

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: 1000507143

Other FDA Registrations:

Blood:

Devices:

Drugs:

Reason For Last Submission: Annual Registration/Listing
Last Annual Registration Year: 2021
Last Registration Receipt Date: 11/24/2020
Summary Report Print Date: 11/30/2020

Legal Name and Location:

Xytex Laboratories
1100 Emmett Street

Augusta, Georgia 30904
USA

Phone: 706-733-0130

Ext.:

Reporting Official:

James T Spradlin, Chief Medical & Laboratory Director
1100 Emmett Street
Augusta, Georgia 30904
USA
Phone: 706-733-0130 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)).

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

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

X

X

Skin

Tendon

Testicular Tissue

Tooth Pulp

Umbilical Cord Tissue

Additional Information: No additional information provided.

Proprietary Name(s):

FEI: 1000507143

Legal Name:

Xytex Laboratories