



發明名稱

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市場及需求:

克雷伯氏肺炎桿菌可以引起多種感染症，包含肺炎、泌尿道感染、菌血症、腦膜炎及肝膿瘍等。已知克雷伯氏肺炎桿菌是院內呼吸道感染最常見的菌，在台灣成人嚴重社區性肺炎更是略多於肺炎鏈球菌成為最常見的細菌。另外在革蘭氏陰性菌引起的菌血症與泌尿道感染，克雷伯氏肺炎桿菌也是第二常見的菌種。近年來在亞洲甚至於全世界被廣泛注意的化膿性肝膿瘍，克雷伯氏肺炎桿菌更是最主要引起疾病的細菌，且其發生率有逐年增加的趨勢。除此之外，最近克雷伯氏肺炎桿菌引起壞死性筋膜炎也是和以往最常見的 A 型鏈球菌同為主要的致病菌。目前已證實莢膜為克雷伯氏肺炎桿菌重要之致病因子，因此針對莢膜設計預防與治療應為最有效的方法。

技術摘要(含成果):

本研究團隊由自然界分離之新穎噬菌體與其莢膜分解酵素，具有莢膜特異性，對於特異莢膜型菌株與莢膜具有高度敏感性與專一性，目前分離的噬菌體與其莢膜分解酵素已可用於鑑定克雷伯氏肺炎桿菌所有莢膜型。除了增加敏感性與專一性外，此鑑定方法省去萃取細菌莢膜的步驟，可在一片培養基上完成全部莢膜型鑑定，本技術為一快速、準確和具穩定性與一致性的分型方法，且可進行大量檢體常規檢驗。目前已利用實驗室開發原型對臨床菌株進行莢膜分型，將各種具莢膜特異性的噬菌體與酵素分別分裝至 96 孔盤，欲分型之菌株培養液加入頂層瓊脂後倒入培養基中，待瓊脂凝固後，以八爪吸管器將之前分裝的 96 孔盤滴點到培養基對應位置，等待隔夜後（結果最為清楚明顯，最快可在 6-8 小時後看到初步結果），觀察產生透明溶菌斑或半透明酵素溶解莢膜圈的位置，即可判讀該菌株之莢膜型。

優勢:

1. 高度敏感性與專一性
2. 操作簡便快速，可進行大量檢體常規檢驗
3. 穩定性與一致性

競爭產品:

以往是利用血清鑑定克雷伯氏肺炎桿菌菌株莢膜型，但其敏感性與特異性皆不佳，因此臨床無此項檢查。目前開發之噬菌體技術，是更快速與準確之方法。目前技術優於傳統之血清分型技術，具競爭性，本專利之產品相當有機會進入市場

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專利現況：

本技術已申請台灣與美國專利，台灣專利近日已審定核准

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Title of Invention

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Experience:

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Market Needs:

Klebsiella pneumoniae is an important pathogen which causes various diseases in human. Recently, community-acquired pyogenic liver abscess (PLA) caused by *Klebsiella pneumoniae* complicated with metastatic meningitis and endophthalmitis has emerged globally, especially in Asia. Besides causing PLA, *K. pneumoniae* also has been reported to cause invasive infections leading to abscesses at other sites (such as kidney, spleen, brain, and prostate), necrotizing fasciitis, and severe pneumonia with bacteremia. The bacterial capsule is an important virulence factor for encapsulated human pathogens. Different capsular types are associated with different kinds of specific infections in humans. Accordingly, it is important to understand the prevalence rates of capsular types in clinical diseases. This information is essential in disease control and prevention.

Our Technology:

Our invention, the phage/enzyme typing system can be applied easily and accurately for capsular typing the *K. pneumoniae* bacteria in routine hospital labs. No capsule extraction or any molecular technique is needed. One μL of phage or glycosidase solution was spotted on the plate by an eight-channel micro-pipetter after the top agar with plating bacteria solidified. After 6-8 hours, the locations of the plaque(s) or semi-clear zone(s) were identified and the capsular type was then determined.

Strength:

1. high sensitivity and specificity
2. convenient
3. consistency

Competing Products:

Immunological diagnosis is usually used for identifying the capsular serotypes of *Klebsiella*. However, the anti-sera are expensive and have to be purchased from limited resources. Besides, a previous survey reported that approximately 50% of their *Klebsiella* strains were non-typable or reacted to more than one serotype by using anti-sera. Our invention will be more convenient and accurate in medical microbiological laboratory.

Intellectual Properties:

USA patent (pending), Taiwan patent (approval)

Contact (do not need to fill out):

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