## 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: 3007950337

Other FDA Registrations: Blood: Devices:

Drugs:

Reason For Last Submission: Annual Registration/Listing
Last Annual Registration Year: 2024
Last Registration Receipt Date: 12/18/2023
Summary Report Print Date: 01/05/2024

Legal Name and Location:

Dorotea, LLC dba BioRepository Service

5844 Rocky Point

San Antonio, Texas 78249

USA

FEI:

Phone: 800-226-9091

Reporting Official:

Miles D Lanning, Vice President, QA/RA

P.O. Box 691433

San Antonio, Texas 78269

USA

Phone: 210-738-2663 Ext. 18 mlanning@alamobiologics.com

Satellite Recovery Establishment: Yes

Parent Manufacturing Establishment FEI No.: 3009085719

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)).

			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)
Amniotic Membrane							Х					AmnioBioGraft
Blood Vessel							Х					
Bone							Х					
Cardiac Tissue - non-valved												
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												
Oocyte	Anonymous, Directed, SIP						Х					
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium							Х					
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera							Х					
Semen	Anonymous, Directed, SIP						Х					
Skin							Х					
Tendon							Х					
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue							Х					

Additional Information:	No additional information provided

Proprietary Name(s):

FEI: 3007950337 Legal Name: Dorotea, LLC dba BioRepository Service