

## 2011 年最新臍血樣本品質檢定報告 (9 – 10 月)

### Latest cord blood samples quality assurance test results

#### 全面檢測 信心保證 Comprehensive Quality Assurance Test

CRYOLIFE 每年進行兩次品質檢定，確保每年檢測範圍覆蓋每一個儲存缸及每一個年度的樣本。全面而透明度高的檢測除了顯示 CRYOLIFE 對實驗室儀器及專業技術人員的信心外，亦同時反映其對品質之要求極高。

Committed to deliver the highest quality of service, and taking pride in its cutting edge facilities, CRYOLIFE undergoes a comprehensive quality assurance test twice a year. At least one sample from each storage tank – of all preservation years – will be tested, with test results publish on website.

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恢復之存活能力。然而，對 CRYOLIFE 而言，這只是最基本的測試，並未能確保幹細胞最具醫療價值的特性未被破壞！幹細胞的珍貴，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，血庫於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)」測試確保幹細胞品質，足以證明 CRYOLIFE 的定期質檢超越國際水平。

Conventional cord blood bank will conduct Recovery of Viability Test to evaluate the preservation of viability. CRYOLIFE's quality control is far more than that. Apart from basic tests, CRYOLIFE conducts the advanced Colony Forming Unit (CFU) Test since 2008 to investigate the ability of proliferation and differentiation of hematopoietic stem cells. According to AABB, industry's leading authority, this CFU test shall be performed before distribution to ensure the quality and stability of the sample. Again this highlights CRYOLIFE's international assessment standard.

CRYOLIFE 新一期的測試剛於 9-10 月進行。今次從儲存缸中提取了 11 份樣本檢測，其中 4 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於解凍後，幹細胞恢復之存活能力均超逾 90%，重複測試結果證明，長期超低溫低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，是次測試結果令人非常滿意。

In the latest test carried out in September to October, eleven samples have been thawed and to evaluate the preservation of viability, in which four of the samples had been chosen to be tested to compare the results against previous testing. The result is satisfying, showing that the recovery of viability of all samples is over 90%. The result of repeated evaluation indicates that long-term storage has no evidence to suggest its affects on cord blood cell viability. The quality test result is encouraging.

#### 2011 年 9 - 10 月品質檢定 – 細胞存活能力測試結果

##### Sep to Oct 2011 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 <sup>4</sup> /mL)
2003	7/9	91.3%	0.3-11.1
2007	4/3	100%	
2007	3/11	96.8%	
2007	3/10	93.0%	
2008	3/8	95.0%	
2010	1/2	100%	
2011	0/4	95.4%	

#### 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
1998	23/06/2000	1/7	90.0%
	26/09/2011	12/11	93.3%
2001	16/04/2002	1/2	94.3%
	28/09/2011	10/8	100%
2001	22/04/2005	4/1	97.0%
	19/09/2011	10/6	90.3%
2009	10/11/2010	1/10	92.3%
	19/09/2011	2/8	91.0%