

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: 3007279191

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

VALIDATION FOR FDA USE ONLY
DISTRICT: Dallas
PRINTED BY FDA-27-JAN-2018

PART I - ESTABLISHMENT INFORMATION		PART II - PRODUCT INFORMATION							14. PROPRIETARY NAME(S)								
3. OTHER FDA REGISTRATIONS		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				
		Types of HCT / PS		Recover	Screen	Test	Package	Process	Store	Label	Distribute						
a. BLOOD FDA 2830 NO. FEI: 3007279191 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 Immunohematology Reference Laboratory 6211 IH 10 West San Antonio, Texas 78201		a. Bone <input checked="" type="checkbox"/> b. Cartilage <input checked="" type="checkbox"/> c. Cornea <input checked="" type="checkbox"/> d. Dura Mater <input type="checkbox"/> e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymus <input type="checkbox"/> f. Fascia <input checked="" type="checkbox"/> g. Heart Valve <input checked="" type="checkbox"/> h. Ligament <input checked="" type="checkbox"/> i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymus <input type="checkbox"/> j. Pericardium <input type="checkbox"/> k. Peripheral Blood Stem <input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic <input type="checkbox"/> l. Sclera <input checked="" type="checkbox"/> m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymus <input type="checkbox"/> n. Skin <input type="checkbox"/> o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic <input type="checkbox"/> p. Tendon <input checked="" type="checkbox"/> q. Umbilical Cord Blood <input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic <input type="checkbox"/> r. Vascular Graft <input checked="" type="checkbox"/> s. <input type="checkbox"/> t. <input type="checkbox"/> u. <input type="checkbox"/> v. <input type="checkbox"/>															
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 Immunohematology Reference Laboratory 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@qualtextlabs.org c. TITLE Chief Operating Officer d. DATE 26-DEC-2017																	