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: 3011213917

Reporting Official:

Other FDA Registrations: Blood: FEI: 0301121397

Devices: Drugs:

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2022 Last Registration Receipt Date: 12/09/2021 Summary Report Print Date: 12/15/2021

Legal Name and Location:

MD Tox Laboratory dba Innovative Health Diagnostics

1565 McGaw Ave Ste A/B

Mina Kalantari, Lab Manager 1565 McGaw Ave Ste A/B Irvine, California 92614

Satellite Recovery Establishment:

Parent Manufacturing Establishment FEI No.:

Testing For Micro-Organisms Only: No

Irvine, California 92614

USA

Phone: 949-973-6112

Ext.:

Phone: 800-820-8803 Ext. mkalantari@ihdlab.com

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)).

No

		Establishment Functions										
HCT/P(s)	Donor Type(s)	Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute	Date of Discontinuance	Date of Resumption	Proprietary Name(s)
										Discontinuarios		
Amniotic Membrane												
Blood Vessel												
Bone												
Cardiac Tissue - non-valved												
Cartilage												
Cornea												
Dura Mater												
Embryo												
Fascia												
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament												
Nerve Tissue												
Oocyte	Anonymous, Directed, SIP		Х	Х								
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen	Anonymous, Directed, SIP		Х	Х							· · · · · · · · · · · · · · · · · · ·	
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information:	No additional information provided.
Additional information.	140 additional information provided.

Proprietary Name(s):

FEI: 3011213917 Legal Name: MD Tox Laboratory dba Innovative Health Diagnostics