

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: 2026
 Last Registration Receipt Date: 12/17/2025
 Summary Report Print Date: 01/09/2026

Legal Name and Location: UR Medicine Labs Central Laboratory 211 Bailey Road West Henrietta, New York 14586 USA Phone: 585-758-0466		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)).			

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: No additional information provided.

Proprietary Name(s):

FEI: 3016712600

Legal Name:

UR Medicine Labs Central Laboratory