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			Blood	Other FDA Registrations: Blood: Devices: Drugs:				Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2024 Last Registration Receipt Date: 12/22/2023 Summary Report Print Date: 01/05/2024		
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.: Yes 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)).			
			Establishment Functions										
HCT/P(s)	Donor Type(s)	Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute	Date of Discontinuance	Date of Resumption	Proprietary Name(s)	
Amniotic Membrane													
Blood Vessel				Х									
Bone				х									
Cardiac Tissue - non-valved													
Cartilage				х									
Cornea				х									
Dura Mater				х									
Embryo													
Fascia				х									
Heart Valve				х									
HPC Apheresis													
HPC Cord Blood													
Ligament				х									
Nerve Tissue				х									
Oocyte													
Ovarian Tissue													
Pancreatic Islet Cells - autologous													
Parathyroid													
Pericardium				х									
Peripheral Blood Mononuclear Cells													
Peritoneal Membrane													
Sclera				Х									
Semen													
Skin				Х									
Tendon				Х									
Testicular Tissue													
Tooth Pulp													
Umbilical Cord Tissue													

Legal Name:

Additional Information: No additional information provided.

Proprietary Name(s):

FEI: 3016712600

Legal Name:

UR Medicine Labs Central Laboratory