

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

1. REGISTRATION NUMBER
FEI: 2173943
CFN: 2173943

2. U.S. LICENSE NUMBER

This form is authorized by Sections 510(b), (f) and 704 of the Federal Food, Drug, and Cosmetic Act (Title 21, United States Code 360(b), (f) 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)).

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



FOR FDA USE ONLY 1

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 and Clinics of Minnesota
345 North Smith Avenue
St. Paul, MN 55102

4.1 PHONE 612-220-6550 X6558

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 and Clinics of Minnesota
ATTN: Jed B. Gorlin, Vice President, Medical and Quality A
345 North Smith Avenue
St. Paul, MN 55102

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 1/21/15

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. BROKERWAREHOUSE
10. OTHER (Specify):

U.S. LICENSE NUMBER OF PARENT FIRM

11. PRODUCTS		COLLECT	MANUAL APHERESIS	AUTOMATED APHERESIS	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR RETESTED	TEST	STORE AND DISTRIBUTE TO OTHERS	
ALLOGENIC	AUTOLOGOUS	DIRECTED	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>									
WHOLE BLOOD											
RED BLOOD CELLS (RBC)								X		X	
RBC FROZEN											
RBC DEGLYCEROLIZED								X		X	
RBC REJUVENATED											
RBC REJUVENATED FROZEN											
RBC REJUVENATED DEGLYCEROLIZED								X		X	
CRYOPRECIPITATED AHF											
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											

31515