See Instructions for OMB Statement. FORM APPROVED:OMB No.0910-0543. Expiration Date: 3/31/2017

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 (HCT/Ps)

(See reverse side for instructions)

1. REGISTRATION NUMBER
(FDA Establishment Identifier)
FEI: 0001372065

2. REASON FOR SUBMISSION
a. ☐ INITIAL REGISTRATION / LISTING
b. ☒ ANNUAL REGISTRATION / LISTING
c. ☐ CHANGE IN INFORMATION
d. ☐ INACTIVE

VALIDATION–FOR FDA USE ONLY 1
VALIDATED BY FDA:22-NOV-2014
DISTRICT: New York
PRINTED BY FDA:04-DEC-2014

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS
a. BLOOD FDA 2830 NO. FEI: 0001372065
b. DEVICES FDA 2891 NO.
c. DRUG FDA 2656 NO.

4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)
University of Roch-Strong Memorial Hospital
601 Elmwood Avenue
Box 608
Rochester, New York 14642-0001

a. PHONE 585-275-3189 EXT
b. ☐ SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO.
c. ☒ TESTING FOR MICRO-ORGANISMS ONLY

5. ENTER CORRECTIONS TO ITEM 4

6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code)
University of Rochester Medical Center
Attn: Neil Blumberg, MD
601 Elmwood Avenue
Box 608
Rochester, New York 14642-0001

a. PHONE 585-275-3189 EXT

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME Neil Blumberg, MD
b. E-MAIL Neil_Blumberg@urmc.rochester.edu
c. TITLE Director Transfusion Medicine d. DATE 21-NOV-2014

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

Types of HCT / Ps	Establishment Functions: Recover	Screen	Test	Package	Process	Store	Label	Distribute	11. HCT/Ps DESCRIBED IN 21 CFR 1271.10	12. HCT/Ps REGULATED AS MEDICAL DEVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)
a. Bone												
b. Cartilage												
c. Cornea												
d. Dura Mater												
e. Embryo ☐ SIP ☐ Directed ☐ Anonymous												
f. Fascia												
g. Heart Valve												
h. Ligament												
i. Oocyte ☐ SIP ☐ Directed ☐ Anonymous												
j. Pericardium												
k. Peripheral Blood Stem ☒ Autologous ☒ Family Related ☒ Allogeneic	X			X	X	X	X	X	X		X	
l. Sclera												
m. Semen ☐ SIP ☐ Directed ☐ Anonymous												
n. Skin												
o. Somatic Cell Therapy Products ☐ Autologous ☐ Family Related ☐ Allogeneic												
p. Tendon												
q. Umbilical Cord Blood ☐ Autologous ☐ Family Related ☒ Allogeneic					X	X	X		X		X	
r. Vascular Graft												
s. Parathyroid	X				X	X	X				X	
t. Therapeutic Cells	X			X	X	X	X	X			X	
u.												
v.												

FORM APPROVED: OMB No. 0910-0052. Expiration Date: March 31, 2015. See instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING

1. REGISTRATION NUMBER
FEI: 1372065
CFN: 1372065

2. U.S. LICENSE NUMBER

3. REASON FOR SUBMISSION
.1 [x] ANNUAL REGISTRATION
.2 [ ] INITIAL REGISTRATION
.3 [ ] CHANGE IN INFORMATION

FOR FDA USE ONLY 1

PLEASE READ INSTRUCTIONS CAREFULLY. Be sure to indicate any changes in your legal name or actual location in item 4, and any changes in your mailing address in item 6. Print all entries and make all corrections in red ink, if possible. Enter your phone number in item 8.3 and the phone number of your actual location in item 4.1. Sign the form and return to FDA. After validation, you will receive your Official Registration for the ensuing year.

This form is authorized by Sections 510(b), (j) and 704 of the Federal Food, Drug, and Cosmetic Act (Title 21, United States Code 360(b), (j) and 374). Failure to report this information is a violation of Section 301(f) and (p) of the Act (Title 21, United States Code 331(f) and (p)) and can result in a fine of up to $1,000 or imprisonment up to one year or both, pursuant to Section 303(a) of the Act (Title 21, United States Code 33.3(a)).

DISTRICT OFFICE: New York
VALIDATED BY FDA: 21-NOV-2014
PRINTED BY FDA: 08-JAN-2015

ENTER ALL CHANGES IN RED INK AND CIRCLE.

4. LEGAL NAME AND LOCATION (Include legal name, number and street, city, state, country, and post office code)

University of Rochester-Strong Memorial Hospital Blood Bank
601 Elmwood Avenue Box 608
Rochester, NY 14642-0001

4.1 PHONE 585-275-2251

5. OTHER NAMES USED AT THIS LOCATION (Include trade name, doing-business-as, previous names, and other firms co-located. If applicable, include registration number.)

6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code)

University of Rochester - Strong Memorial Hospital - Blood B
ATTN: Neil Blumberg, M.D.
601 Elmwood Avenue Box 608
Rochester, NY 14642-0001

7. U.S. AGENT (Include name, institution name if applicable, number and street, city, state, and zip code)

7.1 E-MAIL ADDRESS
7.2 PHONE

8. REPORTING OFFICIAL'S SIGNATURE

8.1 TYPED NAME Neil Blumberg, M.D.
8.2 E-MAIL ADDRESS Neil_Blumberg@URMC.rochester.edu
8.3 PHONE 585-275-3189 8.4 DATE

9. TYPE OF OWNERSHIP
.1 [ ] SINGLE PROPRIETORSHIP
.2 [ ] PARTNERSHIP
.3 [x] CORPORATION profit___ non-profit✓
.4 [ ] COOPERATIVE ASSOCIATION
.5 [ ] FEDERAL (non-military)
.6 [ ] U.S. MILITARY
.7 [ ] STATE
.8 [ ] COUNTY/MUNICIPAL/HOSPITAL AUTHORITY
.9 [ ] OTHER (Specify) :

10. TYPE ESTABLISHMENT (Check all boxes that describe routine or autologous operations.)
.1 [ ] COMMUNITY (NON-HOSPITAL) BLOOD BANK
.2 [x] HOSPITAL BLOOD BANK
.3 [ ] PLASMAPHERESIS CENTER
.4 [ ] PRODUCT TESTING LABORATORY
a. ____ INDEPENDENT
____ ASSOCIATED W/ COMMUNITY or HOSPITAL BLOOD BANK
.5 [ ] HOSPITAL TRANSFUSION SERVICE
a. ____ APPROVED FOR MEDICARE REIMBURSEMENT
____ NOT APPROVED FOR MEDICARE REIMBURSEMENT
.6 [ ] COMPONENT PREPARATION FACILITY
.7 [ ] COLLECTION FACILITY
.8 [ ] DISTRIBUTION CENTER
U.S. LICENSE NUMBER OF PARENT FIRM
.9 [ ] BROKER/WAREHOUSE
.10 [ ] OTHER (Specify) :

11. PRODUCTS
[ ] ALLOGENEIC [X] AUTOLOGOUS [ ] DIRECTED

		COLLECT (.1)	MANUAL APHERESIS (.2)	AUTOMATED APHERESIS (.3)	PREPARE (.4)	LEUKOCYTES REDUCED (.5)	IRRADIATED (.6)	DONOR RETESTED (.7)	TEST (.8)	STORE and DISTRIBUTE to OTHERS (.9)
WHOLE BLOOD	1	X					X		X	
RED BLOOD CELLS (RBC)	2				X	X	X		X	
RBC FROZEN	3				X				X	
RBC DEGLYCEROLIZED	4				X		X		X	
RBC REJUVENATED	5				X		X			
RBC REJUVENATED FROZEN	6				X					
RBC REJUVENATED DEGLYCEROLIZED	7				X		X		X	
CRYOPRECIPITATED AHF	8						X			
PLATELETS	9						X			
LEUKOCYTES/GRANULOCYTES	10						X		X	
PLASMA	11									
PLASMA CRYOPRECIPITATE REDUCED	12						X			
FRESH FROZEN PLASMA	13						X			
LIQUID PLASMA	14									
THERAPEUTIC EXCHANGE PLASMA	15									
SOURCE LEUKOCYTES	16									
SOURCE PLASMA	17									
RECOVERED PLASMA	18									
BLOOD PRODUCTS FOR DIAGNOSTIC USE	19									
BLOOD BANK REAGENTS	20									
OTHER	21									