

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION <b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS,  TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS  DESCRIBED IN 21 CFR 1271.10</b>	<b>FEI:</b> 3016712600	<b>Other FDA Registrations:</b> <b>Blood:</b> <b>Devices:</b> <b>Drugs:</b>	Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2023 Last Registration Receipt Date: 12/06/2022 Summary Report Print Date: 12/15/2022
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<b>Legal Name and Location:</b> UR Medicine Labs Central Laboratory 211 Bailey Road  West Henrietta, New York 14586 USA  Phone: 585-758-0466 <b>Ext.:</b>	<b>Reporting Official:</b> 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	<b>Satellite Recovery Establishment:</b> No <b>Parent Manufacturing Establishment FEI No.:</b> <b>Testing For Micro-Organisms Only:</b> 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												
HPC Cord Blood												
Ligament				X								
Nerve Tissue				X								
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium				X								
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera				X								
Semen												
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