

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: 2026
Last Registration Receipt Date: 11/18/2025
Summary Report Print Date: 12/01/2025

Legal Name and Location:

Quest Diagnostics Nichols Institute
14225 Newbrook Drive

Chantilly, Virginia 20151
USA

Phone: 703-802-6900 Ext.: 67830

Reporting Official:

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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: No additional information provided.

Proprietary Name(s):

FEI: 3005010397

Legal Name: Quest Diagnostics Nichols Institute