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 DESCRIBED IN 21 CFR 1271.10

Ext.:

FEI: 0002183472

Other FDA Registrations: Blood: FEI: 0002183472

Devices: Drugs: Reason For Last Submission: Change in Information

Last Annual Registration Year: 2019
Last Registration Receipt Date: 05/14/2019
Summary Report Print Date: 06/13/2019

Legal Name and Location:

Burlington, North Carolina 27215

Phone: 800-582-0077

Laboratory Corporation of America ViroMed Laboratories

1447 York Court

1447 York Court Burlington, North Carolina 27215

Michael Roberts, General Manager, Senior Vice President

USA

Phone: 336-436-3555 Ext. robertm@labcorp.com

Reporting Official:

Satellite Recovery Establishment:

Parent Manufacturing Establishment FEI No.:

Testing For Micro-Organisms Only: No

Note: FDA acceptance of an establishment registration and HCT/P listing does not constitute a determination that an establishment is in compliance with applicable rules and regulations or that the HCT/P is licensed or approved by FDA (21 CFR 1271.27(b)).

No

| | Donor Type(s) | Establishment Functions | | | | | | | | | | |
|-------------------------------------|----------------------------|-------------------------|--------|---------------|---------|---------|-------|-------|------------|---------------------------|-----------------------|---------------------|
| HCT/P(s) | | Recover | Screen | Donor Testing | Package | Process | Store | Label | Distribute | Date of Discontinuance | Date of Resumption | Proprietary Name(s) |
| Amniotic Membrane | | | | Х | | | | | | | | |
| Blood Vessel | | | | X | | | | | | | | |
| Bone | | | | X | | | | | | | | |
| Cardiac Tissue - non-valved | | | | | | | | | | | | |
| Cartilage | | | | X | | | | | | | | |
| Cornea | | | | X | | | | | | | | |
| Dura Mater | | | | | | | | | | | | |
| Embryo | Anonymous, Directed, SIP | | | х | | | | | | | | |
| Fascia | | | | х | | | | | | | | |
| Heart Valve | | | | х | | | | | | | | |
| HPC Apheresis | Autologous, Family Related | | | х | | Х | | | | | | |
| HPC Cord Blood | Autologous, Family Related | | | х | | Х | | | | | | |
| Ligament | | | | х | | | | | | | | |
| Nerve Tissue | | | | | | | | | | | | |
| Oocyte | Anonymous, Directed, SIP | | | х | | | | | | | | |
| Ovarian Tissue | | | | | | | | | | | | |
| Pancreatic Islet Cells - autologous | | | | | | | | | | | | |
| Parathyroid | | | | | | | | | | | | |
| Pericardium | | | | х | | | | | | | | |
| Peripheral Blood Mononuclear Cells | Autologous, Family Related | | | х | | Х | | | | | | |
| Peritoneal Membrane | | | | | | | | | | | | |
| Sclera | | | | х | | | | | | | | |
| Semen | Anonymous, Directed, SIP | | | х | | | | | | | | |
| Skin | | | | Х | | | | | | | | |
| Tendon | | | | Х | | | | | | | | |
| Testicular Tissue | | | | | | | | | | | | |
| Tooth Pulp | | | | | | | | | | | | |
| Umbilical Cord Tissue | | | | | | | | | | | | |

Additional Information:

No additional information provided.

Proprietary Name(s):

FEI: 0002183472

Legal Name: