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: 3000233845

Other FDA Registrations: Blood:

Devices:FEI: 0001721109 Drugs: FEI: 0151663234 Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2025 Last Registration Receipt Date: 12/12/2024 Summary Report Print Date: 12/20/2024

Legal Name and Location:

Nelson Laboratories, LLC 6280 South Redwood Road

Ext.:

Salt Lake City, Utah 84123

USA

Phone: 801-290-7500

Reporting Official:

Kevyn House, Sr. Manager Quality Assurance

6280 South Redwood Road Salt Lake City, Utah 84123

Phone: 801-290-9066 Ext. khouse@nelsonlabs.com

Satellite Recovery Establishment:

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)).

No

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

Additional	Information:	No

No additional information provided.

Proprietary Name(s):

FEI: 3000233845

Legal Name: Nelson Laboratories, LLC