## DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE

## FOOD AND DRUG ADMINISTRATION

## ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS **DESCRIBED IN 21 CFR 1271.10**

FEI: 3002733251

Reporting Official:

Other FDA Registrations: Blood:

Devices: Drugs:

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2022 Last Registration Receipt Date: 12/06/2021 Summary Report Print Date: 12/15/2021

No

Legal Name and Location:

New England Cryogenic Center, Inc. 500 Donald J. Lynch Blvd

Suzanne Sussman, Quality Administrator 500 Donald J. Lynch Blvd

Marlborough, Massachusetts 01752

Phone: 774-843-2936 Ext. ssussman@necryogenic.com Satellite Recovery Establishment:

Parent Manufacturing Establishment FEI No.:

Testing For Micro-Organisms Only: No

Note: FDA acceptance of an establishment registration and HCT/P listing does not constitute a determination that an establishment is in compliance with applicable rules and regulations or that the HCT/P is licensed or approved by FDA (21 CFR 1271.27(b)).

Marlborough, Massachusetts 01752

USA

FEI:

3002733251

Phone: 508-305-2548 Ext.:

		Establishment Functions										
HCT/P(s)	Donor Type(s)	Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute	Date of Discontinuance	Date of Resumption	Proprietary Name(s)
Amniotic Membrane												
Blood Vessel												
Bone												
Cardiac Tissue - non-valved												
Cartilage												
Cornea												
Dura Mater												
Embryo	SIP						Х		X			
Fascia												
Heart Valve												
HPC Apheresis												
HPC Cord Blood	Autologous, Family Related		Х		Х	X	Х	Х	Х			
Ligament												
Nerve Tissue												
Oocyte	Anonymous, Directed, SIP						Х		X			
Ovarian Tissue							Х		Х			
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen	Anonymous, Directed, SIP				х	х	Х	Х	х			
Skin												
Tendon												
Testicular Tissue					Х	Х	Х	Х	Х			
Tooth Pulp					Х	Х	Х	Х	Х			
Umbilical Cord Tissue			Х		Х	х	Х	Х	х			

Additional Information: Testicular Tissue is cryopreserved for SIP only	Additional Information:	Testicular Tissue is cryopreserved for SIP only.
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Dental pulp tissue is cryopreserved for autologous use only. No donor screening is done.

Proprietary Name(s):

FEI: 3002733251 Legal Name: New England Cryogenic Center, Inc.