

2013 年最新臍血樣本品質檢定報告 (12 月) Latest cord blood samples quality assurance test results

CRYOLIFE 每年進行兩次品質檢定，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，亦反映 CRYOLIFE 對檢測質量要求極高。

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造血功能。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。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 的定期質檢已達到甚至超越國際水平。

CRYOLIFE 新一期的測試剛於 12 月進行。此次檢測從儲存缸中提取了 5 份樣本檢測，其中 1 份樣本曾於以往進行測試，以作對比檢定。測試結果顯示，所有樣本在解凍後，恢復之存活能力均超逾 90%，重複測試結果證明，長期超低溫儲存對臍血幹細胞之存活率、自我倍增及自我分化能力並無影響。總括而言，此次測試結果非常令人滿意。

CRYOLIFE are committed to delivering only the highest quality of service and we take great pride in our state-of-the-art facility, what we do and our loyalty to our customers. This is why CRYOLIFE undergoes a comprehensive quality check twice a year.

Most conventional cord blood banks only conduct Recovery of Viability Tests. However, CRYOLIFE's quality control is more advanced and to an international standard. Aside from basic tests, CRYOLIFE has been conducting the Colony Forming Unit (CFU) Test since 2008 to investigate the ability of proliferation and differentiation of hematopoietic stem cells. AABB, the industry's leading authority, believe this CFU test is crucial before distribution to ensure the quality and stability of the sample.

In recent tests carried out in December 2013, five samples were thawed to evaluate the preservation of viability. One samples was chosen to be tested against previous results, in which we found that the recovery of viability in CRYOLIFE's samples is over 90%. Such testing has proven there is no evidence to suggest that long-term storage has an effect on cord blood cell viability. A result that is extremely satisfying and encouraging to both CRYOLIFE and our clients.

2013 年 12 月品質檢定 - 細胞存活能力測試結果 Dec 2013 Quality Assurance - Viability Results

臍血處理年份 Year of Processing	存放時間 (年/月) Preservation Period (Y/M)	解凍後幹細胞恢復之 存活能力 Recovery of Viability	細胞聚落形成單位 CFU (x 10 ⁴ /mL)
2006	7/8	95.9%	0.11-1.60
2007	6/3	99.7%	
2008	5/8	95.3%	
2011	1/11	99.0%	

重複測試結果比較 Comparison of Repeat Evaluation

臍血處理年份 Year of Processing	測試日期 Date of Evaluation	存放時間 (年/月) Preservation Period (Y/M)	解凍後幹細胞恢復之 存活能力 Recovery of Viability
2004	8/10/2013	9/9	93.4%
	16/12/2010	6/11	95.5%