，除了醫療人員的負擔倍增，各國紛紛面臨試劑不足的窘境。許多國家從他國進口檢驗試劑時，面臨了是否給予特殊進口授權許可的問題；而嘗試在國內自行生產時，也面臨了是否進行緊急授權製造體外診斷醫療器材的窘境。

PCR核酸檢測（Reverse transcriptase polymerase chain reaction, RT-PCR）作為當前全球判斷染疫的標準檢測，雖較其他檢驗方式耗時、成本也較高，且須在生物安全性二級以上