

QUALITY ASSURANCE

Birth Tissue is donated by healthy mothers at the time of scheduled cesarean section. Through an informed consent process, expectant mothers submit their past medical and social history which is prescreened through an extensive and complete medical review and pre-natal evaluation. This process is performed prior to delivery utilizing the protocols established by various regulatory agencies. Prior to the recovery of birth tissue, stringent guidelines must be met. Eligibility for tissue donation is based on the following:

- Medical, sexual and social history
- Physical exam
- Tissue retrieval possible within acceptable time limit
- Patient with no known high risk for HIV or hepatitis
- Patient free from transmissible disease
- Patient free from active malignancy
- Patient free from sepsis/systemic infection
- Serology results

Additionally, prior to delivery, the mother is tested for communicable diseases following the requirements of the Food and Drug Administration (FDA), Center for Disease Control (CDC), and the American Association of Tissue Banks:

TESTING	PURPOSE
HIV I/II Ab	Antibody to HIV Virus Type 1
HBsAG	Hepatitis B Surface Antigen
HBc Ab	Hepatitis B Core Antibody
HCV Ab	Hepatitis C Antibody
HIV I/II NAT	HIV and HCV Nucleic Assay Testing
RPR	Syphilis Detection Test
WNV	West Nile Virus

The recovery is performed by specifically trained technicians at the time of the delivery and no harm is brought to the newborn and parents will still

have the option of storing the cord blood, if desired.

All processing is performed in cGMP laboratories following the guidelines of both the FDA and the American Association of Tissue Banks. In addition to serologies, culturing is performed in every step of the process. All products are retested post processing to demonstrate the absence of bacterial and fungal pathogens.



Birth tissue has been used for over 100 years for a broad range of therapeutic applications. However, it is only recently that birth tissue was discovered to have great clinical benefit when cryopreserved to protect its residual cells. Since the discovery of birth tissue as a viable cellular matrix, there have been no reports of disease transmission. Additionally, birth tissue is considered immune privileged and as such does not express Class II antigens. Finally, birth tissue products are easy to use as it can be applied directly into the injured site. To date, tens of thousands of patients have been treated with these types of products.

