

# 2018 年 5-6 月品質檢 (細胞活躍測試結果) May - June Quality Assurance (Variability Results)

## 全面檢測 • 信心保證

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。

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。

CRYOLIFE 新一期的測試剛於 6 月 12 日進行，從儲存缸中提取了 5 份<sup>#</sup>樣本檢測。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 82.1%，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。

## 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 sample from each storage tank – 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 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, 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 stem cells meeting transplantation requirements. This highlights CRYOLIFE's achievement in international assessment standard on stored stem cells from umbilical cord blood.

In the latest test carried out in 12 June 2018, 5 samples<sup>#</sup> have been thawed to evaluate the viability of preservation. The result shows that the recovery of viability of all samples is at least over 82.1%. The result indicates that long-term storage has no negative effects on the cord blood stem cell's viability. Overall the quality test result is encouraging.

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 * Recovery Rate of Viability*
2001 (17 年 Y)	84.7%
2002 (16 年 Y)	99.6%
2004 (13 年 Y)	82.1%
2007 (11 年 Y)	94.9%
2008 (10 年 Y)	87.0%
* 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的結果。 QA Results shown are from randomly selected samples. It does not represent that other samples within the storage will bear the same result.	