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

Other FDA Registrations: Blood: FEI: 0001372065

Devices: Drugs:

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2019 Last Registration Receipt Date: 12/28/2018 Summary Report Print Date: 01/28/2019

Legal Name and Location:

University of Roch-Strong Memorial Hospital

601 Elmwood Avenue

Box 608

Rochester, New York 14642-0001

Phone: 585-275-3189

Ext.:

Reporting Official:

Neil Blumberg, Director Transfusion Medicine

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Box 608

Rochester, New York 14642-0001

Phone: 585-275-3189 Ext.

FEI: 0001372065

Neil_Blumberg@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									·	
		Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute	Date of Discontinuance	Date of Resumption	Proprietary Name(s)
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	Х			X	х	Х	Х	Х			
HPC Cord Blood										28-DEC-18		
Ligament				x								
Nerve Tissue				x								
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium				x								
Peripheral Blood Mononuclear Cells	Autologous, Family Related	Х			Х	х	Х	Х	Х			
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: 0001372065

Legal Name: