## 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: 1000507143

Other FDA Registrations:
Blood:
Devices:

Drugs:

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2025 Last Registration Receipt Date: 11/15/2024 Summary Report Print Date: 12/05/2024

No

Legal Name and Location:

Augusta, Georgia 30904

Phone: 706-733-0130

Xytex Laboratories 1100 Emmett Street

USA

Reporting Official:

James T Spradlin, Chief Medical & Laboratory Director

1100 Emmett Street Augusta, Georgia 30904

Augusta, Ge

Phone: 706-733-0130 Ext. tspradlin@xytex.com

Satellite Recovery Establishment:

Parent Manufacturing Establishment FEI No.:

Testing For Micro-Organisms Only:  $$\operatorname{\textsc{No}}$$ 

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)).

	Donor Type(s)	Establishment Functions								i		
HCT/P(s)		Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute	Date of Discontinuance	Date of Resumption	Proprietary Name(s)
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	Х	Х		Х	Х	Х	Х	Х			
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information:	No additional information provided

Proprietary Name(s):

FEI: 1000507143 Legal Name: Xytex Laboratories