

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

1. REGISTRATION NUMBER
 FEI: 3006339676
 CFN:

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



FOR FDA USE ONLY 113

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)

QualTex Laboratories
 6211 IH 10 West at First Park Ten Blvd
 San Antonio, TX 78201

4.1 PHONE 210-731-5555 x2529

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.)

South Texas Blood and Tissue Center

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

QualTex Laboratories
 ATTN: Norman D. Kalmin, M.D.
 6211 IH 10 West at First Park Ten Blvd
 San Antonio, TX 78201

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

7.1 EMAIL ADDRESS
 7.2 PHONE

8. REPORTING OFFICIAL'S SIGNATURE

Norman D. Kalmin

8.1 TYPED NAME Norman D. Kalmin, M.D.
 8.2 E-MAIL ADDRESS kim.ratliff@qualtextlabs.org
 8.3 PHONE 210-731-5555 x2529 8.4 DATE

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(f), (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)).

9. TYPE OF OWNERSHIP

- 1. SINGLE PROPRIETORSHIP
- 2. PARTNERSHIP
- 3. CORPORATION prof: 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. PLASMA/HERESIS 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 | ALLOGENIC | AUTOLOGOUS | DIRECTED | COLLECT (1) | MANUAL APHERESIS (2) | AUTOMATED APHERESIS (3) | PREPARE (4) | LEUKOCYTES REDUCED (5) | IRRADIATED (6) | DONOR RETESTED (7) | TEST (8) | STORE and DISTRIBUTE to OTHERS (9) |
|-----------------------------------|--------------------------|--------------------------|--------------------------|-------------|----------------------|-------------------------|-------------|------------------------|----------------|--------------------|----------|------------------------------------|
| WHOLE BLOOD | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | | | | | | | X | |
| RED BLOOD CELLS (RBC) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | | | | | | | X | |
| RBC FROZEN | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | | | | | | | X | |
| RBC DEGLYCEROLIZED | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | | | | | | | X | |
| RBC RELIVENATED | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | | | | | | | X | |
| RBC RELIVENATED FROZEN | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | | | | | | | X | |
| RBC RELIVENATED DEGLYCEROLIZED | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | | | | | | | X | |
| CRYOPRECIPITATED AHF | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | | | | | | | X | |
| PLATELETS | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | | | X | | | | X | |
| LEUKOCYTES/GRANULOCYTES | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | | | | | | | X | |
| PLASMA | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | | | | | | | X | |
| PLASMA CRYOPRECIPITATE REDUCED | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | | | | | | | X | |
| FRESH FROZEN PLASMA | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | | | | | | | X | |
| LIQUID PLASMA | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | | | | | | | X | |
| THERAPEUTIC EXCHANGE PLASMA | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | | | | | | | X | |
| SOURCE LEUKOCYTES | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | | | | | | | X | |
| SOURCE PLASMA | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | | | | | | | X | |
| RECOVERED PLASMA | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | | | | | | | X | |
| BLOOD PRODUCTS FOR DIAGNOSTIC USE | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | | | | | | | X | |
| BLOOD BANK REAGENTS | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | | | | | | | X | |
| OTHER | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | | | | | | | X | |