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.:

FEI: 3016052847

Other FDA Registrations: Blood:

Devices:

Drugs:

Reason For Last Submission: Annual Registration/Listing
Last Annual Registration Year: 2025

Last Annual Registration Year: 2025

Last Registration Receipt Date: 11/19/2024

Summary Report Print Date: 12/05/2024

Legal Name and Location:

University of Iowa Hospitals and Clinics IVF Clinic

UI Healthcare North Dodge 1360 N Dodge Street Suite 2000

Iowa City, Iowa 52245

USA

FEI:

3016052847

Phone: 319-384-8354

Reporting Official:

Joseph B Clamon, Associate Vice President, Legal Affairs

UI Healthcare North Dodge 1360 N Dodge Street

Suite 2000 Iowa City, Iowa 52245

1167

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Satellite Recovery Establishment:

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)).

No

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

Additional Information:	This site began these activities August 1, 2019.	This site does not accept anonymous testicular tissue,	only Directed, SI

Proprietary Name(s):

FEI: 3016052847 Legal Name: University of Iowa Hospitals and Clinics IVF Clinic