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: 1000477683

Other FDA Registrations: Blood: FEI: 1000477683

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

USA

6933 South Revere Parkway

Centennial, Colorado 80112

Phone: 303-790-1844

Reporting Official:

Craig P Thomsen, Director of RA/QA

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

Satellite Recovery Establishment:

No

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)).

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

Additional Information:	No additional information provided

Proprietary Name(s):

FEI: 1000477683 Legal Name: VRL Eurofins