

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. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input checked="" type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	VALIDATION--FOR FDA USE ONLY VALIDATED BY FDA:27-DEC-2017 DISTRICT: Dallas PRINTED BY FDA:27-JAN-2018
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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		Establishment Functions															
		Recover	Screen	Test	Package	Process	Store	Label	Distribute									
a. BLOOD FDA 2830 NO. FEI: 3007279191 b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 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. PHONE 888-789-5527 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY		a. Bone			X						X							
		b. Cartilage			X						X							
		c. Cornea			X						X							
		d. Dura Mater																
		e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																
		f. Fascia			X						X							
		g. Heart Valve			X						X							
		h. Ligament			X						X							
		i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																
		j. Pericardium			X						X							
		k. Peripheral Blood Stem <input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic			X										X			
		l. Sclera			X						X							
		m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																
		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 _____		n. Skin			X					X						
7. ENTER CORRECTIONS TO ITEM 6																		
8. U.S. AGENT a. E-MAIL _____		o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																
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		p. Tendon			X					X								
		q. Umbilical Cord Blood <input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic			X									X				
		r. Vascular Graft			X						X							
		s.																
		t.																
		u.																
		v.																