

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 (HCT/PS)**
(See reverse side for instructions)

1. REGISTRATION NUMBER
(FDA Establishment Identifier)
FEI: 3008670156

2. REASON FOR SUBMISSION
a. INITIAL REGISTRATION / LISTING
b. ANNUAL REGISTRATION / LISTING
c. CHANGE IN INFORMATION
d. INACTIVE

VALIDATION FOR FDA USE ONLY
VALIDATED BY FDA-27-DEC-2017
DISTRICT: Atlanta
PRINTED BY FDA-27-JAN-2018

3. OTHER FDA REGISTRATIONS
a. BLOOD FDA 2830 NO. FEI: 3008670156
b. DEVICES FDA 2891 NO. _____
c. DRUG FDA 2856 NO. _____

4. PHYSICAL LOCATION (include legal name, number and street, city, state, country, and post office code)
QualTex Laboratories
4258 Communications Drive
Norcross, Georgia 30093-2922
a. PHONE 678-924-6505 EXT _____
b. SATELLITE RECOVERY ESTABLISHMENT
c. MANUFACTURING ESTABLISHMENT FEI NO. _____
d. TESTING FOR MICRO-ORGANISMS ONLY

5. ENTER CORRECTIONS TO ITEM 4

6. MAILING ADDRESS OF REPORTING OFFICIAL (include institution name if applicable, number and street, city, state, country, and post office code)
QualTex Laboratories
Attn: Ward Carter
6211 IH 10 West
San Antonio, Texas 78201
a. PHONE 210-731-5508 EXT _____
b. PHONE _____

7. ENTER CORRECTIONS TO ITEM 6

8. U.S. AGENT

9. REPORTING OFFICIAL'S SIGNATURE
a. TYPED NAME Ward Carter
b. E-MAIL ward.carter@qualtexlabs.org
c. TITLE Chief Operating Officer
d. DATE 26-DEC-2017

PART II - PRODUCT INFORMATION					10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps			11. HCT/PS DESCRIBED IN 21 CFR 1271.10			12. HCT/PS REGULATED AS MEDICAL DEVICES			13. HCT/PS REGULATED AS DRUGS OR BIOLOGICAL DRUGS			14. PROPRIETARY NAME(S)		
Types of HCT / Ps	Recover	Screen	Test	Package	Establishment Functions			11	12	13	14	14	14	14	14	14	14	14	
					Process	Store	Distribute												
a. Bone			X					X											
b. Cartilage			X					X											
c. Cornea			X					X											
d. Dura Mater																			
e. Embryo																			
f. Fascia			X					X											
g. Heart Valve			X					X											
h. Ligament			X					X											
i. Coccyte																			
j. Pericardium			X					X											
k. Peripheral Blood Stem			X					X										X	
l. Sclera			X					X											
m. Semen																			
n. Skin			X					X											
o. Somatic Cell Therapy Products																			
p. Tendon			X					X											
q. Umbilical Cord Blood			X					X										X	
r. Vascular Graft			X					X											
s. Placenta			X					X											
t. Therapeutic Cells			X					X										X	
u.																			
v.																			