

2017 年 10-11 月品質檢定 (細胞活躍測試結果)

Oct - Nov 2017 Quality Assurance Variability Results

嚴格要求每項儲存步驟。全面而高透明度檢測

為確保每一份臍帶血樣本的品質，CRYOLIFE 從開業起，於不同儲存缸及不同儲存年份中抽取樣本，定期每年進行兩次細胞活性檢測，包括幹細胞存活率及聚落形成數值等，並公開讓公眾查閱。

根據國際品質鑑定機構 — 美國血庫協會 (AABB) 標準，任何存放於血庫的幹細胞，必須進行「細胞聚落形成單位 (CFU)」測試確保幹細胞品質及隱定性，才能用作醫療用途。

CRYOLIFE 於 2017 年 10 - 11 月進行樣本檢測。抽檢的 5 份樣本中，有 1 份樣本於 2015 年被選中作重複檢測。測試結果顯示，所有幹細胞樣本於解凍後，恢復存活能力遠超於國際醫療標準的 50%，**均達 82.1% 以上**。由此足以證明，儲存在 CRYOLIFE 的臍帶血幹細胞不只是『用得嘅』，而是高療效及活躍能力高的臍帶血幹細胞。

Committed to delivering the highest service quality of cord blood storage. Comprehensive and high transparency of QA test

CRYOLIFE conducts comprehensive quality assurance variability test on its stored stem cell twice a year. Samples were randomly selected from different tanks with different years for testing the recovery rate of the viability & Colony Forming Unit (CFU).

Advanced Colony-Forming Units (CFU) test shows the ability of differentiation and proliferation power of cryopreserved Hematopoietic Stem Cells. According to AABB, industry's leading authority, this CFU test must be performed before transplantation to ensure quality and stability of the sample.

Recent Quality Assurance variability tests were conducted in Oct – Nov 2017 with 5 randomly selected dummy samples. For relevant comparison, a SAME sample which was being tested 2 years ago was also selected in this latest QA test too.

The result reveals that all recovered stem cells' viabilities are above 82.1%，which is far better than the international medical standards of 50%. Results also indicate that long-term cord blood storages with Cryolife sustain high stem cell variability for medical treatment.

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*
2000 (17 年)	83.5%
2001 (16 年)	82.1%
2007 (10 年)	83.3%
2003 (14 年)	83.6%
2007 (7 年)	83.3%

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

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 * Recovery Rate of Viability*
2007	26.10.2015	14 年 7 月	81.8%
	16.10.2017	16 年 7 月	82.1%