

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) <i>(See reverse side for instructions)</i>		1. REGISTRATION NUMBER (Field Establishment Identifier) FEI: 0002183828	2. REASON FOR SUBMISSION a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input checked="" type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	VALIDATION--FOR FDA USE ONLY 1 VALIDATED BY FDA:14-APR-2010 DISTRICT: Minneapolis PRINTED BY FDA:14-APR-2010												
PART I - ESTABLISHMENT INFORMATION		PART II - PRODUCT INFORMATION						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)							
3. OTHER FDA REGISTRATIONS a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. FEI: 0002183828 c. DRUG FDA 2656 NO. _____		10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps														
		<i>Establishment Functions</i>														
		<i>Types of HCT / Ps</i>	Recover	Screen	Test	Package	Process	Store	Label	Distribute						
4. PHYSICAL LOCATION <i>(Include legal name, number and street, city, state, country, and post office code)</i> Biotest Laboratories, Inc. 9303 West Broadway Ave. Brooklyn Park, Minnesota 55445 a. PHONE 763-315-1200 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input checked="" type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY		a. Bone					X					X				
		b. Cartilage					X						X			
		c. Cornea														
		d. Dura Mater														
		e. Embryo	<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous													
		f. Fascia						X						X		
		g. Heart Valve														
		h. Ligament						X							X	
		i. Oocyte	<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous													
		j. Pericardium														
a. PHONE 763-315-1200 EXT _____		k. Peripheral Blood Stem Cells	<input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic													
		l. Sclera														
7. ENTER CORRECTIONS TO ITEM 6 a. PHONE _____ EXT _____ b. PHONE _____		m. Semen	<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous													
		n. Skin					X						X			
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													
		p. Tendon					X						X			
		q. Umbilical Cord Blood Stem Cells	<input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic													
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Jean M. Gerlach b. E-MAIL jgerlach@biotestlabs.com c. TITLE QA Manager d. DATE 30-MAR-2010		r. Vascular Graft														
		s.														
		t.														
		u.														
		v.														