

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

1. REGISTRATION NUMBER
FEE 3008744240
CFN:
2. U.S. LICENSE NUMBER

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

FOR FDA USE ONLY



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 4.3. Sign the form and return to FDA. After validation, you will receive your Official Registration for the ensuing year.

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)).

DISTRICT OFFICE Chicago
VALIDATED BY FDA: 19-DEC-2011
PRINTED BY FDA: 11-JAN-2012

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)

LifeSource
Testing Laboratory
5505 Pearl Street
2nd Floor
Rosemont, IL 60018

4.1 PHONE 847-260-2683

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)

Institute for Transfusion Medicine
ATTN: Elizabeth A. DeAngelo
Five Parkway Center
875 Greentree Road
Pittsburgh, PA 15220

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

Elizabeth DeAngelo 1/11/12

8.1 TYPE NAME Elizabeth A. DeAngelo

8.2 E-MAIL ADDRESS edeangelo@itxm.org

8.3 PHONE 412-209-7042

8.4 DATE

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
- 5 INDEPENDENT
ASSOCIATED W/ COMMUNITY or HOSPITAL BLOOD BANK
- 6 HOSPITAL TRANSFUSION SERVICE
- 7 APPROVED FOR MEDICARE REIMBURSEMENT
NOT APPROVED FOR MEDICARE REIMBURSEMENT
- 8 COMPONENT PREPARATION FACILITY
- 9 COLLECTION FACILITY
- 10 DISTRIBUTION CENTER
- 11 BROKER/WAREHOUSE
- 12 OTHER (Specify)

U.S. LICENSE NUMBER OF PARENT FIRM

11. PRODUCTS

PRODUCTS	COLLECT		MANUAL APHERESIS		AUTOMATED APHERESIS		PREPARE		LEUKOCYTES REDUCED		IRRADIATED		DONOR RETELED		TEST		STORE and DISTRIBUTE to OTHERS		
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)	(14)	(15)	(16)	(17)	(18)	
WHOLE BLOOD	1																		X
RED BLOOD CELLS (RBC)	2																		X
RBC FROZEN	3																		X
RBC DEGLYCEROLIZED	4																		X
RBC REJUVENATED	5																		X
RBC REJUVENATED FROZEN	6																		X
RBC REJUVENATED DEGLYCEROLIZED	7																		X
CRYOPRECIPITATED AMF	8																		X
PLATELETS	9																		X
LEUKOCYTES/GRANULOCYTES	10																		X
PLASMA	11																		X
PLASMA CRYOPRECIPITATE REDUCED	12																		X
FRESH FROZEN PLASMA	13																		X
LIQUID PLASMA	14																		X
THERAPEUTIC EXCHANGE PLASMA	15																		
SOURCE LEUKOCYTES	16																		X
SOURCE PLASMA	17																		X
RECOVERED PLASMA	18																		X
BLOOD PRODUCTS FOR DIAGNOSTIC USE	19																		X
BLOOD BANK REAGENTS	20																		X
OTHER	21																		