

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

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:04-DEC-2011  
DISTRICT: Minneapolis  
PRINTED BY FDA:15-DEC-2011

**ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,  
AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps)**  
(See reverse side for instructions)

**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 \_\_\_\_\_


7. ENTER CORRECTIONS TO ITEM 6

b. PHONE \_\_\_\_\_

8. U.S. AGENT

a. E-MAIL \_\_\_\_\_

9. REPORTING OFFICIAL'S SIGNATURE

  
a. TYPED NAME Robert S. Fogerson  
b. E-MAIL bfogerson@lbcorp.com  
c. TITLE General Manager

16 Dec 2011

d. DATE 02-DEC-2011

**PART II - PRODUCT INFORMATION**

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 | Store | Label | Distribute |  |   |   |                         |
| 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 Cells     |                         |        | X    |         |         |       |       |            | 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                                      |   | X   |                         |
|                                    |                         |        |      |         |         |       |       |            |  |   |   |                         |
| r. Vascular Graft                  |                         |        | X    |         |         |       |       |            | X                                      |   |   |                         |
|                                    |                         |        |      |         |         |       |       |            |  |   |   |                         |
| s. Therapeutic Cells               |                         |        | X    |         |         |       |       |            | X                                      |   | X   |                         |
|                                    |                         |        |      |         |         |       |       |            |  |   |   |                         |
| t.                                 |                         |        |      |         |         |       |       |            |  |   |   |                         |
|                                    |                         |        |      |         |         |       |       |            |  |   |   |                         |
| u.                                 |                         |        |      |         |         |       |       |            |  |   |   |                         |
|                                    |                         |        |      |         |         |       |       |            |  |   |   |                         |
| v.                                 |                         |        |      |         |         |       |       |            |  |   |   |                         |