

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

**1. REGISTRATION NUMBER**

FEI: 1000307079

CFN: 2577704

**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 4.1. 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 33.3(a)).

DISTRICT OFFICE: Philadelphia  
VALIDATED BY FDA: 03-DEC-2016  
PRINTED BY FDA: 19-DEC-2016

**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)

ITxM Clinical Services  
Attn: Blood Bank  
D.L. Clark Building  
501 Martindale Street  
Pittsburgh, PA 15212

4.1 PHONE 412-209-7460

**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.)

Central Transfusion Services

**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 DeAngelo, Quality Assurance Manager  
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 12/19/16*

8.1 TYPED NAME Elizabeth DeAngelo, Quality Assurance Manager

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
  - a. \_\_\_ INDEPENDENT
  - \_\_\_ ASSOCIATED W/ COMMUNITY or HOSPITAL BLOOD BANK
- 5  HOSPITAL TRANSFUSION SERVICE
  - a. \_\_\_ APPROVED FOR MEDICARE REIMBURSEMENT
  - \_\_\_ 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<br>(.1) | MANUAL<br>APHERESIS<br>(.2) | AUTOMATED<br>APHERESIS<br>(.3) | PREPARE<br>(.4) | LEUKOCYTES<br>REDUCED<br>(.5) | IRRADIATED<br>(.6) | DONOR<br>RETESTED<br>(.7) | TEST<br>(.8) | STORE and<br>DISTRIBUTE<br>to OTHERS<br>(.9) |
|-----------------------------------|------------|------------|----------|-----------------|-----------------------------|--------------------------------|-----------------|-------------------------------|--------------------|---------------------------|--------------|--|
| WHOLE BLOOD                       |            |            |          | 1               |                             |                                |                 |                               | X                  |                           | X            | X  |
| RED BLOOD CELLS (RBC)             |            |            |          | 2               |                             |                                |                 | X                             | X                  |                           | X            | X  |
| RBC FROZEN                        |            |            |          | 3               |                             |                                | X               |                               |                    |                           |              | X  |
| RBC DEGLYCEROLIZED                |            |            |          | 4               |                             |                                | X               |                               | X                  |                           | X            | X  |
| RBC REJUVENATED                   |            |            |          | 5               |                             |                                |                 |                               | X                  |                           |              |  |
| RBC REJUVENATED FROZEN            |            |            |          | 6               |                             |                                |                 |                               |                    |                           |              |  |
| RBC REJUVENATED DEGLYCEROLIZED    |            |            |          | 7               |                             |                                |                 |                               | X                  |                           | X            | X  |
| CRYOPRECIPITATED AHF              |            |            |          | 8               |                             |                                |                 |                               | X                  |                           |              |  |
| PLATELETS                         |            |            |          | 9               |                             |                                |                 | X                             | X                  |                           |              | X  |
| LEUKOCYTES/GRANULOCYTES           |            |            |          | 10              |                             |                                |                 |                               | X                  |                           | X            | X  |
| PLASMA                            |            |            |          | 11              |                             |                                |                 |                               | X                  |                           |              | X  |
| PLASMA CRYOPRECIPITATE REDUCED    |            |            |          | 12              |                             |                                |                 |                               | X                  |                           |              |  |
| FRESH FROZEN PLASMA               |            |            |          | 13              |                             |                                |                 |                               | X                  |                           |              | X  |
| LIQUID PLASMA                     |            |            |          | 14              |                             |                                |                 |                               | X                  |                           |              |  |
| THERAPEUTIC EXCHANGE PLASMA       |            |            |          | 15              |                             |                                |                 |                               |                    |                           |              |  |
| SOURCE LEUKOCYTES                 |            |            |          | 16              |                             |                                |                 |                               |                    |                           |              |  |
| SOURCE PLASMA                     |            |            |          | 17              |                             |                                |                 |                               |                    |                           |              |  |
| RECOVERED PLASMA                  |            |            |          | 18              |                             |                                |                 |                               |                    |                           |              |  |
| BLOOD PRODUCTS FOR DIAGNOSTIC USE |            |            |          | 19              |                             |                                |                 |                               |                    |                           |              |  |
| BLOOD BANK REAGENTS               |            |            |          | 20              |                             |                                |                 |                               |                    |                           |              |  |
| OTHER Pooled Platelets -5d        |            |            |          | 21              |                             |                                | X               | X                             | X                  |                           |              | X  |
| Red Blood Cells Washed            |            |            |          |                 |                             |                                | X               |                               | X                  |                           | X            | X  |