

1. REGISTRATION NUMBER  
 (Field Establishment Identifier)  
 FEI: 3007072964

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)

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

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / PS

Types of HCT / Ps	Establishment Functions					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)
	Recover	Screen	Test	Package	Process				
a. Bone			X						
b. Cartilage			X						
c. Cornea			X						
d. Dura Mater									
e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous									
f. Fascia			X						
g. Heart Valve			X						
h. Ligament			X						
i. Oocyte <input checked="" type="checkbox"/> SIP <input checked="" type="checkbox"/> Directed <input checked="" type="checkbox"/> Anonymous			X						
j. Pericardium			X						
k. Peripheral Blood Stem Cells <input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic			X					X	
l. Sclera			X						
m. Semen <input checked="" type="checkbox"/> SIP <input checked="" type="checkbox"/> Directed <input checked="" type="checkbox"/> Anonymous			X						
n. Skin			X						
o. Somatic Cell Therapy Products <input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic			X					X	
p. Tendon			X						
q. Umbilical Cord Blood Stem Cells <input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic			X					X	
r. Vascular Graft			X						
s.									
t.									
u.									
v.									

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS  
 a. BLOOD FDA 2830 NO. \_\_\_\_\_  
 b. DEVICES FDA 2881 NO. \_\_\_\_\_  
 c. DRUG FDA 2656 NO. \_\_\_\_\_

4. PHYSICAL LOCATION (include legal name, number and street, city, state, country, and post office code)  
 LABS - Midwest  
 1110 Highlands Plaza Drive East  
 Suite # 100  
 St. Louis, Missouri 63110

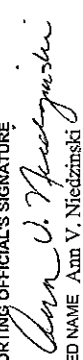
5. ENTER CORRECTIONS TO ITEM 4  
 a. PHONE 720-488-4460 EXT \_\_\_\_\_  
 b.  SATELLITE RECOVERY ESTABLISHMENT  
 (MANUFACTURING ESTABLISHMENT FEI NO. \_\_\_\_\_)  
 c.  TESTING FOR MICRO-ORGANISMS ONLY

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-B South Revere Parkway  
 Centennial, Colorado 80112

a. PHONE 720-528-4774 EXT \_\_\_\_\_  
 b. PHONE \_\_\_\_\_

7. ENTER CORRECTIONS TO ITEM 6

8. U.S. AGENT

9. REPORTING OFFICIAL'S SIGNATURE  
  
 a. TYPED NAME Ann V. Niedzinski  
 b. E-MAIL ann\_niedzinski@labs-inc.org  
 c. TITLE Director, Regulatory and Quality  
 d. DATE 20-DEC-2011