



循環癌細胞之篩選培養系統

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市場及需求：

根據 BCC Research 的資料顯示，2016 年全球液態切片市場規模約為 19.7 億美元，CTCs 檢測之市場規模約 2.7 億美元，而 CTCs 檢測的市場占比則為 13.8%，預估 2020 年可達到 6.2 億美元，年複合成長率達到 22.7%。因此，CTCs 的檢測應用市場的技術發展，都是帶動液態切片市場快速成長的重要技術。目前新一代產品仍未形成標準，投入開發全自動的循環腫瘤細胞分離平台，並與國內醫療機構合作進行臨床研究，未來完成臨床驗證仍有機會競爭國際市場。資料來源：EMBO Mol Med (2015)；Nature Partner Journals: Precision Oncology (2017)；工研院 IEK 研究團隊整理(2017/08)

技術摘要(含成果)：

本技術係為一種從血液中篩選癌細胞的方法，運用特殊生醫材料本身具有使血液中的白血球貼附其上的特性，並可讓癌細胞懸浮於培養液中，進而達到將癌細胞從血液中分離出來的效果，可進一步由培養系統中取出癌細胞做相關的分析及檢測。

優勢：

本計畫優點與現有技術完全不同，若一開始即以特定抗體對血液中對極少量之循環癌細胞進行大海撈針，若未選到之抗體，則無法捕捉特定循環癌細胞，故往往要使用大量且多種之昂貴抗體，而增加產品使用及判讀過程成本的提高。本技術可減少抗體用量，且可最後才在對捕捉到之細胞加入特定抗體進行分類與判讀，大幅降低產品使用及判讀過程所需花費的成本，且本技術操作流程簡單、方便且快速，更可大幅縮短循環癌細胞的篩選流程及判讀時間。

競爭產品：

目前分離 CTCs 的技術發展可區分為兩個主要方向，一為利用標誌物的分離方法 (Label-dependent)，大多使用能夠捕捉 CTCs 的相關抗體，並配合系統收集捕獲的 CTCs。例如最早發展的 CellSearch® 系統，透過磁流體結合 EpCAM 抗體捕捉 CTCs；AdnaTest® 透過磁珠結合 EpCAM 與 MUC1 抗體在樣品中捕捉 CTCs；Isoflux® 則是以梯度離心初步分離樣品，再以微流體裝置配合 EpCAM 抗體分離 CTCs，提升分離效率；EasySep® 以負富集 (negative enrichment) 的策略透過 CD45 等抗體捕捉 CTCs 以外的細胞而在樣品中留下 CTCs；除了體外樣品檢測外，CellCollector™ 產品則是透過抗體與靜脈留置針在體內滯留 30 分鐘收集 CTCs。

專利現況：

本研究團隊具有多年開發生醫材料之經驗，並已開發出最佳不吸附癌細胞，但會吸附白血球細胞之生醫材料，目前亦在申請專利中。此外，主持人近年來更積極從事專利發表與產學合作，已 25 個專利獲證，相信未來會有更好的成果應用在生醫材料領域。

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Isolated culture system of circulating tumor cells

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Market Needs:

According to BCC Research, the global liquid biopsy market is estimated to be approximately US\$1.97 billion in 2016, the market size of CTCs testing is approximately US\$270 million, and the market share of CTCs detection is 13.8%, and is expected to reach 6.2 billion by 2020. In the US dollar, the compound annual growth rate reached 22.7%. Therefore, the technical development of CTCs testing and application market is an important technology that drives the rapid growth of the liquid slicing market. At present, a new generation of products has yet to form a standard. It has invested in the development of a fully automated platform for the separation of circulating tumor cells, and has cooperated with domestic medical institutions to conduct clinical research. In the future, clinical verification will still have the opportunity to compete in the international market. Source: EMBO Mol Med (2015); Nature Partner Journals: Precision Oncology (2017); ITRI Research Team, ITRI (2017/08)

Our Technology:

The present technology is a method for screening cancer cells from the blood. The use of a special medical material itself has the property of attaching leukocytes in the blood to it, and allows the cancer cells to be suspended in the culture fluid so as to achieve the goal of cancer cells. The effect of separation from the blood can be further removed from the culture system for relevant analysis and detection.

Strength:

The advantages of the project are completely different from those of the prior art. If a specific antibody is used to carry out needles in a small amount of circulating cancer cells in the blood from the beginning, if no antibody is selected, specific circulating cancer cells cannot be captured, so a large number of them are often used. And a variety of expensive antibodies increase the cost of product use and interpretation. The technology can reduce the amount of antibodies, and can finally classify and interpret the specific antibodies added to the captured cells, greatly reducing the cost for the use and interpretation of the product, and the technical operation flow is simple, convenient and rapid. Can greatly reduce the screening process and interpretation time of circulating cancer cells.

Competing Products:

At present, the technical development of the separation of CTCs can be divided into two main directions. One is to use the Label-dependent method of labeling. Most of them use relevant antibodies that can capture CTCs and collect the captured CTCs in conjunction with the system. For example, the earliest CellSearch® system captures CTCs through magnetic fluid binding to EpCAM antibodies; AdnaTest® captures CTCs in the sample through magnetic beads and binds to EpCAM and MUC1 antibodies; and Isoflux® preliminarily separates samples by gradient centrifugation, followed by microfluidic devices. EpCAM antibody isolates CTCs to increase separation efficiency; EasySep® uses a negative enrichment strategy to capture cells other than CTCs through antibodies such as CD45 leaving CTCs in samples; CellCollector™ products pass antibodies in addition to in vitro sample detection. Collecting CTCs with an intravenous indwelling needle for 30 minutes in the body

Intellectual Properties:

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The research team has many years of experience in the development of medical materials, and has developed the best non-adsorption cancer cells, but the biomaterials that will adsorb blood cells are also currently in the patent application. In addition, the host has been more actively engaged in patent publication and industry-university cooperation in recent years, and 25 patents have been approved. I believe there will be better results in the future in the field of biomedical materials.

Contact (do not need to fill out):

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