



Quality Evaluation of Umbilical Cord Blood Cells in a AABB Accredited Cord Blood Bank in Hong Kong (QT16)
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2018 年美國血庫協會年度會議 發表臍血幹細胞質量研究報告

2018 Annual Meeting of the AABB Published research report about quality evaluation of umbilical cord blood cells

對跨奧多年的臍血幹細胞質量 報告表示肯定 Accredited CRYOLIFE's Quality Assurance Test for years

2018 AABB 美國血庫協會年度會議於 10 月 13 日至 10 月 16 日美國波士頓舉行。CRYOLIFE 於會議期間發表臍血幹細胞質量報告。報告指出，除了幹細胞的存活率外，以隨機方式選取臍帶血樣本進行解凍的「細胞聚落形成單位 (CFU)」測試 (與功能性幹細胞的數量有關)，結果顯示質量是非常高的。足以證明所有測驗過程及臍帶血儲存均符合 AABB 的嚴格規管和指引。

CRYOLIFE 向來自世界各地的醫生、護士、醫療技術和研究人員、以及臍血庫機構發表了臍血幹細胞質量報告。會議同期還發表了 120 篇學術報告及 500 篇壁報論文，讓業內人士交流最新血液及創新醫療技術。

2018 Annual meeting of the AABB was held from 13 – 16 October in Boston, USA.

CRYOLIFE presented the quality evaluation of umbilical cord blood cells research report during this Annual Meeting. Results show that besides stem cells' viability, the CFU (Colony Form Unit, which is related to the quantity of functional stem cells) from thawed samples of randomly selected cord blood units are of impressively high. All processing and cryopreservation are according to strict protocols and guidelines of AABB.

Cryolife's report and presentation were well received by attending medical and healthcare practitioners including doctors, nurses, technologists and researchers, as well as cord blood bank institutions from around the world. The annual meeting also published 120 academic reports and 500 poster papers for medical participants to exchange the latest blood and innovative medical technologies.

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2018 年 10-11 月品質檢定 (細胞活躍測試結果) Oct - Nov Quality Assurance (Variability Results)

全面檢測 • 信心保證

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，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 的定期質檢已到甚至超越國際水平。

CRYOLIFE 新一期的測試剛於 10 月進行。此次檢測從儲存缸中提取了 6 份樣本檢測。測試結果顯示，所有樣本在解凍後，恢復之存活能力均超逾 83.3%。總括而言，此次測試結果非常令人滿意。

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 most prior preservation years – will be tested, with test results publish 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, industry's leading authority, this CFU test must be performed before the cord blood is being released for any medical treatments to ensure the quantity, quality and stability of 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 test carried out in 30th Oct, 2018, 6 samples[#] have been thawed to evaluate the preservation of viability. The result is satisfying, showing that the recovery of viability of all samples is over 83.3%. 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*	細胞聚落形成單位 CFU (x 10 ⁴ /mL)
2001 (17 ^年)	90.8	1.20
2002 (16 ^年)	83.3	1.15
2003 (13 ^年)	83.8	0.12
2006 (11 ^年)	85.6	0.42
2007 (10 ^年)	93.7	0.20
2010 (8 ^年)	85.6	0.76

* 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.