

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: 3006339676	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:23-DEC-2012 DISTRICT: Dallas PRINTED BY FDA:16-JAN-2013
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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					
	Establishment Functions																
	Types of HCT / Ps	Recover	Screen	Test	Package	Process	Store	Label	Distribute								
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) QualTex Laboratories 6211 IH 10 West at First Park Ten Blvd San Antonio, Texas 78201 a. PHONE 210-731-5555 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				X							
	b. Cartilage			X		X				X							
	c. Cornea			X		X				X							
	d. Dura Mater																
	e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																
	f. Fascia			X		X					X						
	g. Heart Valve			X		X					X						
	h. Ligament			X		X					X						
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																
	j. Pericardium			X		X					X						
6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) QualTex Laboratories Attn: Linda K. Myers, MT (ASCP) SBB 6211 IH 10 West at First Park Ten Blvd San Antonio, Texas 78201 a. PHONE 210-731-5526 EXT _____ b. PHONE _____	k. Peripheral Blood Stem <input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic			X		X				X			X				
	l. Sclera			X		X				X							
	m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																
	n. Skin			X		X				X							
	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																
	p. Tendon			X		X					X						
	q. Umbilical Cord Blood <input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic				X		X							X			
	r. Vascular Graft			X		X					X						
	s. Placenta			X		X					X						
	t. Therapeutic Cells			X		X								X			
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Linda K. Myers, MT (ASCP) SBB b. E-MAIL linda.myers@qualtexlabs.org c. TITLE President/COO d. DATE 22-DEC-2012	u.																
	v.																