

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

1. REGISTRATION NUMBER
FEI: 3004509482
CFN:
2. U.S. LICENSE NUMBER
244

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



FOR FDA USE ONLY

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 (g) of the Act (Title 21, United States Code 331(f) and (g)) 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: Dallas
VALIDATED BY FDA: 04-DEC-2015
PRINTED BY FDA: 22-DEC-2015

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)

Central Texas Regional Blood and Tissue Center
2132 North Mays
Suite 900
Round Rock, TX 78664

4.1 PHONE 512-206-1266

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.)

Round Rock Community Blood Center
Round Rock Donor Center

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

Central Texas Regional Blood and Tissue Center
ATTN: Wendy R. Bailey, QA Compliance Manager
4300 North Lamar Boulevard
Austin, TX 78756

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:

Wendy R. Bailey 12-28-15

8.1 TYPED NAME Wendy R. Bailey, QA Compliance Manager

8.2 E-MAIL ADDRESS wbailey@ctcms.com

8.3 PHONE 512-206-1134

8.4 DATE

9. TYPE OF OWNERSHIP

- SINGLE PROPRIETORSHIP
- PARTNERSHIP
- CORPORATION profit non-profit
- COOPERATIVE ASSOCIATION
- FEDERAL (non-military)
- U.S. MILITARY
- STATE
- COUNTY/MUNICIPAL/HOSPITAL AUTHORITY
- OTHER (Specify):

10. TYPE ESTABLISHMENT (Check all boxes that describe routine or autologous operations.)

- COMMUNITY (NON-HOSPITAL) BLOOD BANK
- HOSPITAL BLOOD BANK
- PLASMAPHERESIS CENTER
- PRODUCT TESTING LABORATORY
- INDEPENDENT
- ASSOCIATED w/ COMMUNITY or HOSPITAL BLOOD BANK
- HOSPITAL TRANSFUSION SERVICE
- APPROVED FOR MEDICARE REIMBURSEMENT
- NOT APPROVED FOR MEDICARE REIMBURSEMENT
- COMPONENT PREPARATION FACILITY
- COLLECTION FACILITY
- DISTRIBUTION CENTER
- BROKER/WAREHOUSE
- OTHER (Specify):

244 U.S. LICENSE NUMBER OF PARENT FIRM

11. PRODUCTS

PRODUCT	ALLOGENIC	AUTOLOGOUS	DIRECTED	COLLECT (1)	MANUAL APHERESIS (2)	AUTOMATED APHERESIS (3)	PREPARE (4)	LEUKOCYTES REDUCED (5)	IRRADIATED (6)	DONOR TESTED (7)	TEST (8)	STORE and DISTRIBUTE to OTHERS (9)
WHOLE BLOOD	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>									
RED BLOOD CELLS (RBC)						<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>				
RBC FROZEN												
RBC DEGLYCEROLIZED												
RBC RELIUVENATED												
RBC RELIUVENATED FROZEN												
RBC RELIUVENATED DEGLYCEROLIZED												
CRYOPRECIPITATED AHF												
PLATELETS						<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>				
LEUKOCYTES/GRANULOCYTES												
PLASMA												
PLASMA CRYOPRECIPITATE REDUCED												
FRESH FROZEN PLASMA								<input checked="" type="checkbox"/>				
LIQUID PLASMA												
THERAPEUTIC EXCHANGE PLASMA												
SOURCE LEUKOCYTES												
SOURCE PLASMA												
RECOVERED PLASMA												
BLOOD PRODUCTS FOR DIAGNOSTIC USE												
BLOOD BANK REAGENTS												
OTHER												