附件四、技術說明表

紙噴灑微型質譜儀平台：現場快速簡易篩檢癌症的新技術

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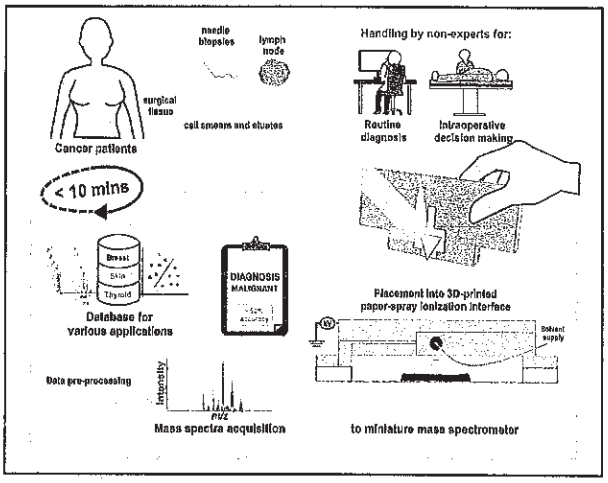

市場及需求: 組織病理學診斷癌症耗時且需專業人員。隨著全球癌症患者數量逐年上升，診斷需求將超出供應，而延後病人治療的時間。因此，提供一個現場快速簡易診斷癌症的方法，能協助醫務人員在常規檢測及手術中立即做出決策，極為重要。

技術摘要(含成果):
使用四極桿(single quadrupole)的微型質譜儀，解決臨床診斷的難題。我們提供了一個經濟易於操作的平台，即使非專業人員也能夠快速檢測癌症。操作人員只需將待測樣品放在濾紙上，裁剪後放入 3D 列印的支撐架並固定平台，約兩分鐘後即可開始收集質譜圖。透過本實驗室建立的大型資料庫 (其中不同預測模型分別用於三種癌症，樣本數超過 1000 筆)，我們能夠在 10 分鐘內對樣品進行癌症篩檢，準確率高達 90 %，可協助醫務人員在診斷或手術中做出決策。

優勢: 此質譜平台的優點為快速和高效，易於非專業人員於醫療現場進行癌症篩檢。目前已證實該技術可適用於病理學中常見的檢體，協助病理學家減少主觀判斷的誤差並保持標準檢測程序不受影響。此外，該平台還能協助搜尋癌症標誌物，深具多方面的應用潛力。

競爭產品: 組織病理學診斷，細胞學診斷，分子診斷方法—免疫組化(Immunohistochemistry)、螢光原位雜交(fluorescent in situ hybridization)、次世代定序 (Next Generation Sequencing)，以及其他質譜技術 —MasSpec Pen and iKnife。

專利現況:
（1） 專利申請中
（2） 本研究團隊對於質譜方法與臨床應用的開發有多年的經驗，更是質譜快篩技術的國際先驅。

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A rapid, simplified, on-site cancer diagnosis alternative using paper spray ionization miniature mass spectrometry

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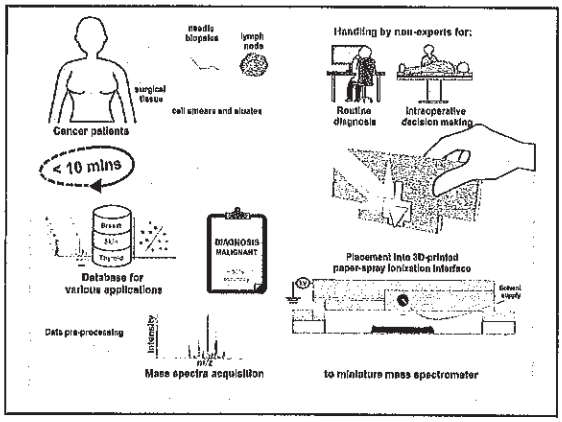
Experience: https://cchlabblog.wordpress.com/



Market Needs: Traditional histopathology involves time-consuming procedures and requires pathologists' availability for cancer diagnosis. With the increase in global cancer burden, the current health system could be overwhelmed, resulting in patients' delayed treatment. Hence, developing a rapid, on-site cancer diagnosis alternative that can be easily operated by any personnel is necessary to assist medical personnel with routine workloads and intraoperative decision-making.

Our Technology: Our technology focuses on being a rapid and cost-effective alternative for cancer diagnosis that is operational even by personnel without a background in mass spectrometry. We opted for a single quadrupole miniaturized mass spectrometer, thereby reducing space requirements. To further boost its adaptability into clinical settings, our proposed workflow for sample acquisition does not interfere with current standard operating procedures for cancer diagnosis. The acquired specimen will then be transferred onto a filter paper and placed into a self-designed 3D-printed paper spray interface. Mass spectra of the specimen can then be collected and pre-processed for prediction using our self-constructed database. The database consists of over 1000 mass spectra of various specimens and cancers, intended for different applications. Using the appropriate machine learning model, prediction of the specimen can be to provide a reference cancer diagnosis for routine applications or intraoperative decision making within 10 minutes at a ~90% accuracy.

Strength: Rapid and cost-effective technique with high adaptability into various clinical settings and operational by non-professional with minimal training. It is also applicable to specimens commonly used for histopathological examinations, and capable of providing a second, objective opinion for diagnostically challenging specimens, without affecting current standard operating procedures for cancer diagnosis. Collected data can also be utilized for research on cancer biomarker discovery.

Competing Products: Histopathology examination, cytology, molecular diagnosis methods (e.g. immunohistochemistry, fluorescence in-situ hybridization, next generation sequencing), and other mass spectrometry-based cancer diagnosis techniques (e.g. MasSpec Pen and iKnife)

Intellectual Properties:

1. Patent application in progress.
2. Prof. Cheng Chih Hsu's lab has years of experience in developing metabolites' analytical method for clinical applications.

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