

QUALITY OF LONG-TERM CRYOPRESERVED UMBILICAL CORD BLOOD UNITS IN A CORD BLOOD BANK IN SOUTHERN BRAZIL

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Introduction/objective: Umbilical cord blood (UCB) is an important source of hematopoietic stem/progenitor cells (HSPCs) for transplantation and the quality of cryopreserved samples is essential for ensuring future engraftment success. Several critical factors, including cryopreservation, storage, and thawing processes, can significantly affect the quality of these cell products. To address these concerns, accreditation organizations recommend establishing an HSPC stability program with specific parameters for assessing viable cell recovery and functional potency. In this study, we present the results of quality analyses for UCB samples that have been cryopreserved for up to 15 years at a private cord blood bank in southern Brazil (Hemocord Biotecnologia). **Methods:** This study was approved by the Human Research Ethics Committee of the University of Vale do Rio dos Sinos (n°6.185.705), and all donors provided informed consent. A total of 48 UCB units collected, cryopreserved, and stored in one of four nitrogen tanks at the company between 2005 and 2020 were included in this analysis. The viability of CD34 cells was determined using flow cytometry with 7-AAD staining. Additionally, functional assays were conducted using colony-forming unit (CFU) assays in methylcellulose. Outsourced services conducted all analyses. Results are reported as mean $\pm$ standard error. **Results:** We evaluated the cell viability in an average of three samples per year between 2005-2020. CFU analysis was conducted on 7 samples from 2005-2010, 9 from 2011-2015, and 6 from 2016-2020. The mean total nucleated cell (TNC) count per unit was $8.42 \times 10^8 \pm 0.7 \times 10^8$, with 37.5% of samples having final cell counts exceeding 900 million. After thawing, the average CD34+ cell concentration was $5.0 \times 10^6 \pm 0.8 \times 10^6$, with a mean viability of $95.1\% \pm 0.8\%$. While the lowest value was 76.2%, 40/48 samples had viability of CD34+ cells above 90%. CFU assays demonstrated colony growth in 47/48 samples. The mean total CFU per unit was $33.0 \times 10^5 \pm 5.9 \times 10^5$ (range: 1.0×10^5 to 113.0×10^5). All samples showed CFU of granulocyte/macrophage (CFU-GM) ($10.9 \times 10^5 \pm 2.1 \times 10^5$) and erythroid burst-forming units (BFU-E) ($21.9 \times 10^5 \pm 4.8 \times 10^5$), while 37/48 samples had granulocyte, erythrocyte, macrophage, and megakaryocyte (CFU-GEMM) growth ($1.6 \times 10^4 \pm 4.8 \times 10^3$). **Discussion:** CD34+ cell viability and CFU growth in analyzed samples met the criteria set by the Foundation for the Accreditation of Cellular Therapy (FACT), which recommends viable CD34+ cells $\geq 70\%$ post-thaw and CFU growth in UCB units intended for clinical use. Additionally, 37.5% of the analyzed samples met the rigorous criteria for TNC count, matching these results to American public cord blood banks. Recent studies have also highlighted the importance of the quantity and quality of viable cells in predicting successful engraftment outcomes. Thus, quantifying post-thaw viable CD34+ cells and CFU assays are valuable predictors of hematopoietic stem cell engraftment potential.

Conclusion: : Our results support previous studies demonstrating that the quality and potency of UCB units are preserved over the long term. These findings underscore the importance of maintaining rigorous quality control and maintenance in cryopreservation in cord blood banking to ensure the availability of high-quality samples for potential therapeutic use.

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ESTUDO COMPARATIVO ENTRE TESTE DE SOLUBILIDADE/TESTE DA MANCHA E ELETROFORESE DE HEMOGLOBINA NA TRIAGEM DE HEMOGLOBINA S EM DOADORES DE SANGUE

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Objetivo: Comparar o Teste de Solubilidade/Teste da Mancha com a Eletroforese de Hemoglobina na identificação de Hemoglobina S (Hb S) em doadores de sangue do HEMOGO. **Material e métodos:** As amostras testadas foram obtidas dos doadores de sangue no Hemocentro Coordenador Estadual de Goiás Prof. Nion Albernaz (HEMOGO), durante o período de 27/04/24 a 30/07/24. Estas foram submetidas à triagem para pesquisa de hemoglobina variante em sistema automatizado multiparâmetros (CAPILLARYS 2). As amostras identificadas com presença de hemoglobina variante, foram submetidas ao teste de solubilidade e à identificação da hemoglobina variante realizada por capilaridade, no equipamento CAPILLARYS 2. **Resultados:** No período foram avaliadas 20.344 amostras. O teste de triagem automatizado, através da técnica eletroforese capilar para HbA1c, detectou-se a presença de hemoglobina variante em 580 amostras (2,85%). A análise destas amostras, através da identificação da hemoglobina variante, demonstrou que 351 (60,6%) apresentaram Hemoglobina S (Hb S) presente, 135 (23,2%) foram identificadas como Hemoglobina C, 16 amostras (2,7%) identificadas como Hemoglobina E e 78 amostras (13,5%) foram detectadas outras hemoglobinas. O Teste da Mancha foi realizado nas 580 amostras, destas, 351 (60,6%) apresentaram resultados positivos. Após confirmação por eletroforese, evidenciamos a compatibilidade das técnicas em 100% das amostras analisadas. **Discussão:** Constatou-se que o traço falcêmico foi encontrado com frequência de 1,72% entre os doadores de sangue atendidos no período definido deste estudo. A compreensão da prevalência da Hb S em doadores de sangue é importante para delinear o melhor direcionamento do concentrado de hemácias (CH), para minimizar os riscos e priorizar a qualidade da transfusão, pois não é permitido a transfusão de CH em pacientes com hemoglobinopatias, acidose grave, recém-nascidos, transfusão intrauterina, procedimentos cirúrgicos com circulação extracorpórea e paciente apresentando hipotermia. **Conclusão:** Os resultados da identificação de Hb S por Eletroforese Capilar e Solubilidade/Teste da Mancha positivo foram 100% compatíveis. As duas técnicas mostraram-se