Signature CordTM & Signature MatrixTM Storage Temperature Viability Study

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ABTRACT

There are many different Human Cells, Tissues, and Cellular and Tissue-Based products available on the market today. Some are prepared for room temperature storage. Other products are stored at cryogenic temperatures to preserve relevant tissue characteristics. Signature Biologics has designed Signature Cord and Signature Matrix allografts for storage at -65 degrees Celsius or colder. With so many products and different ideas on the market, healthcare professionals may ask, "How does Signature Biologics arrive at this storage temperature?" This study examines real world results and qualifiable viability of Signature Cord and Signature Matrix Products at multiple lengths of cryopreservation as a measure of the Signature Process and storage temperature guidance.

METHODOLOGY

Minimally manipulated Signature Cord and Signature Matrix products manufactured by Signature Biologics are identified by original date of manufacturer for multiple storage lengths. Products are then removed from finished goods inventory stored at -80 °C. Once received into the Research Lab, each vial is thawed in a gloved hand, according to manufacturer instructions. Each vial is then independently centrifuged to a pellet and suspended in 3mL of PBS. Tissue is then stained using eBioscience Carboxyfluorescein Succinimidyl Ester (CFSE) Proliferation Dye (Invitrogen) and 4',6-Diamidino-2-Phenylindole Dihydrochloride (DAPI) Nucleic Acid Stain (Invitrogen) following the protocol of the supplier. Tissue was placed on a slide and spread using a No. 1.5 Coverslip. Images were collected using a LionHeart FX Automated Microscope (BioTek) on Z-stack configuration and analyzed using Gen5 software (Biotek).

RESULTS

Qualitative images of tissues from the 7 lots examined demonstrated viable cells. These lots included several lengths of cryostorage at -80 °C. Observations were made utilizing microscopy, CFSE (green) to stain intact cellular membranes, and DAPI Nuclear (blue) staining which adheres to the material in an intact nucleus. Combining these images and observing double positives (green cells with blue nucleus within) a living cell can be identified within the samples.

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Product	Tissue Source	Lot Number	Manufacture	Age At Observation	Viability
Signature Cord	Umbilical Cord	SC-031020A	10-Mar-20	6 Months	Yes
Signature Cord	Umbilical Cord	SC-082019A	20-Aug-19	12 Months	Yes
Signature Cord	Umbilical Cord	SC-020519A	5-Feb-19	19 Months	Yes
Signature Matrix	Amnion	SM-011520A	15-Jan-20	8 Months	Yes
Signature Matrix	Amnion	SM-082919A	29-Aug-19	12 Months	Yes
Signature Matrix	Amnion	SM-030719A	7-Mar-19	18 Months	Yes
Signature Matrix	Amnion	SM-101818A	18-Oct-18	22 Months	Yes

Figure 1 – Sampled Product & Lot Information

Figure 2 – Signature Cord Examined at 20x by Lot





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Figure 2 – Signature Cord Examined at 20x by Lot, Continued...

SC-020519A at 19 Months

Figure 3 – Signature Matrix Examined at 20x by Lot



