

State of Illinois
Health Care Facilities and Programs
Laboratory Regulations
525 W. Jefferson St., (4th Floor)
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ILLINOIS

TISSUE AND SPERM BANK REGISTRATION

Registration Number 7416

New Application? ☐

Change(s): ☐ None ☒ Director ☐ Facility Name ☐ Address ☐ Ownership ☐ Other: _____

1) Name of Facility Director or Manager Joshua Mansavage New Directors,
Managers or first time registration, please include a brief curriculum vitae and copy of academic degree.

2) Facility Name New Life Medical Services, LLC

Address 244 Crystal Grove Blvd.

City Lutz State FL ZIP Code 33548

Telephone 813-461-8100 Fax 813-364-6522 E-mail joshm@newliferegen.com

3) Facility Specialty(s): ☐ Musculoskeletal ☐ Skin ☐ Reproductive ☐ Sperm Bank ☒ Tissue Bank
☐ Other (cells, tissue, organs, etc.): _____

4) Name and address of entity operating the sperm or tissue bank, if different from above.

Name _____ Address _____

City _____ State _____ ZIP Code _____ Telephone _____

5) If applicable, include a list of addresses and phone number utilized in operating the sperm or tissue bank.

6) Include a description of services provided (attach additional information if more space is required)
The Storage and Distribution of HCTP Allograft to Licensed practitioners throughout states we are licensed in,

7) Is your sperm or tissue bank registered with the FDA? ☒ Yes ☐ No If not, explain _____

8) Accreditation information: ☐ AATB ☐ CAP ☐ COLA ☐ JCAHO ☒ N/A OTHER _____

9) Date of last FDA on-site inspection 03/2017 Date of last Accredited on-site inspection _____

Is the facility in compliance? yes if not, explain _____

10) Is the sperm or tissue tested for "relevant communicable diseases?" Explain below.
See Attached

11) **Certification and Signature:** Under penalty of perjury, I certify the information provided herein is correct.
I understand that misrepresentation will be cause for removal from the state of Illinois Sperm and Tissue Bank
registration files, and subject to fines and other penalties allowed by the law.

12) Signature [Signature] Date 3/3/2022
(Facility Director)

Completed forms can be submitted via email to Dph.Clia@Illinois.gov faxed to 217-782-0382, or mailed to IDPH

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.