2019 年 10-11 月品質檢定（細胞活躍測試結果）
Oct - Nov 2019 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 多年前起引入「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 2019 年 10 月 25 日進行。此次檢測從儲存缸中提取了 9 份樣本檢測，當中，於 5 年前測試過的臍帶血樣品亦再度測試以作比較。結果顯示，不論長達 21 年的樣本在解凍後，恢復之存活能力均超逾 87%。總括而言，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 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.

In the latest QA Test conducted from 25th October 2019, 9 dummy samples were selected according to schedule and thawed to evaluate their respective viability and CFU. For relevant comparison, a similar cord blood sample being tested 5 years ago was also selected in the recent QA Test too. The slight result differences are due to seeding and counting variations.

Overall, the result shows that the recovery of viability for all samples, even with a cryopreserved period of above 21 years are at least 87% with the mode range above 93% together active CFU. This result indicates that long term storage in CRYOLIFE has no negative effects on the cord blood stem cell's viability and CFU. 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 (x 10^4/mL)
2008 (11 年 Y)	95.70	1.05
2006 (13 年 Y)	93.00	2.03
2003 (16 年 Y)	96.50	1.22
2003 (16 年 Y)	94.80	1.10
2002 (17 年 Y)	93.00	0.66
1998 (21 年 Y)	87.10	0.26

* 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.

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)	解凍後幹細胞存活能力之恢復率* Viability Rate After Thaw*	細胞聚落形成單位 CFU
2000	25.10.2019	19 年 Y	89.30	0.29
	24.04.2014	14 年 Y	82.50	0.35