


DEPARTMENT OF HEALTH AND HUMAN SERVICES
 PUBLIC HEALTH SERVICE
 FOOD AND DRUG ADMINISTRATION
BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING

1. REGISTRATION NUMBER
 FEI: 3008670156
 CFN:
2. U.S. LICENSE NUMBER

3. REASON FOR SUBMISSION
 .1 ANNUAL REGISTRATION
 .2 INITIAL REGISTRATION
 .3 CHANGE IN INFORMATION

FOR FDA USE ONLY



DISTRICT OFFICE: Atlanta
 VALIDATED BY FDA: 22-DEC-2017
 PRINTED BY FDA: 08-JAN-2018

This form is authorized by Sections 510(b), (j), and 704 of the Federal Food, Drug, and Cosmetic Act (Title 21, United States Code 360(b), (j) and 374). Failure to report this information is a violation of Section 301(f) and (p) of the Act (Title 21, United States Code 331(f) and (p)) and can result in a fine of up to \$1,000 or imprisonment up to one year or both, pursuant to Section 303(a) of the Act (Title 21, United States Code 333(a)).

9. TYPE OF OWNERSHIP
 .1 SINGLE PROPRIETORSHIP
 .2 PARTNERSHIP
 .3 CORPORATION profit non-profit
 .4 COOPERATIVE ASSOCIATION
 .5 FEDERAL (non-military)
 .6 U.S. MILITARY
 .7 STATE
 .8 COUNTY/MUNICIPAL/HOSPITAL AUTHORITY
 .9 OTHER (Specify): _____

10. TYPE ESTABLISHMENT (Check all boxes that describe routine or autologous operations.)
 .1 COMMUNITY (NON-HOSPITAL) BLOOD BANK
 .2 HOSPITAL BLOOD BANK
 .3 PLASMAPHERESIS CENTER
 .4 PRODUCT TESTING LABORATORY
 a. INDEPENDENT
 b. ASSOCIATED W/ COMMUNITY or HOSPITAL BLOOD BANK
 .5 HOSPITAL TRANSFUSION SERVICE
 a. APPROVED FOR MEDICARE REIMBURSEMENT
 b. NOT APPROVED FOR MEDICARE REIMBURSEMENT
 .6 COMPONENT PREPARATION FACILITY
 .7 COLLECTION FACILITY
 .8 DISTRIBUTION CENTER
 .9 BROKER/WAREHOUSE
 .10 OTHER (Specify): _____ U.S. LICENSE NUMBER OF PARENT FIRM: _____

11. PRODUCTS

ALLOGENEIC	AUTOLOGOUS	DIRECTED	COLLECT	MANUAL APHERESIS	AUTOMATED APHERESIS	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR RETESTED	TEST	STORE and RETURN to OTHERS
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	WHOLE BLOOD							X	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	RED BLOOD CELLS (RBC)							X	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	RBC FROZEN							X	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	RBC DEGLYCEROLIZED							X	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	RBC REJUVENATED							X	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	RBC REJUVENATED FROZEN							X	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	RBC REJUVENATED DEGLYCEROLIZED							X	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CRYOPRECIPITATED AHF							X	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	PLATELETS							X	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	LEUKOCYTES/GRANULOCYTES							X	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	PLASMA							X	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	PLASMA CRYOPRECIPITATE REDUCED							X	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	FRESH FROZEN PLASMA							X	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	LIQUID PLASMA							X	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	THERAPEUTIC EXCHANGE PLASMA							X	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	SOURCE LEUKOCYTES							X	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	SOURCE PLASMA							X	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	RECOVERED PLASMA							X	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	BLOOD PRODUCTS FOR DIAGNOSTIC USE							X	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	BLOOD BANK REAGENTS							X	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	OTHER T-Cells							X	

7. U.S. AGENT (Include name, institution name if applicable, number and street, city, state, and zip code)

7.1 E-MAIL ADDRESS
7.2 PHONE

8. REPORTING OFFICIAL'S SIGNATURE

8.1 TYPED NAME Ward Carter
8.2 E-MAIL ADDRESS ward.carter@qualtexlabs.org
8.3 PHONE 210-731-5508
8.4 DATE