

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: 3005010397	Other FDA Registrations: Blood: FEI: 3005010397 Devices: Drugs:	Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2022 Last Registration Receipt Date: 11/15/2021 Summary Report Print Date: 12/01/2021
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Legal Name and Location: Quest Diagnostics Nichols Institute 14225 Newbrook Drive Chantilly, Virginia 20151 USA Phone: 703-802-6900 Ext.: 67830	Reporting Official: Janine A Brown, Director, Quality Assurance 14225 Newbrook Drive P.O. Box 10841 Chantilly, Virginia 20151 USA Phone: 703-802-6900 Ext. 67830 janine.a.brown@questdiagnostics.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)).
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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: No additional information provided.

Proprietary Name(s):

FEI: 3005010397

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