

FOR FDA USE ONLY



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

DISTRICT OFFICE: Minneapolis  
 VALIDATED BY FDA: 21-NOV-2014  
 PRINTED BY FDA: 08-JAN-2015

1. REGISTRATION NUMBER  
 FEI: 2170666  
 CFN: 2170666

2. U.S. LICENSE NUMBER

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 33.3(a)).

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.  BROKERWAREHOUSE
- 10.  OTHER (Specify): \_\_\_\_\_

U.S. LICENSE NUMBER OF PARENT FIRM \_\_\_\_\_

9. TYPE OF OWNERSHIP

- 1.  SINGLE PROPRIETORSHIP
- 2.  PARTNERSHIP
- 3.  CORPORATE non-profit, non-profit
- 4.  COOPERATIVE ASSOCIATION
- 5.  FEDERAL (non-military)
- 6.  U.S. MILITARY
- 7.  STATE
- 8.  COUNTY/MUNICIPAL/HOSPITAL AUTHORITY
- 9.  OTHER (Specify): \_\_\_\_\_

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

PLEASE READ INSTRUCTIONS CAREFULLY. Be sure to indicate any changes in your legal name or actual location in item 4, and any changes in your mailing address in item 6. Print all entries and make all corrections in red ink, if possible. Enter your phone number in item 8.3 and the phone number of your actual location in item 4.1. Sign the form and return to FDA. After validation, you will receive your Official Registration for the ensuing year.

ENTER ALL CHANGES IN RED INK AND CIRCLE.

4. LEGAL NAME AND LOCATION (include legal name, number and street, city, state, country, and post office code)  
 Children's Hospital & Clinics of Minneapolis  
 2525 Chicago Avenue South  
 Lab-Blood Bank  
 Minneapolis, MN 55404  
 4.1 PHONE 612-813-6280 x6824

5. OTHER NAMES USED AT THIS LOCATION (include trade name, doing-business-as, previous names, and other firms co-located. If applicable, include registration number.)

\_\_\_\_\_

6. MAILING ADDRESS OF REPORTING OFFICIAL (include institution name if applicable, number and street, city, state, country, and post office code)

Children's Hospital & Clinics-Minneapolis  
 ATTN: Jed B. Gorlin, Vice President, Medical and Quality A  
 2525 Chicago Avenue South  
 Lab-Blood Bank  
 Minneapolis, MN 55404

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

*Jed B. Gorlin*  
 8.1 TYPED NAME Jed B. Gorlin, Vice President, Medical and Quality  
 8.2 E-MAIL ADDRESS jed@mbc.org  
 8.3 PHONE 651-332-7284  
 8.4 DATE 1/12/15

11. PRODUCTS	ALLOGENEIC	AUTOLOGOUS	DIRECTED	COLLECT	MANUAL APHERESIS	AUTOMATED APHERESIS	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR RETESTED	TEST	STORE AND DISTRIBUTE TO OTHERS
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)
WHOLE BLOOD												
RED BLOOD CELLS (RBC)									X		X	
RBC FROZEN									X		X	
RBC DEGLYCEROLIZED												
RBC REJUVENATED												
RBC REJUVENATED FROZEN									X		X	
RBC REJUVENATED DEGLYCEROLIZED												
CRYOPRECIPITATED AHF									X			
PLATELETS									X			
LEUKOCYTES/GRANULOCYTES									X		X	
PLASMA												
PLASMA CRYOPRECIPITATE REDUCED												
FRESH FROZEN PLASMA												
LIQUID PLASMA												
THERAPEUTIC EXCHANGE PLASMA												
SOURCE LEUKOCYTES												
SOURCE PLASMA												
RECOVERED PLASMA												
BLOOD PRODUCTS FOR DIAGNOSTIC USE												
BLOOD BANK REAGENTS												
OTHER												

52/27/15