Utah Cord Bank
WE CHANGE LIVES

Postnatal Stem Cells and FDA Regulations

Several articles concerning the use of postnatal stem cells and the governing regulations of the FDA have been published recently. The FDA has acknowledged that stem cell products have the potential to treat many medical conditions and diseases and have strict regulatory restrictions in place. The FDA often reviews manufacturers' processes and procedures for compliance.

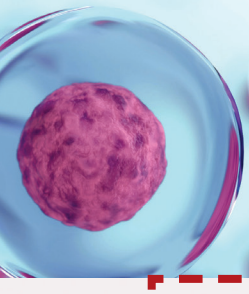
As part of the FDA review, investigators must show how each product will be manufactured so the FDA can make sure appropriate steps are being taken to help assure the product's safety, purity, and strength (potency).

We are proud of our 15-year history of remaining compliant without any violations issued.

Through our meticulous processes, we take numerous precautions to ensure that our products are safe, in their purest form and maintain the highest quality of potency.

ELIGIBILITY

Our proprietary process begins with meticulous screening of the donor mother and father as well as family members for several generations.



COLLECTION

A recovery specialist, once given the donation information from the director of procurement, will collect the postnatal donation at the designated hospital. A recovery specialist will return the donation to Utah Cord Bank for processing.

TESTING

Our lots are quarantined for 14 days and thoroughly tested for bacterial and disease contamination by a CLIA-certified lab.

PROCESSING

Our proprietary process meets the FDA requirements of minimal manipulation.

More info on back of card

UTAH CORD BANK EMPHASIZES A 100% Chain of Custody

Donor Eligibility Requirement:

Our proprietary process begins with meticulous screening of the donor mother and father as well as family members for several generations. In addition to routine industry screens for bloodborne pathogens, we also screen for heritable and non-heritable conditions, environmental contaminants from medications, alcohol, drugs, tobacco, and electronic vaping. Only healthy families who meet or exceed these criteria are considered. Postnatal tissue donations are promptly collected from local hospitals by Utah Cord Bank specialists following a successful Cesarean birth. After processing, allografts are tested again to ensure they are free of contaminants or infection, and contain healthy, viable cells prior to cryopreservation.

Testing Procedures:

Our lots are quarantined for 14 days and throughly tested for bacterial, communicable, and other disease contamination by a CLIA-certified lab. In addition, plate testing is conducted in multiple phases of the process to ensure zero contamination.

Diseases that are tested prior to donation eligibility:

1. Hepatitis Bs Ag
2. Hepatitis Bc Ab
3. HTLV I/II Ab
4. Hepatitis C Ab
5. HIV 1&2 Plus O Ab
6. CMV ab
7. RPR (Non-treponemal syphilis)
8. HIV-1/HCV/HBV NAT (Ultrio)
9. WNV NAT

FDA Requirements of Minimal Manipulation:

For structural tissue, the process does not alter the original relevant characteristics of the tissue related to the tissue's utility for reconstruction, repair, or replacement. For the cells or nonstructural tissues, the process does not alter the relevant biological characteristics of cell tissues.

Cryopreservation: We use a unique cryopreservation technique that includes using the donation's own natural components integrated with a natural cryoprotectant to help ensure maximum functional cells post-thaw for homologous use.

Shipping: All orders are carefully packed in specially insulated overnight containers to maintain the cryopreservation of the cellular material. Products are shipped only to licensed medical professionals.

Utah Cord Bank

WE CHANGE LIVES