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: 3007203928

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:12-DEC-2016
DISTRICT: Philadelphia
PRINTED BY FDA:15-DEC-2016

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS
a. BLOOD FDA 2830 NO. FEI: 3007203928
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)
LABS - Northeast

401 North 3rd Street
Suite 279
Philadelphia, Pennsylvania 19123

a. PHONE 1-800-321-6088 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)
LABS, Inc
Attn: Ann V. Niedzinski
6933 South Revere Parkway
Centennial, Colorado 80112

a. PHONE 720-528-4774 EXT

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE
Ann V. Niedzinski
a. TYPED NAME Ann V. Niedzinski
b. E-MAIL ann_niedzinski@labs-inc.org
c. TITLE Sr. Director, Regulatory and Quality d. DATE 11-DEC-2016

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			X						X			
b. Cartilage			X						X			
c. Cornea			X						X			
d. Dura Mater												
e. Embryo ☐ SIP ☐ Directed ☐ Anonymous												
f. Fascia			X						X			
g. Heart Valve			X						X			
h. Ligament			X						X			
i. Oocyte ☒ SIP ☒ Directed ☒ Anonymous			X						X			
j. Pericardium			X						X			
k. Peripheral Blood Stem ☒ Autologous ☒ Family Related ☒ Allogeneic			X						X		X	
l. Sclera			X						X			
m. Semen ☒ SIP ☒ Directed ☒ Anonymous			X						X			
n. Skin			X						X			
o. Somatic Cell Therapy Products ☒ Autologous ☒ Family Related ☒ Allogeneic			X						X		X	
p. Tendon			X						X			
q. Umbilical Cord Blood ☒ Autologous ☒ Family Related ☒ Allogeneic			X						X		X	
r. Vascular Graft			X						X			
s.												
t.												
u.												
v.												