

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: 3008772203	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 1 VALIDATED BY FDA:05-DEC-2014 DISTRICT: Denver PRINTED BY FDA:22-DEC-2014
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PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION			14. PROPRIETARY NAME(S)																																																																																																																																																																																																																																																																								
3. OTHER FDA REGISTRATIONS a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	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">13. HCT/PS REGULATED AS DRUGS OR BIOLOGICAL DRUGS</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> </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	13. HCT/PS REGULATED AS DRUGS OR BIOLOGICAL DRUGS	Recover	Screen	Test	Package	Process	Store	Label	Distribute																																																																																																																																																																																																																																																						
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4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) VRL Laboratories 6665 South Kenton Street Suite #205 Centennial, Colorado 80111 a. PHONE 855-875-5227 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	<table border="1" style="width:100%; border-collapse: collapse;"> <tr><td>a. Bone</td><td></td><td></td><td>X</td><td></td><td>X</td><td></td><td></td><td></td><td>X</td><td></td><td></td></tr> <tr><td>b. Cartilage</td><td></td><td></td><td>X</td><td></td><td>X</td><td></td><td></td><td></td><td>X</td><td></td><td></td></tr> <tr><td>c. Cornea</td><td></td><td></td><td>X</td><td></td><td>X</td><td></td><td></td><td></td><td>X</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. 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