

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: 3015976668		Other FDA Registrations: Blood: Devices: Drugs:		Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2026 Last Registration Receipt Date: 12/23/2025 Summary Report Print Date: 01/09/2026						
Legal Name and Location: Eurofins Donor & Product Testing, LLC, Winston Salem 1430 Westbrook Plaza Dr Suite B Winston-Salem, North Carolina 27103 USA Phone: 855-875-5227 Ext.:		Reporting Official: Ann V Niedzinski, Director of RA/QA 6933 South Revere Parkway Centennial, Colorado 80112 USA Phone: 855-875-5227 Ext. 803 RegulatoryAffairs@dpt.eurofinsus.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)).						
HCT/P(s)	Donor Type(s)	Establishment Functions								Date of Discontinuance	Date of Resumption	Proprietary Name(s)
		Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute			
Amniotic Membrane				X								
Blood Vessel				X								
Bone				X								
Cardiac Tissue - non-valved				X								
Cartilage				X								
Cornea				X								
Dura Mater				X								
Embryo	Anonymous, Directed, SIP			X								
Fascia				X								
Heart Valve				X								
HPC Apheresis	Autologous, Family Related			X								
HPC Cord Blood	Autologous, Family Related			X								
Ligament				X								
Nerve Tissue				X								
Oocyte	Anonymous, Directed, SIP			X								
Ovarian Tissue				X								
Pancreatic Islet Cells - autologous				X								
Parathyroid				X								
Pericardium				X								
Peripheral Blood Mononuclear Cells	Autologous, Family Related			X								
Peritoneal Membrane				X								
Sclera				X								
Semen	Anonymous, Directed, SIP			X								
Skin				X								
Tendon				X								
Testicular Tissue				X								
Tooth Pulp				X								
Umbilical Cord Tissue				X								

Additional Information: Notification of Ownership Change Effective June 30, 2025:
From: Eurofins Clinical Testing US Holdings, LLC
To: Eurofins US Holdings, Inc.

There is no impact to laboratory name, location or the testing performed.

Proprietary Name(s):

FEI: 3015976668 Legal Name: Eurofins Donor & Product Testing, LLC, Winston Salem