

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: 3019356415	Other FDA Registrations: Blood: Devices: Drugs:	Reason For Last Submission: Initial Registration/Listing Last Annual Registration Year: 2021 Last Registration Receipt Date: 06/07/2021 Summary Report Print Date: 06/07/2021
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Legal Name and Location: Xytex Laboratories 11020 David Taylor Drive Suite 310 Charlotte, North Carolina 28262 USA Phone: 706-671-2738 Ext.:	Reporting Official: James T Spradlin, Chief Medical and Laboratory Director 1100 Emmett Street Augusta, Georgia 30904 USA Phone: 762-444-6854 Ext. tspradlin@xytex.com	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)).
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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												
Blood Vessel												
Bone												
Cardiac Tissue - non-valved												
Cartilage												
Cornea												
Dura Mater												
Embryo												
Fascia												
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament												
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen	Anonymous	X	X		X	X	X	X				
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information: Donor site is anticipated to begin operation July 19, 2021.

Proprietary Name(s):

FEI: 3019356415

Legal Name:

Xytex Laboratories