

Stability Testing Report of Cryogenically Stored Umbilical Cord Blood



Sample Details:

Report Date : 30/11/2021
Unique Identifier : L050236
Duration of Continuous Cryogenic Storage at below -190°C : 8 YEARS 5 MONTHS 10 DAYS
Volume of Cord Blood Stored : 26 ml

Results of Sentinel Sample Testing (Post Thaw)

1. Total Nucleated Cell Concentration : 19.3 X 10³/μL

Total Nucleated Cell Concentration - Total nucleated cells present per micro-liter of the cryopreserved sample after continuous storage of 8 years 5 months 10 days in cryogenic condition.

2. Total Viable Nucleated Cell Count : 4.8 X 10⁸ Cells

Total Viable Nucleated Cell Count - Total number of viable nucleated cells present in the entire cryopreserved sample after continuous storage of 8 years 5 months 10 days in cryogenic condition. Calculation of Total Viable Nucleated Cell Count = (Total Nucleated Cell Concentration x Volume of Cord Blood Stored x Viability of Cells)

3. Total Nucleated Cell Viability : 95.3 %

Viability - Here viability (post cryopreserved sample) indicates the percentage of viable cells present in the cryopreserved sample, kept in continuous cryogenic condition for 8 years 5 months 10 days.

4. Microbial Sterility : Sterile

Microbial Sterility - Microbial sterility is the determination of presence or absence of microbial contaminants in the cryopreserved sample. This test is performed for both Aerobic and Anaerobic organisms from the sample kept in the cryogenic condition for 8 years 5 months 10 days.

We will continue to test the samples as the years go by.

Prof Dr Menaka Hariharan
Medical Director

Dr Zhu Peng Cheng
Laboratory Director

GUIDE TO THE SENTINEL SAMPLE REPORT



This report details the results of stability tests performed once a year on a donated sentinel sample that is unrelated to our clients' samples.

The sentinel sample was stored in the same cryogenic storage tank as clients' samples and was subjected to similar storage conditions. Since clients' samples should not be removed from cryopreservation unless they are to be used in a transplant, the only way to evaluate the quality of our clients' samples is to conduct stability testing on the sentinel sample.

Stability test parameters include total nucleated cell count, percentage of total nucleated cell viability, and sterility testing. The sentinel sample used for this stability validation report is 8.5 years old, which means it was donated, processed, and cryopreserved 8.5 years ago. The number of viable cells in the sample is represented by the total nucleated cell count. Microbial sterility testing is performed to ensure that there are no contaminants or microbes present, such as bacteria and fungus.

The test results of this stability testing shows that the sentinel sample has retained its viability, is sterile, and free of microbial contamination after being cryopreserved for 8.5 years. This means that our clients' samples would have retained their quality because they are stored in the same conditions.

Cryopreserved cord blood can be kept indefinitely at temperatures below -150°C while retaining cell properties and functionality. According to research, cord blood stem cells that had been stored for 23.5 years were still viable.¹ We will continue to monitor the academic community for any new information about the viability of cord blood samples that have been stored for an extended period of time.

The oldest sentinel sample processed and cryopreserved by StemLife was tested after 17 years of storage. The sample met all of the acceptance criteria, according to our standard operating procedures and AABB standards.² StemLife has performed 19 cord blood releases at the request of our clients so far. The oldest sample among the releases was released after 11.1 years in storage. This sample was accepted by the transplant physician and used successfully in the treatment.

References: ¹ Broxmeyer HE, Lee MR, Gao H, et al. Hematopoietic stem/progenitor cells, generation of induced pluripotent stem cells, and isolation of endothelial progenitors from 21- to 23.5- year cryopreserved cord blood. *Blood*. 2011 117:4773-4777. Doi:10.1182/blood2011-01-330514

² Association for the Advancement of Blood & Biotherapies, Standards for Cellular Therapy Services, 10th Edition.

All information is accurate at the time of printing. PM-074 REV.00 Effective date: 01/01/2023.

