

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

**1. REGISTRATION NUMBER**  
FEI: 2020808  
CFN: 2020808

**2. U.S. LICENSE NUMBER**

**3. REASON FOR SUBMISSION**  
 ANNUAL REGISTRATION  
 INITIAL REGISTRATION  
 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 333.3(a)).

DISTRICT OFFICE: Los Angeles  
VALIDATED BY FDA: 09-OCT-2017  
PRINTED BY FDA: 12-DEC-2017

**4. LEGAL NAME AND LOCATION** (Include legal name, number and street, city, state, country, and post office code)  
  
Scantibodies Laboratory  
9336 Abraham Way  
Santee, CA 92071-2861

**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  
 a.  INDEPENDENT  
 ASSOCIATED W/ COMMUNITY or HOSPITAL BLOOD BANK  
 b.  APPROVED FOR MEDICARE REIMBURSEMENT  
 NOT APPROVED FOR MEDICARE REIMBURSEMENT  
 COMPONENT PREPARATION FACILITY  
 COLLECTION FACILITY  
 DISTRIBUTION CENTER  
 BROKER/WAREHOUSE  
 OTHER (Specify) In-Vitro Diagnostics Manufacturer  
 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
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
ALLOGENEIC <input type="checkbox"/> AUTOLOGOUS <input type="checkbox"/> DIRECTED <input type="checkbox"/>								
WHOLE BLOOD								X
RED BLOOD CELLS (RBC)								X
RBC FROZEN								
RBC DEGLYCEROLIZED								
RBC REJUVENATED								
RBC REJUVENATED FROZEN								
RBC REJUVENATED DEGLYCEROLIZED								
CRYOPRECIPITATED AHF								
PLATELETS								
LEUKOCYTES/GRANULOCYTES								X
PLASMA								X
PLASMA CRYOPRECIPITATE REDUCED								X
FRESH FROZEN PLASMA								X
LIQUID PLASMA								X
THERAPEUTIC EXCHANGE PLASMA								X
SOURCE LEUKOCYTES								
SOURCE PLASMA								X
RECOVERED PLASMA								X
BLOOD PRODUCTS FOR DIAGNOSTIC USE								X
BLOOD BANK REAGENTS								X
OTHER								

**4.1 PHONE** 619-258-9300

**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)  
  
Scantibodies Laboratory Inc.  
ATTN: Julio C. Padilla Gil, QARA Manager  
9336 Abraham Way  
Santee, CA 92071-2861

**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**

**8.1 TYPED NAME** Julio C. Padilla Gil, QARA Manager  
**8.2 E-MAIL ADDRESS** julio.padilla@scantibodies.com  
**8.3 PHONE** 619-258-9300 **8.4 DATE**