

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: 3011694452	Other FDA Registrations: Blood: Devices: Drugs:	Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2024 Last Registration Receipt Date: 12/01/2023 Summary Report Print Date: 12/15/2023
--	------------------------	--	---

Legal Name and Location: National Jewish Health 1400 Jackson Street Denver, Colorado 80206 USA Phone: 800-550-6227 Ext.:	Reporting Official: Ali Willey, Manager Quality Management 1400 Jackson Street Attn: Ali Willey Denver, Colorado 80206 USA Phone: 303-270-2778 Ext. WilleyA@NJHealth.org	Satellite Recovery Establishment: No Parent Manufacturing Establishment FEI No.: Testing For Micro-Organisms Only: Yes 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)).
---	--	---

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

Additional Information: No additional information provided.

Proprietary Name(s):

FEI: 3011694452

Legal Name:

National Jewish Health