

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: 3016712600	Other FDA Registrations: Blood: Devices: Drugs:	Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2025 Last Registration Receipt Date: 12/16/2024 Summary Report Print Date: 12/20/2024
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Legal Name and Location: UR Medicine Labs Central Laboratory 211 Bailey Road West Henrietta, New York 14586 USA Phone: 585-758-0466 Ext.:	Reporting Official: Dwight J Hardy, Medical Director-Donor Services Serology 211 Bailey Road West Henrietta, New York 14586 USA Phone: 585-275-1408 Ext. Dwight_Hardy@urmc.rochester.edu	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)).
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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												
Blood Vessel				X								
Bone				X								
Cardiac Tissue - non-valved												
Cartilage				X								
Cornea				X								
Dura Mater				X								
Embryo												
Fascia				X								
Heart Valve				X								
HPC Apheresis	Autologous, Family Related			X								
HPC Cord Blood												
Ligament				X								
Nerve Tissue				X								
Oocyte	Directed, SIP			X								
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium				X								
Peripheral Blood Mononuclear Cells	Autologous, Family Related			X								
Peritoneal Membrane												
Sclera				X								
Semen	Directed, SIP			X								
Skin				X								
Tendon				X								
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information: Additions to function/sample

Proprietary Name(s):

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