

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: 3003652672	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-NOV-2014 DISTRICT: New Jersey PRINTED BY FDA:04-DEC-2014																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																								
PART I - ESTABLISHMENT INFORMATION 3. OTHER FDA REGISTRATIONS a. BLOOD FDA 2830 NO. FEI: 3003652672 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) Bio-Reference Laboratories, Inc. 481 Edward H.Ross Drive Elmwood Park, New Jersey 07407 a. PHONE 1-800-229-5227 EXT 8351 b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	PART II - PRODUCT INFORMATION 10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th rowspan="2">Types of HCT / Ps</th> <th colspan="8">Establishment Functions</th> <th rowspan="2">11. HCT/PS DESCRIBED IN 21 CFR 1271.10</th> <th rowspan="2">12. HCT/PS REGULATED AS MEDICAL DEVICES</th> <th rowspan="2">13. HCT/PS REGULATED AS DRUGS OR BIOLOGICAL DRUGS</th> <th rowspan="2">14. PROPRIETARY NAME(S)</th> </tr> <tr> <th>Recover</th> <th>Screen</th> <th>Test</th> <th>Package</th> <th>Process</th> <th>Store</th> <th>Label</th> <th>Distribute</th> </tr> </thead> <tbody> <tr><td>a. Bone</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>b. Cartilage</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>c. Cornea</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>d. Dura Mater</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>e. Embryo</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td> <input type="checkbox"/> SIP</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td> <input type="checkbox"/> Directed</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td> <input type="checkbox"/> Anonymous</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>f. Fascia</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>g. Heart Valve</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>h. Ligament</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>i. Oocyte</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td> <input type="checkbox"/> SIP</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td> <input type="checkbox"/> Directed</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td> <input type="checkbox"/> Anonymous</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>j. Pericardium</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>k. Peripheral Blood Stem</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td> <input type="checkbox"/> Autologous</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td> <input checked="" type="checkbox"/> Family Related</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td> <input type="checkbox"/> Allogeneic</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>l. Sclera</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>m. Semen</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td> <input type="checkbox"/> SIP</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td> <input type="checkbox"/> Directed</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td> <input type="checkbox"/> Anonymous</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>n. Skin</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>o. Somatic Cell Therapy Products</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td> <input type="checkbox"/> Autologous</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td> <input type="checkbox"/> Family Related</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td> <input type="checkbox"/> Allogeneic</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>p. Tendon</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>q. Umbilical Cord Blood</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td> <input type="checkbox"/> Autologous</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td> <input type="checkbox"/> Family Related</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td> <input type="checkbox"/> Allogeneic</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>r. Vascular Graft</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>s.</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>t.</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>u.</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>v.</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> </tbody> </table>		Types of HCT / Ps	Establishment Functions								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)	Recover	Screen	Test	Package	Process	Store	Label	Distribute	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												g. Heart Valve												h. Ligament												i. Oocyte												<input type="checkbox"/> SIP												<input type="checkbox"/> Directed												<input type="checkbox"/> Anonymous												j. Pericardium												k. Peripheral Blood Stem												<input type="checkbox"/> Autologous												<input checked="" type="checkbox"/> Family Related												<input type="checkbox"/> Allogeneic												l. Sclera												m. Semen												<input type="checkbox"/> SIP												<input type="checkbox"/> Directed												<input type="checkbox"/> Anonymous												n. Skin												o. Somatic Cell Therapy Products												<input type="checkbox"/> Autologous												<input type="checkbox"/> Family Related												<input type="checkbox"/> Allogeneic												p. Tendon												q. Umbilical Cord Blood												<input type="checkbox"/> Autologous												<input type="checkbox"/> Family Related												<input type="checkbox"/> Allogeneic												r. Vascular Graft												s.												t.												u.												v.												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) BioReference Laboratory Attn: Nick Cetani, VP 481 Edward H. Ross Drive Elmwood Park, New Jersey 07407 a. PHONE 1-800-229-5227 EXT 8351	7. ENTER CORRECTIONS TO ITEM 6 b. PHONE _____	8. U.S. AGENT a. E-MAIL _____	9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Nick Cetani, VP b. E-MAIL ncetani@bioreference.com c. TITLE Adm. Director d. DATE 26-NOV-2014
Types of HCT / Ps	Establishment Functions								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)																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											
	Recover	Screen	Test	Package	Process	Store	Label	Distribute																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
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																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											
g. Heart Valve																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											
h. Ligament																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											
i. Oocyte																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											
<input type="checkbox"/> SIP																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											
<input type="checkbox"/> Directed																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											
<input type="checkbox"/> Anonymous																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											
j. Pericardium																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											
k. Peripheral Blood Stem																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											
<input type="checkbox"/> Autologous																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											
<input checked="" type="checkbox"/> Family Related																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											
<input type="checkbox"/> Allogeneic																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											
l. Sclera																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											
m. Semen																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											
<input type="checkbox"/> SIP																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											
<input type="checkbox"/> Directed																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											
<input type="checkbox"/> Anonymous																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											
n. Skin																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											
o. Somatic Cell Therapy Products																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											
<input type="checkbox"/> Autologous																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											
<input type="checkbox"/> Family Related																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											
<input type="checkbox"/> Allogeneic																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											
p. Tendon																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											
q. Umbilical Cord Blood																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											
<input type="checkbox"/> Autologous																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											
<input type="checkbox"/> Family Related																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											
<input type="checkbox"/> Allogeneic																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											
r. Vascular Graft																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											
s.																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											
t.																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											
u.																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											
v.																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											