

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
 (Field Establishment Identifier)
 FEI: 0002183472

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

VALIDATION--FOR FDA USE ONLY
 VALIDATED BY FDA: 18-NOV-2009
 DISTRICT: Minneapolis
 PRINTED BY FDA: 02-DEC-2009

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS
 a. BLOOD FDA 2830 NO. FEI: 0002183472
 b. DEVICES FDA 2891 NO. FEI: 0002183472
 c. DRUG FDA 2656 NO. _____

4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)
 Laboratory Corporation of America Viromed Laboratories
 6101 Blue Circle Dr.
 Minnetonka, Minnesota 55343


a. PHONE 952-563-3300 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)
 Viromed Laboratories
 Attn: Robert S. Fogerson
 6101 Blue Circle Dr.
 Minnetonka, Minnesota 55343

a. PHONE 952-563-4024 EXT _____
 b. PHONE _____
 7. ENTER CORRECTIONS TO ITEM 6

8. U.S. AGENT

a. E-MAIL
 9. REPORTING OFFICIAL'S SIGNATURE

 a. TYPED NAME Robert S. Fogerson
 b. E-MAIL rfogerson@labcorp.com
 c. TITLE General Manager
 d. DATE 16-NOV-2009

PART II - PRODUCT INFORMATION

Types of HCT / Ps	Establishment Functions						11 HCT/PS DESCRIBED IN 21 CFR 127.10	12 HCT/PS REGULATED AS MEDICAL DEVICES	13 HCT/PS REGULATED AS BIOLOGICAL DRUGS OR DRUGS	14 PROPRIETARY NAME(S)
	Recover	Screen	Test	Package	Process	Store				
a. Bone			X					X		
b. Cartilage			X					X		
c. Cornea			X					X		
d. Dura Mater										
e. Embryo			X					X		
f. Fascia			X					X		
g. Heart Valve			X					X		
h. Ligament			X					X		
i. Oocyte			X					X		
j. Pericardium			X					X		
k. Peripheral Blood Stem			X					X		
l. Sclera			X					X		
m. Semen			X					X		
n. Skin			X					X		
o. Somatic Cell Therapy Products										
p. Tendon			X					X		
q. Umbilical Cord Blood Stem Cells			X					X		
r. Vascular Graft			X					X		
s. _____										
t. _____										
u. _____										
v. _____										