

# 2020 年 10 - 12 月品質檢定 (細胞活躍測試結果) Oct - Dec 2020 Quality Assurance (Variability Results)

## ■全面檢測・信心保證

CRYOLIFE 每年進行兩次品質檢定，從每個儲存缸內抽取最少一個樣本，進行全面而透明度高的檢測，顯示 CRYOLIFE 對實驗室儀器及專業技術人員的信心，測試結果亦會於在網頁上公佈。

一般幹細胞儲存庫都會作「解凍後幹細胞恢復之存活能力」測試，確保幹細胞解凍後仍具備理想的機能。不過，對 CRYOLIFE 而言，這只是最基本的測試，CRYOLIFE 更注重完整保存幹細胞最具醫療價值的特性。幹細胞的珍貴價值，全在於其自我倍增及自我分化的特性。因此，CRYOLIFE 早於 2008 年起引入「細胞聚落形成單位 (CFU)」測試，檢驗不同儲存年份的樣本是否仍能保持自我倍增及自我分化能力，簡單而言即是測試經儲存的幹細胞在解凍後的活性。據國際品質鑑定機構 AABB 標準，血庫在發放幹細胞作任何醫療用途前，必須進行「細胞聚落形成單位 (CFU)」測試，以確保幹細胞品質，足以證明 CRYOLIFE 的定期質檢已到甚至超越國際水平。

CRYOLIFE 新一期的測試剛於 2020 年 11 月進行，但為預防新型冠狀病毒 Covid19 的擴散，實驗室人員需繼續嚴謹遵守最新的社交距離措施，以最低限度輪班工作。此次檢測從儲存缸中提取了一批樣本進行解凍及檢測，進行了「解凍後幹細胞恢復之存活能力」及「細胞聚落形成單位 (CFU)」測試。結果證明即使樣本被冷凍保存超過 17 年，大部分樣本的活性恢復率都超過 88%，遠高於 AABB 指引中規定移植前活性恢復率必需達到的 50%。此證明 CRYOLIFE 的長期保存系統並沒有影響臍帶血幹細胞的活性，質量測試結果令人鼓舞，促使我們的客戶大可放心，孩子們的臍帶血幹細胞在 CRYOLIFE 冷凍保存下仍然活躍，可用於未來的治療。

## ■Comprehensive Quality Assurance Test

Committed to deliver the highest service quality and taking pride in its cutting edge facilities, CRYOLIFE undertakes comprehensive quality assurance test twice a year. At least one dummy sample from different storage tanks – of all prior preservation years – will be evaluated with test results published on website.

Conventional cord blood banks will conduct Recovery of Viability Test to evaluate the preservation of stored stem cell's viability. CRYOLIFE's quality control and quality assurance go beyond that. Apart from basic tests, CRYOLIFE also conducts advanced Colony Forming Unit (CFU) Test to investigate the ability of proliferation and differentiation of hematopoietic stem cells. In essence, this means the ability to thaw stored stem cells to ensure its activeness after long term cryopreservation. According to AABB, the industry's leading authority, this CFU test must be performed before the cord blood is being released for any medical treatment to ensure the quantity, quality and stability of thawed stem cells meet transplantation requirements. This highlights CRYOLIFE's achievement in international assessment standard on stored stem cells from umbilical cord blood.

Complying with the latest social distancing restrictions, the laboratory was operating with limited alternative manpower teams as precaution against COVID-19. A batch of dummy samples were selected in the latest QA Test in Nov 2020 as per schedule. These selected dummy samples were thawed to evaluate their respective viability and CFU. The result shows that the viability recoveries for all samples, even with a cryopreserved period of above 17 years, majorities are over 88%, which are way above AABB's guideline of 50% viability prior to transplantation. This indicates that long term storage in CRYOLIFE has no negative effects on the cord blood stem cell's viability and CFU. Overall the quality test result is encouraging and reassuring to our customers that their child's cryopreserved cord blood's stem cells with CRYOLIFE are still active and viable for future therapies.

臍血處理年份 ( 存放時間 ) Year of Storage ( Storage Period )	解凍後幹細胞存活能力之恢復率 * Viability Recovery Rate*	細胞聚落形成單位 CFU ( $\times 10^4$ /ml)
2003 (17 年 )	89.0%	1.22
2003 (17 年 )	88.8%	3.54
2004 (16 年 )	88.9%	5.25
2007 (13 年 )	90.3%	4.27

\* 國際醫療指標的移植存活能力要求 : >50% International medical viability standard: >50%

# 品質檢定測試結果是來自隨機抽樣方式來選取樣本，測試結果並不代表其他儲存中的樣本會有相同結果。  
QA Results shown are from randomly selected samples. It does not represent that other samples within the storage will bear the same result.