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**

FEI: 3012822744

Other FDA Registrations: Blood:

Devices:

Drugs:

Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2020

Last Registration Receipt Date: 12/04/2019 Summary Report Print Date: 12/10/2019

Legal Name and Location:

VRL Eurofins 1700 Enterprise Way Suite #114

Marietta, Georgia 30067 USA

Ext.: Phone: 678-224-5742

Reporting Official:

Craig P Thomsen, Director of RA/QA 6933 South Revere Parkway Centennial, Colorado 80112

Phone: 855-875-5227 Ext. 810 craigthomsen@vrl-eurofins.com

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				х								
Bone				Х								
Cardiac Tissue - non-valved												
Cartilage				Х								
Cornea				Х								
Dura Mater												
Embryo												
Fascia				Х								
Heart Valve				Х								
HPC Apheresis	Autologous, Family Related			Х								
HPC Cord Blood	Autologous, Family Related			х								
Ligament				Х								
Nerve Tissue				х								
Oocyte	Anonymous, Directed, SIP			Х								
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium				х								
Peripheral Blood Mononuclear Cells	Autologous, Family Related			Х								
Peritoneal Membrane												
Sclera				х								
Semen	Anonymous, Directed, SIP			х								
Skin				х								
Tendon				х								
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue				Х								

Additional Information:	No additional information provided.
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Proprietary Name(s):

FEI: 3012822744 Legal Name: VRL Eurofins