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.: 67830

FEI: 3005010397

Other FDA Registrations: Blood: FEI: 3005010397

Devices: Drugs:

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2024 Last Registration Receipt Date: 11/17/2023 Summary Report Print Date: 12/01/2023

Legal Name and Location:

Chantilly, Virginia 20151

Phone: 703-802-6900

USA

Quest Diagnostics Nichols Institute 14225 Newbrook Drive

Janine A Brown, Director, Quality Assurance 14225 Newbrook Drive

Chantilly, Virginia 20151

Reporting Official:

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)).

	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				Х								
Cartilage				Х								
Cornea				Х								
Dura Mater				Х								
Embryo	Anonymous, Directed, SIP			Х								
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				Х								
Pancreatic Islet Cells - autologous				Х								
Parathyroid				Х								
Pericardium				Х								
Peripheral Blood Mononuclear Cells	Autologous, Family Related			Х								
Peritoneal Membrane				Х								
Sclera				Х								
Semen	Anonymous, Directed, SIP			Х								
Skin				х								
Tendon				Х								
Testicular Tissue				Х								
Tooth Pulp				Х								
Umbilical Cord Tissue				Х								

Additional Information:	No additional information provided

Proprietary Name(s):

FEI: 3005010397 Legal Name: Quest Diagnostics Nichols Institute