DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE

DESCRIBED IN 21 CFR 1271.10

FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS

FEI: 3005513911

Other FDA Registrations:
Blood:
Devices:

Drugs:

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2023
Last Registration Receipt Date: 11/30/2022
Summary Report Print Date: 12/01/2022

No

Legal Name and Location:

LabOne of Ohio, Inc. dba Quest Diagnostics

6700 Steger Drive

Cincinnati, Ohio 45237-3046

USA

Phone: 513-353-6170

3-353-6170 Ext.:

Reporting Official:

Melissa M Fitzgerald, Quality Assurance Manager

Attn: Melissa Fitzgerald, MLT(ASCP)

Quality Assurance 6700 Steger Drive

Cincinnati, Ohio 45237-3046

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Phone: 513-353-6170 Ext.

Melissa.M.Fitzgerald@questdiagnostics.com

Satellite Recovery Establishment:

Parent Manufacturing Establishment FEI No.:

Testing For Micro-Organisms Only:

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

Legal Name:

Additional Information:	No additional information provided.
Additional information.	TVO additional information provided.

Proprietary Name(s):

FEI: 3005513911 Legal Name: LabOne of Ohio, Inc. dba Quest Diagnostics