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SENTINEL REPORT

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SENTINEL SAMPLE REPORT

PROLOGUE

Cord Blood Stem Cells, like any other pharmaceutical product are medicines. There is a fixed time limit beyond which, consumption of a medicine is regarded as harmful. This time is known as "The Date of Expiry". Stem cells derived from umbilical cord blood (UCB) are also required by the Drug regulatory authority and the AABB to be assigned a date of expiration beyond which their usability is doubtful. Such expiration dates are assigned based on a carefully orchestrated stability testing program, in which non-commercial cryogenically preserved samples of the yesteryears are extracted and thawed to study recovery, sterility, viability and potency.

Although internationally 80% is the benchmark, Cordlife requires a minimum of 95% to meet the rigorous internal selection criteria. With its successful stability testing program, Cordlife Sciences India has established the most robust stability testing program, "The Sentinel Sample" without ever touching a commercial sample. The flawless collection, processing, testing and cryopreservation techniques followed over decades have told their tales through the simultaneous testing of 3 sentinel samples with each spanning over half a decade.

These results including the temperature graph from the respective cryopreservation vessels are being shared with you as an assurance that your child's Cord blood is safe with us.

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GUIDE TO THE SENTINEL SAMPLE REPORT

INTERPRETATION

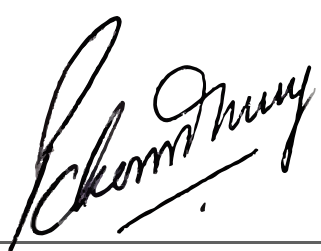
Sentinel sample is non-commercial and not associated with any clients' samples. Such non-commercial samples were processed and cryogenically stored in the same cryogenic storage tank along with other commercial/ clients' samples and exposed to similar conditions during entire tenure of its storage. The stability testing is carried out at least once a year since the commercial samples once cryopreserved are not to be taken out except at the time of transplantation or therapy. Hence, the stability test reports are performed with the Sentinel samples to assess and represent the stability of cryopreserved Umbilical Cord blood samples stored in the similar cryogenic condition. Sentinel sample report consists of Enumeration of Total Viable Nucleated Cell, Percentage viability and Sterility testing.

- **Total Nucleated Cell Count:** Total nucleated cells present per micro-liter of the Umbilical Cord Blood sample.
- **Total Viable Nucleated Cell Count:** Total number of viable nucleated cells present in the entire Umbilical Cord Blood sample.
- **Calculation of Total Viable Nucleated Cell Count =** (Total Nucleated Cell Count X Volume of Cord Blood Stored x Viability of cells).
- **Viability:** Here viability indicates the percentage of viable cells present in the Umbilical Cord Blood Sample.
- **Microbial Sterility:** Microbial sterility is the determination of presence or absence of microbial contaminants in the Umbilical Cord Blood sample. This test is performed for both Aerobic and Anaerobic organisms.
- **The provided temperature charts** depict the last 18 months' temperature readings of the Cryopreservation Tanks that are holding the samples.
- **Haematopoietic Stem Cell Potency Assay** confirms that the stem cells can grow into White Cells, Platelets and Red Blood Cells represented by CFU-GM, CFU-GEMM, CFU-E, BFU-E

The sentinel sample used for stability testing of September'2023 was processed and cryopreserved on 10.09.2008, 26.10.2013 and 26.12.2018 and after keeping the sample at the same cryogenic condition where the commercial samples are kept, it was extracted and thawed to test the vital parameters as mentioned in the report attached.

After comparing the initial and post thaw test results of Total nucleated cell count and % viability of the sample it was found that the Sentinel sample has indeed maintained its viability & is free from any microbial contamination.

Thus, suggesting that the commercial samples preserved in the same cryogenic condition would also preserve their quality in the similar way.



Dr. Prosanto Kumar Chowdhury
Laboratory Director & in-charge

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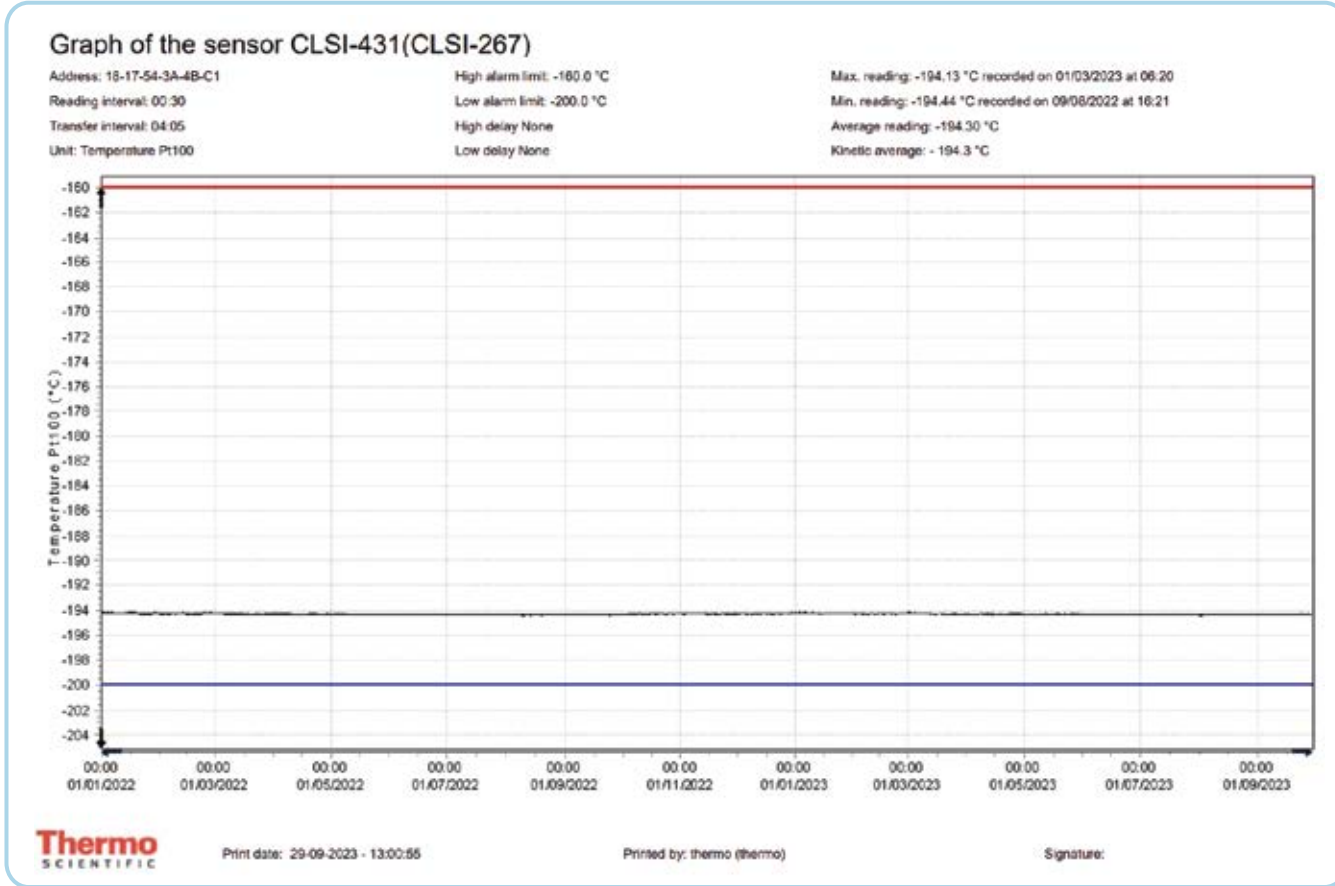
STABILITY TESTING REPORT OF CRYO-PRESERVED
UMBILICAL CORD BLOOD SAMPLE

SAMPLE RELATED DETAILS:

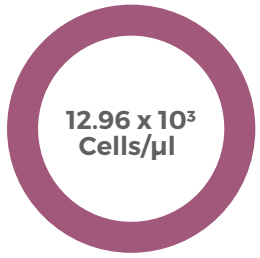
Unique Identifier of the Non-commercial Umbilical Cord Blood used for the Stability testing	DEMO/008/2008
Volume of Cord Blood Stored	25 ml
Segment used for the stability testing	5 ml
Actual Date of processing of the non-commercial Umbilical Cord Blood sample used for the Stability testing	10th September, 2008
Date of Stability Testing	15th September, 2023
Duration of Continuous Cryogenic Storage (at below -150°C)	15 Years 5 Days
Report Date	29th September, 2023

CRYOSTORAGE VESSEL RELATED DETAILS :



CELLULAR RECOVERY RELATED DETAILS:

Total Nucleated Cell Count



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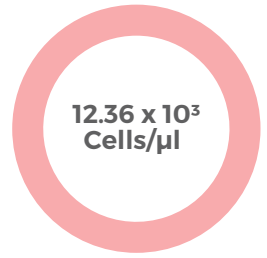
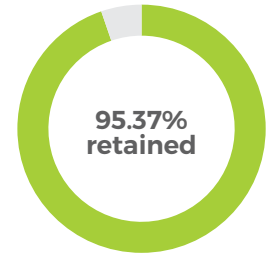


Post-thaw Data

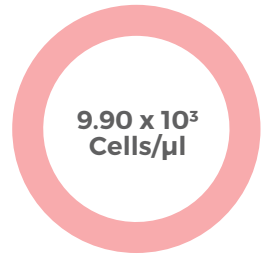


Analysis

VIABILITY RETENTION RELATED DETAILS:

Total Viable Nucleated Cell Count

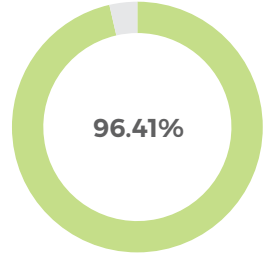
Initial Processing Data



Post-thaw Data

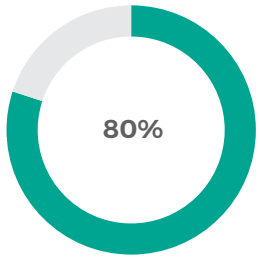
Analysis

CD 34 Viability



Post-thaw Data

CD 45 Viability (Nucleated Cell Viability)



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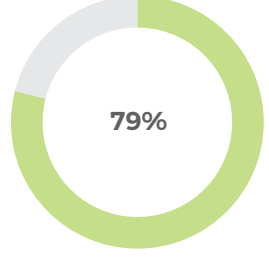
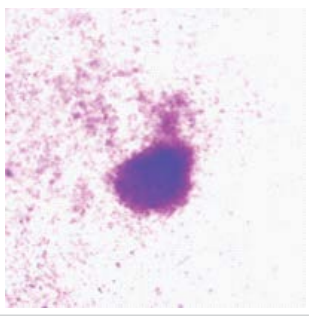
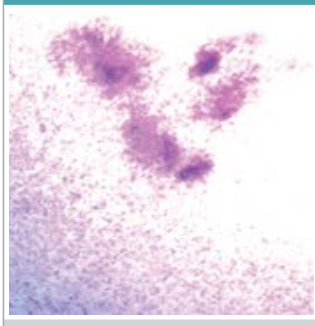
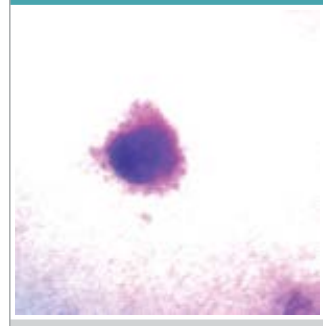
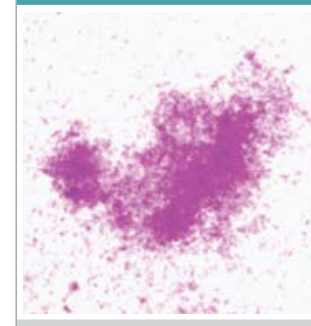


Post-thaw Data

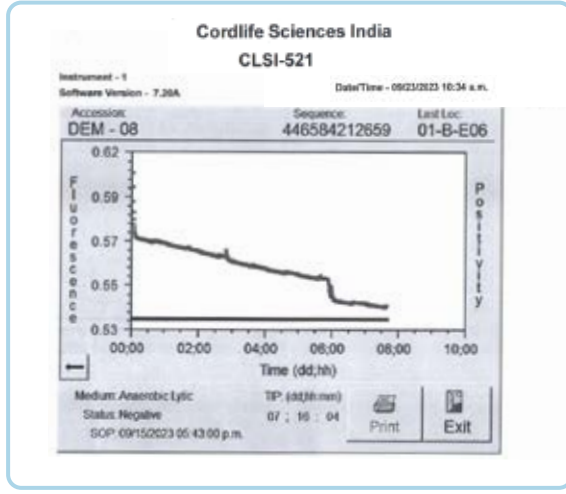
Analysis

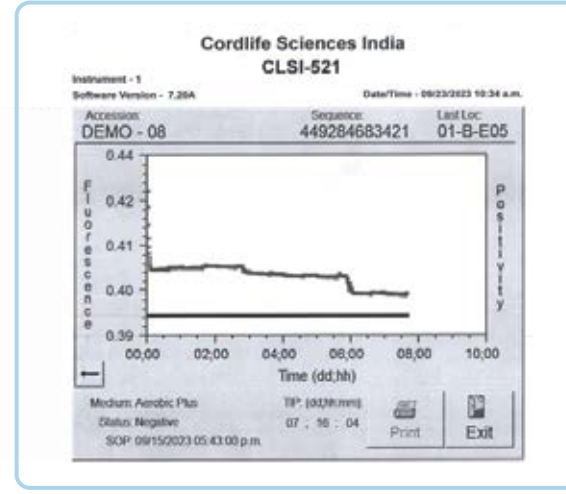
POTENCY PRESERVATION RELATED DETAILS (CFU Assay) :

CFU - GEMM	BFU - E	CFU - GM	CFU - E
			
Acceptable Range (Per 10^5 Cells) : **1 to 59**	**Acceptable Range (Per 10^5 Cells) :** **1 to 310**	**Acceptable Range (Per 10^5 Cells) :** **1 to 303**	**Acceptable Range (Per 10^5 Cells) :** **1 to 48**
Result (Per 10^5 Cells) : **12**	**Result (Per 10^5 Cells) :** **109**	**Result (Per 10^5 Cells) :** **203**	**Result (Per 10^5 Cells) :** **24**

STERILITY PRESERVATION RELATED DETAILS (Cross-contamination) :

Initial Processing Data	Post-thaw Data	Analysis
Negative	Negative	Sterility maintained





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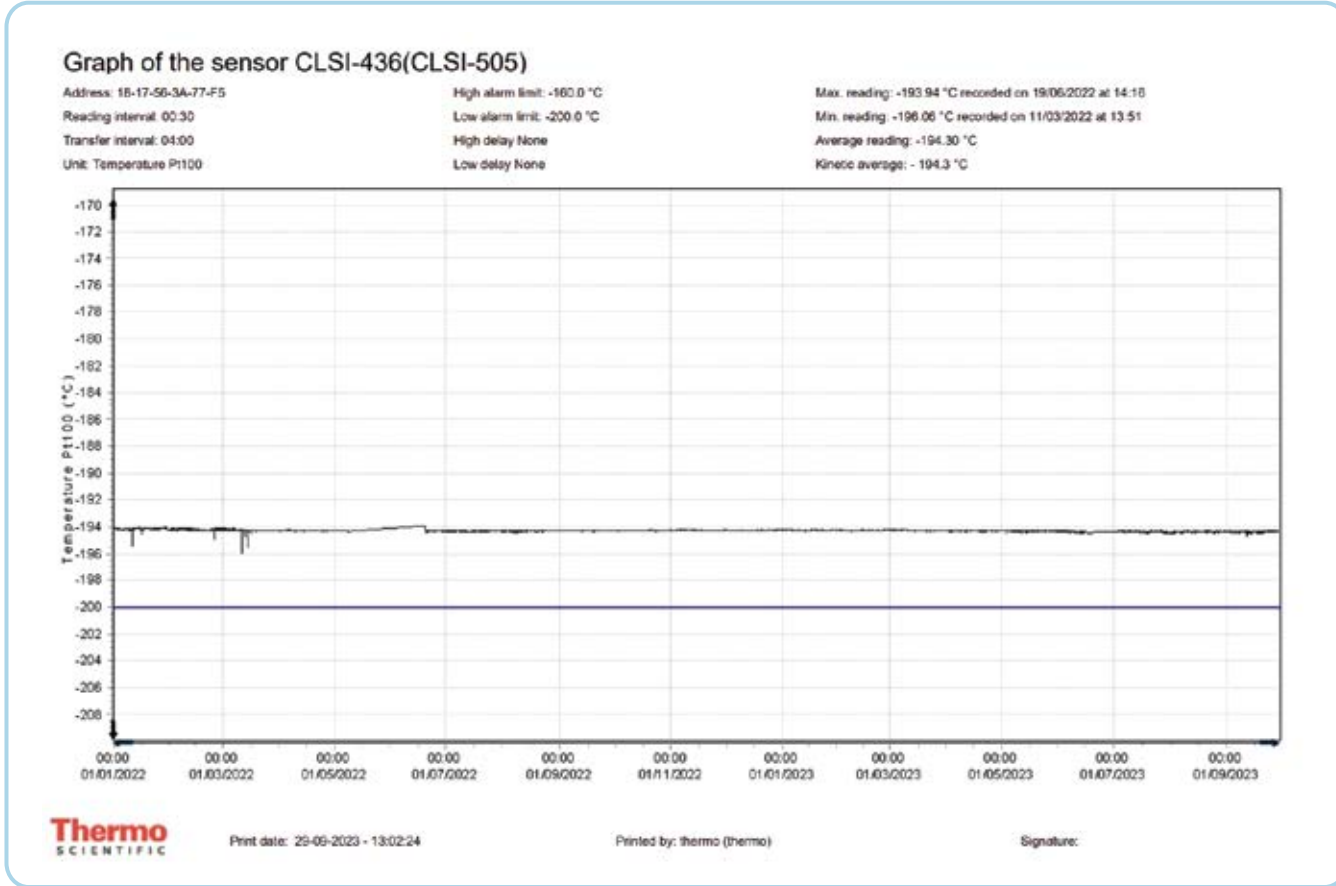
STABILITY TESTING REPORT OF CRYO-PRESERVED UMBILICAL CORD BLOOD SAMPLE

SAMPLE RELATED DETAILS:

Unique Identifier of the Non-commercial Umbilical Cord Blood used for the Stability testing	DEMO/28/2013
Volume of Cord Blood Stored	25 ml
Segment used for the stability testing	20 ml
Actual Date of processing of the non-commercial Umbilical Cord Blood sample used for the Stability testing	26th October, 2013
Date of Stability Testing	15th September, 2023
Duration of Continuous Cryogenic Storage (at below -150°C)	9 Years 11 Months
Report Date	29th September, 2023

CRYOSTORAGE VESSEL RELATED DETAILS :

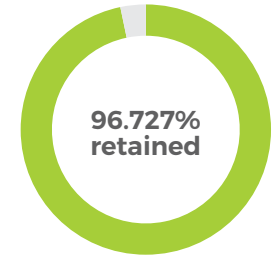


CELLULAR RECOVERY RELATED DETAILS:

Total Nucleated Cell Count

Initial Processing Data

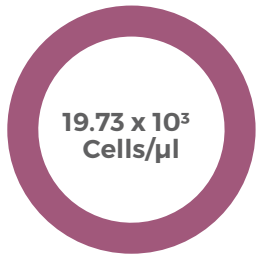
Post-thaw Data



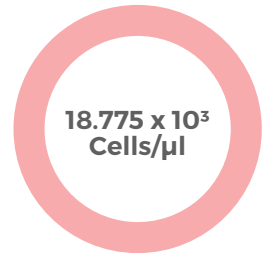
Analysis

VIABILITY RETENTION RELATED DETAILS:

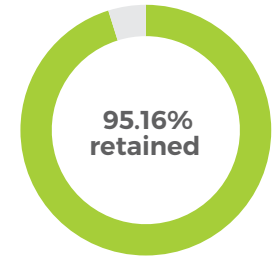
Total Viable Nucleated Cell Count



Initial Processing Data

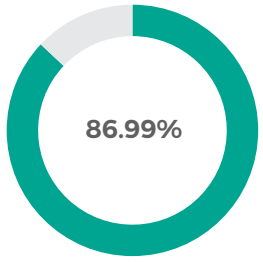


Post-thaw Data



Analysis

CD 34 Viability



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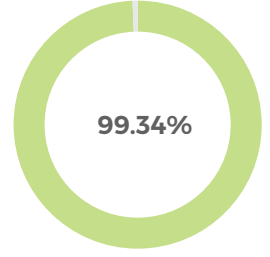
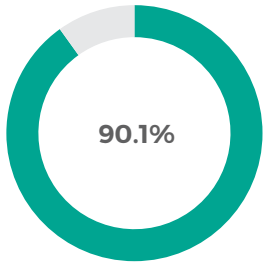


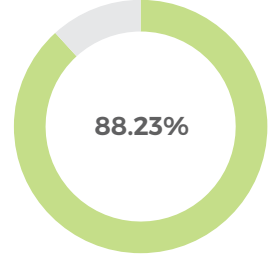
Post-thaw Data

Analysis

CD 45 Viability (Nucleated Cell Viability)



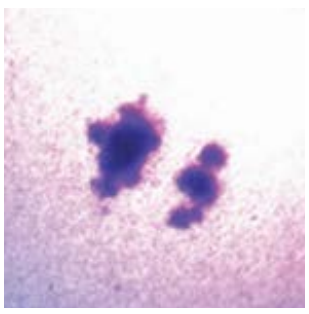
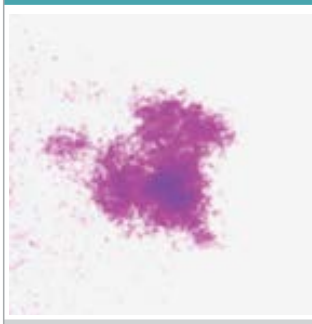
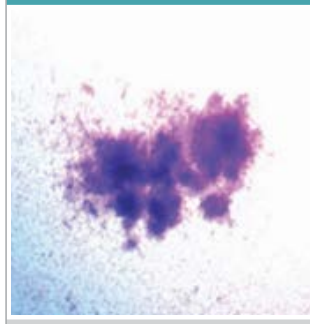
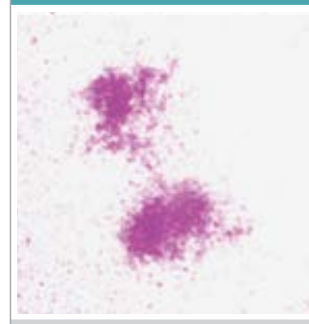
Initial Processing Data



Post-thaw Data

Analysis

POTENCY PRESERVATION RELATED DETAILS (CFU Assay) :

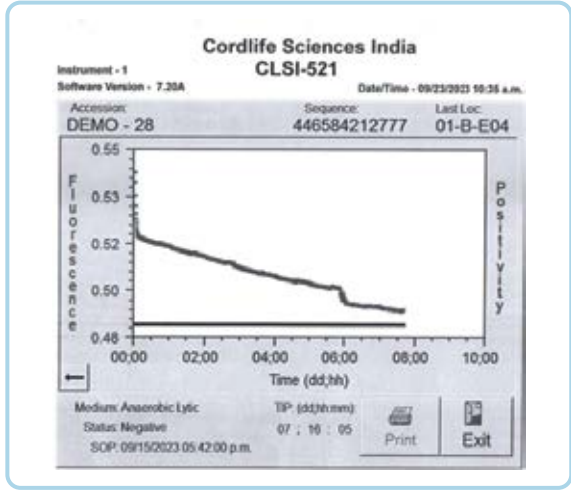
CFU - GEMM	BFU - E	CFU - GM	CFU - E
			
Acceptable Range (Per 10^5 Cells) : **1 to 59**	**Acceptable Range (Per 10^5 Cells) :** **1 to 310**	**Acceptable Range (Per 10^5 Cells) :** **1 to 303**	**Acceptable Range (Per 10^5 Cells) :** **1 to 48**
Result (Per 10^5 Cells) : **17**	**Result (Per 10^5 Cells) :** **100**	**Result (Per 10^5 Cells) :** **168**	**Result (Per 10^5 Cells) :** **24**

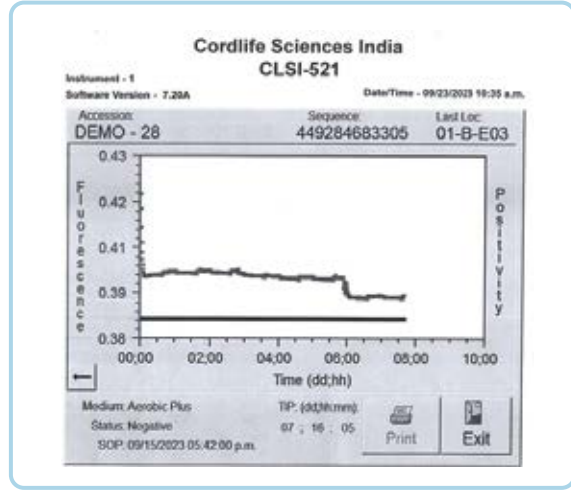
STERILITY PRESERVATION RELATED DETAILS (Cross-contamination) :

Negative — Initial Processing Data

Negative — Post-thaw Data

Sterility maintained — Analysis



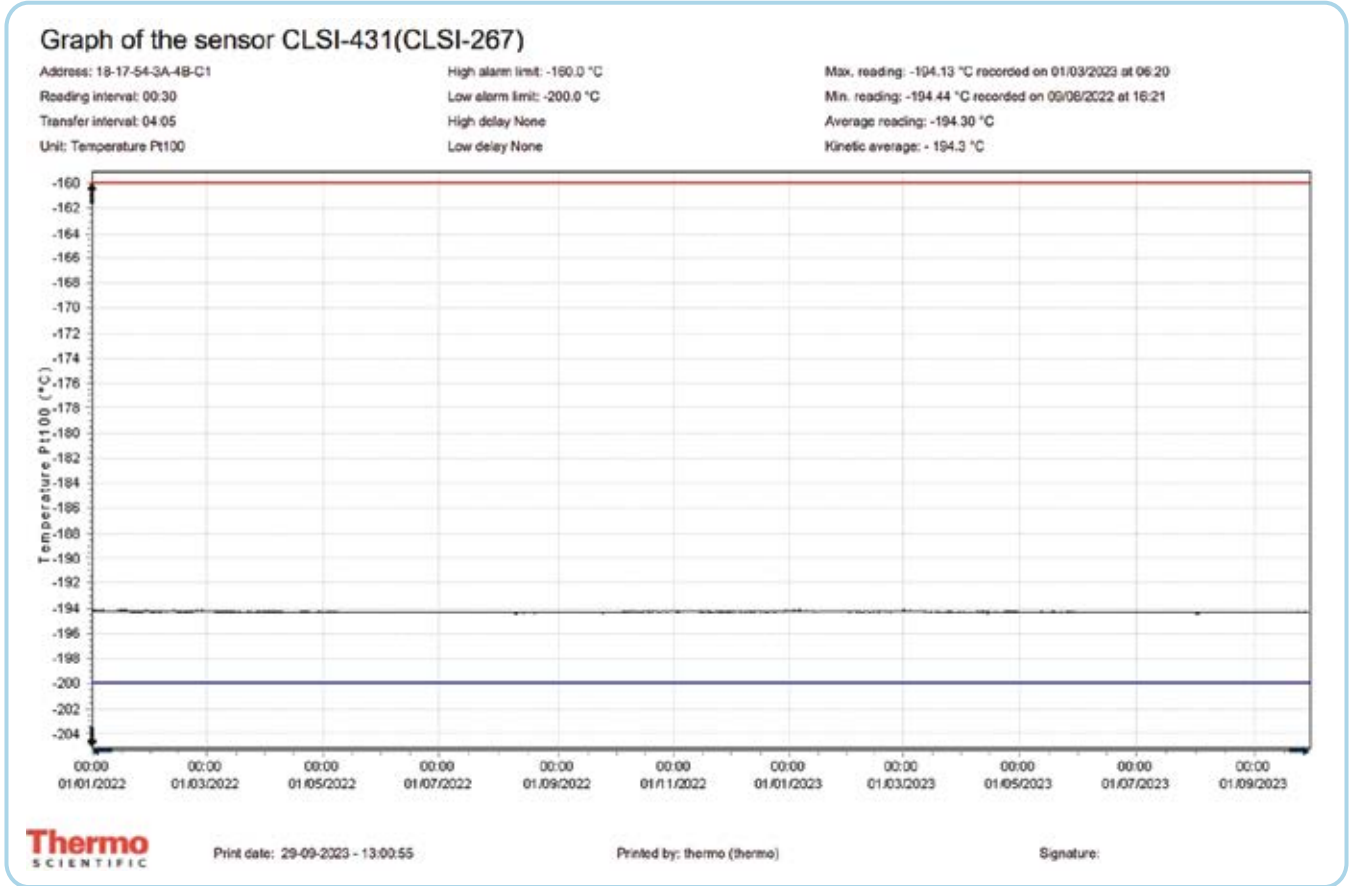


STABILITY TESTING REPORT OF CRYO-PRESERVED UMBILICAL CORD BLOOD SAMPLE

SAMPLE RELATED DETAILS:

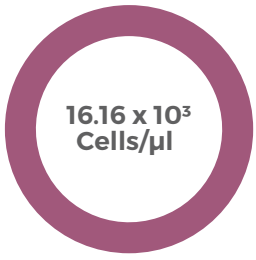
Unique Identifier of the Non-commercial Umbilical Cord Blood used for the Stability testing	DEMO/48/2018
Volume of Cord Blood Stored	25 ml
Segment used for the stability testing	20 ml
Actual Date of processing of the non-commercial Umbilical Cord Blood sample used for the Stability testing	26th December, 2018
Date of Stability Testing	15th September, 2023
Duration of Continuous Cryogenic Storage (at below -150°C)	4 Years 9 Months
Report Date	29th September, 2023

CRYOSTORAGE VESSEL RELATED DETAILS :



CELLULAR RECOVERY RELATED DETAILS:

Total Nucleated Cell Count



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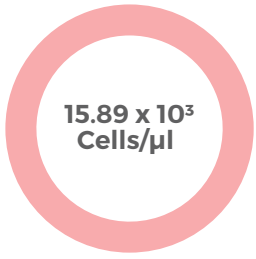
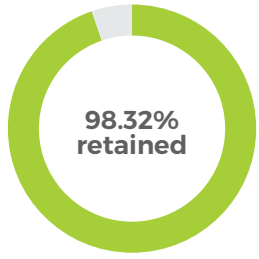


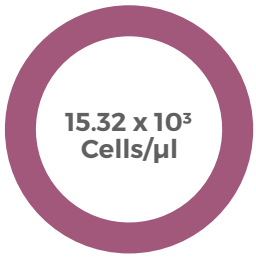
Post-thaw Data



Analysis

VIABILITY RETENTION RELATED DETAILS:

Total Viable Nucleated Cell Count



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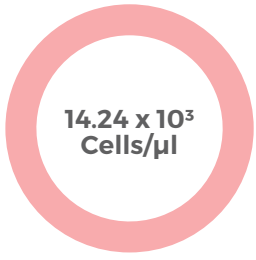
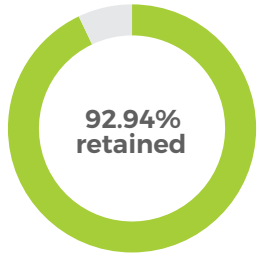
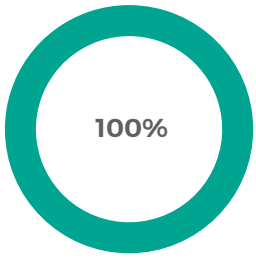


Post-thaw Data

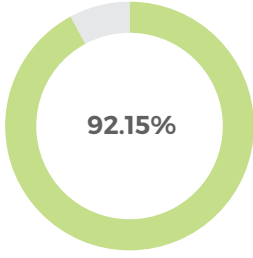


Analysis

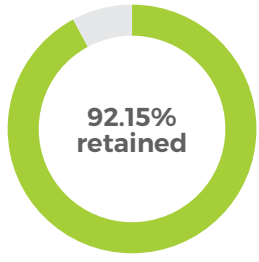
CD 34 Viability



Initial Processing Data

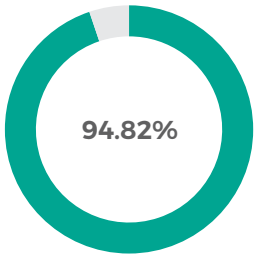


Post-thaw Data



Analysis

CD 45 Viability (Nucleated Cell Viability)



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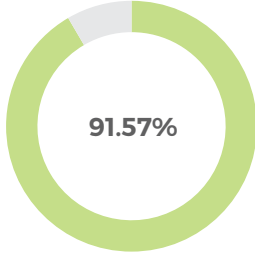
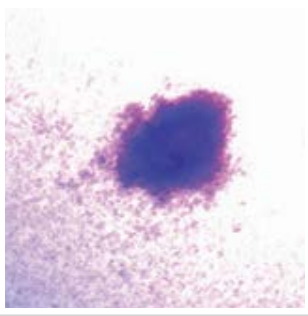
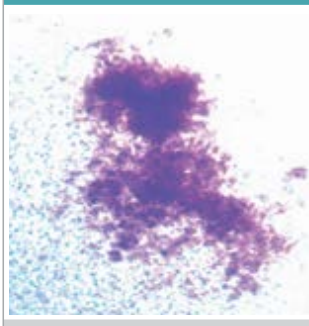
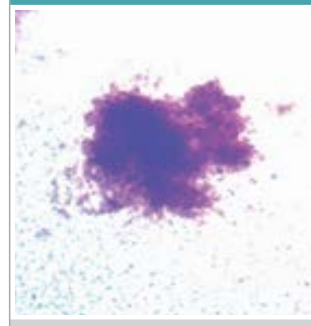
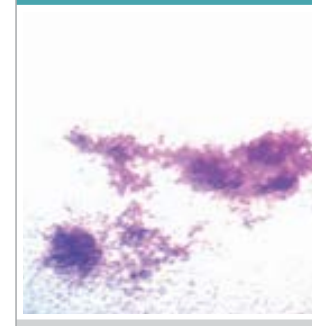


Post-thaw Data

Analysis

POTENCY PRESERVATION RELATED DETAILS (CFU Assay) :

CFU - GEMM	BFU - E	CFU - GM	CFU - E
			
Acceptable Range (Per 10^5 Cells) : **1 to 59**	**Acceptable Range (Per 10^5 Cells) :** **1 to 310**	**Acceptable Range (Per 10^5 Cells) :** **1 to 303**	**Acceptable Range (Per 10^5 Cells) :** **0 to 48**
Result (Per 10^5 Cells) : **10**	**Result (Per 10^5 Cells) :** **107**	**Result (Per 10^5 Cells) :** **196**	**Result (Per 10^5 Cells) :** **29**

STERILITY PRESERVATION RELATED DETAILS (Cross-contamination) :

Initial Processing Data

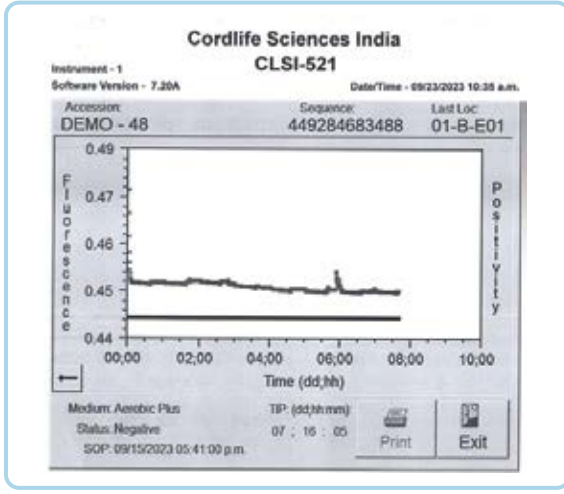
{ – Negative }

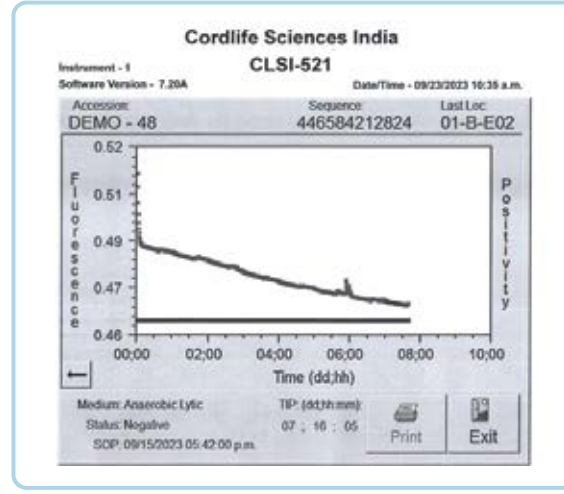
Post-thaw Data

{ – Negative }

Analysis

Sterility maintained





FREQUENTLY ASKED QUESTIONS (FAQS)

Q.1. Is the stability testing for sentinel report performed with our baby's cord blood sample?

Ans: NO. The stability testing has been performed with sentinel samples. Sentinel samples are non-commercial and are not associated with any clients' samples. Such non-commercial samples were processed and cryogenically stored in the same cryogenic storage tank along with other commercial/ clients' samples and exposed to similar conditions during entire tenure of its storage.

Q.2. Why the stability testing is not performed with our baby's cord blood sample?

Ans: As we are cryopreserving 25 ml. of processed Umbilical cord blood sample, it is not feasible to extract 2 ml. of your cryopreserved sample per year only for the Quality Checking purposes, moreover multiple freezing and thawing of cryopreserved sample will grossly affect the viability of the same so it is not recommended to perform stability testing with any commercial sample. However, at the time of release, stability testing of the sample is performed which is a prerequisite for transplantation.

Q.3. Is the sentinel sample used for the stability testing was stored in the same cryogenic storage tank where our baby's sample has been stored?

Ans: The stability testing carried out at least once a year from any of the sentinel sample randomly stored in any of our cryogenic storage tank. Such sentinel samples are kept in each cryogenic storage tank for random checking of the storage condition.

Q.4. How the sentinel sample not even stored in the same cryogenic storage tank where our baby's sample has been stored can ensure the quality of our sample?

Ans: The purpose of the Stability testing is to check the quality of the processed umbilical cord blood samples preserved for prolonged period in the same cryogenic condition (i.e., below -150°C) where actual client samples are being preserved. All our cryogenic storage tanks are programmed to maintain similar cryogenic condition (maintaining temperature below -150°C) throughout the years and strictly monitored for 24X7 with our automated Laboratory Monitoring System.
As all the processed umbilical cord blood samples are stored in similar cryogenic condition and preserved in similar type of metal cassette, the sentinel sample, not even being stored in the same cryogenic storage tank where your baby's sample has been stored can actually ensure the quality of your sample.

Q.5. How the Sentinel samples are processed and cryopreserved?

Ans: The sentinel samples are processed and cryopreserved along with and by maintaining same standard operating procedure as applicable for commercial/client samples.

Q.6. What are the Quality standards to assess the stability testing report?

Ans: According to best industry practices the sentinel sample must retain at least 50% of the initial viability and must maintain sterile condition.