

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. INITIAL REGISTRATION / LISTING
 b. ANNUAL REGISTRATION / LISTING
 c. CHANGE IN INFORMATION
 d. INACTIVE

VALIDATION-FOR FDA USE ONLY
 VALIDATED BY FDA:02-DEC-2016
 DISTRICT: Denver
 PRINTED BY FDA:15-DEC-2016

PART I - ESTABLISHMENT INFORMATION		PART II - PRODUCT INFORMATION						10. ESTABLISHMENT FUNCTIONS AND 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)	
3. OTHER FDA REGISTRATIONS		Types of HCT / Ps		Recover	Screen	Test	Package	Process	Store	Label	Distribute										
a. BLOOD FDA 2830	NO.																				
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) VRL Eurofins 6665 South Kenton Street Suite #205 Centennial, Colorado 80111		<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																			
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																					
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) VRL Eurofins Attn: Miles D. Lanning 6665 South Kenton Street Suite #205 Centennial, Colorado 80111		<input checked="" type="checkbox"/> SIP <input checked="" type="checkbox"/> Directed <input checked="" type="checkbox"/> Anonymous																			
a. PHONE 303-790-1844 EXT 810																					
b. PHONE																					
7. ENTER CORRECTIONS TO ITEM 6																					
8. U.S. AGENT																					
a. E-MAIL																					
9. REPORTING OFFICIAL'S SIGNATURE																					
a. TYPED NAME Miles D. Lanning																					
b. E-MAIL mileslanning@vrl-eurofins.com																					
c. TITLE Director, Regulatory and Quality																					
d. DATE 01-DEC-2016																					