



DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION <b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,                  AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps)</b> <i>(See reverse side for instructions)</i>		<b>1. REGISTRATION NUMBER</b> (Field Establishment Identifier)  FEI: 3005338746	<b>2. REASON FOR SUBMISSION</b> 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	<b>VALIDATION—FOR FDA USE ONLY</b> VALIDATED BY FDA:04-JAN-2008 DISTRICT: Florida PRINTED BY FDA:17-JAN-2008							
<b>PART I - ESTABLISHMENT INFORMATION</b>		<b>PART II - PRODUCT INFORMATION</b>						11. HCT/Ps MANUFACTURED IN 21 CFR 1271.18	12. HCT/Ps REGULATED AS MEDICAL DEVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)
<b>3. OTHER FDA REGISTRATIONS</b> a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2856 NO. _____		<b>10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps</b>									
		<i>Establishment Functions</i>									
		Types of HCT / Ps	Recover	Screen	Test	Package	Process	Store	Label	Distribute	
		No HCT / P Specified			X						
<b>4. PHYSICAL LOCATION</b> <i>(include legal name, number and street, city, state, country, and post office code)</i> Unilab Of Dade 2145 W. Davie Blvd. Suite 106 Ft.Lauderdale, Florida 33312  a. PHONE 954-792-7422 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY		a. Bone									
		b. Cartilage									
		c. Cornea									
		d. Dura Mater									
		e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous									
		f. Fascia									
<b>5. ENTER CORRECTIONS TO ITEM 4</b>		g. Heart Valve									
		h. Ligament									
<b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> <i>(include institution name if applicable, number and street, city, state, country, and post office code)</i> Unilab of Dade Attn: Julio Cortes 2145 W. Davie Blvd. Suite 106 Ft.Lauderdale, Florida 33312  a. PHONE 954-792-7422 EXT _____		i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous									
		j. Pericardium									
		k. Peripheral Blood Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic									
		l. Sclera									
		m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous									
<b>7. ENTER CORRECTIONS TO ITEM 6</b>		n. Skin									
		o. Somatic Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic									
<b>8. U.S. AGENT</b>		p. Tendon									
		q. Umbilical Cord Blood Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic									
		r. Vascular Graft									
<b>9. REPORTING OFFICIAL'S SIGNATURE</b>  a. TYPED NAME Julio Cortes b. E-MAIL julio@infertilitylab.com c. TITLE VP		s.									
		t.									
		u.									
		v.									
		d. DATE 03-JAN-2008									