

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> (See reverse side for instructions)		<b>1. REGISTRATION NUMBER</b> (FDA Establishment Identifier)  FEI: 3008772203	<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	VALIDATION--FOR FDA USE ONLY VALIDATED BY FDA: 18-NOV-2015 DISTRICT: Denver PRINTED BY FDA: 03-DEC-2015																																																																																																																																																																																																																																																																																																																																																																					
<b>PART I - ESTABLISHMENT INFORMATION</b>		<b>PART II - PRODUCT INFORMATION</b>							11. HCT/Ps DESCRIBED IN 21 CFR 1271.10	12. HCT/Ps REGULATED AS MEDICAL DEVICES	13. HCT/Ps REGULATED AS 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 2656 NO. _____		<b>10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps</b>																																																																																																																																																																																																																																																																																																																																																																							
<b>4. PHYSICAL LOCATION</b> (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;"> <thead> <tr> <th rowspan="2" style="text-align: center;">Types of HCT / Ps</th> <th colspan="8" style="text-align: center;">Establishment Functions</th> </tr> <tr> <th style="text-align: center;">Recover</th> <th style="text-align: center;">Screen</th> <th style="text-align: center;">Test</th> <th style="text-align: center;">Package</th> <th style="text-align: center;">Process</th> <th style="text-align: center;">Store</th> <th style="text-align: center;">Label</th> <th style="text-align: center;">Distribute</th> </tr> </thead> <tbody> <tr> <td>a. 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<b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> (Include institution name if applicable, number and street, city, state, country, and post office code) VRL Laboratories Attn: Miles D. Lanning 6665 South Kenton Street Suite #205 Centennial, Colorado 80111  a. PHONE 303-790-1844 EXT 810																																																																																																																																																																																																																																																																																																																																																																									
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<b>9. REPORTING OFFICIAL'S SIGNATURE</b>  a. TYPED NAME Miles D. Lanning b. E-MAIL miles.lanning@vrl.net c. TITLE Quality Manager d. DATE 17-NOV-2015																																																																																																																																																																																																																																																																																																																																																																									