CENTERS FOR MEDICARE & MEDICAID SERVICES

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF ACCREDITATION

LABORATORY NAME AND ADDRESS
UF HEALTH MEDICAL LAB - SHANDS HOSPITA
1600 SW ARCHER ROAD
GAINESVILLE, FL 32610

CLIA ID NUMBER
10D0665884

EFFECTIVE DATE
02/28/2017

LABORATORY DIRECTOR
KENNETH H RAND

EXPIRATION DATE
02/27/2019

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Karen W. Dyer, Acting Director
Division of Laboratory Services
Survey and Certification Group
Center for Clinical Standards and Quality

452 Certs2_013117

If you currently hold a Certificate of Compliance or Certificate of Accreditation, below is a list of the laboratory specialties/subspecialties you are certified to perform and their effective date:

LAB CERTIFICATION (CODE)	EFFECTIVE DATE
HISTOCOMPATIBILTY (010)	09/06/2006
BACTERIOLOGY (110)	11/02/1999
MYCOBACTERIOLOGY (115)	11/02/1999
MYCOLOGY (120)	11/02/1999
PARASITOLOGY (130)	11/02/1999
VIROLOGY (140)	11/02/1999
SYPHILIS SEROLOGY (210)	11/02/1999
GENERAL IMMUNOLOGY (220)	09/06/2006
ROUTINE CHEMISTRY (310)	11/02/1999
URINALYSIS (320)	11/02/1999
ENDOCRINOLOGY (330)	12/20/2001
TOXICOLOGY (340)	11/02/1999
HEMATOLOGY (400)	11/02/1999

LAB CERTIFICATION (CODE)	EFFECTIVE DATE
ABO & RH GROUP (510)	11/02/1999
ANTIBODY TRANSFUSION (520)	11/02/1999
ANTIBODY NON-TRANSFUSION (530)	11/02/1999
ANTIBODY IDENTIFICATION (540)	11/02/1999
COMPATIBILITY TESTING (550)	11/02/1999
HISTOPATHOLOGY (610)	11/02/1999
CYTOLOGY (630)	11/02/1999

FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.GOV/CLIA
OR CONTACT YOUR LOCAL STATE AGENCY. PLEASE SEE THE REVERSE FOR
YOUR STATE AGENCY'S ADDRESS AND PHONE NUMBER.
PLEASE CONTACT YOUR STATE AGENCY FOR ANY CHANGES TO YOUR CURRENT CERTIFICATE.

View current license information at: Floridahealthfinder.gov

LICENSE #: 800000315
CERTIFICATE #: 102533

State of Florida

AGENCY FOR HEALTH CARE ADMINISTRATION
DIVISION OF HEALTH QUALITY ASSURANCE

CLINICAL LABORATORY

Licensed

This is to confirm that SHANDS TEACHING HOSPITAL AND CLINICS INC has complied with Chapter 483, Part I, Florida Statutes, and with Chapter 59A-7, Florida Administrative Code, and is authorized to operate the following laboratory in the specialties or subspecialties of:

ABO Rh, Ab Det(Trans), Antibody Detection (Nontransfusion), Antibody Identification, Bacteriology, Chemistry, Compatibility Testing, Cytology, Endocrinology, General Immunology, Hematology, Histopathology, Mycobacteriology, Mycology, Parasitology, Routine Chemistry, Syphilis Sero, Toxicology, Urinalysis, Virology

UF HEALTH MEDICAL LAB - SHANDS HOSPITAL
1600 S W Archer Road
Gainesville, FL 32610

EFFECTIVE DATE: 02/01/2016

EXPIRATION DATE: 01/31/2018

Molly McKinstry

Deputy Secretary, Division of Health Quality Assurance

COLLEGE of AMERICAN PATHOLOGISTS

CAP ACCREDITED
COLLEGE of AMERICAN PATHOLOGISTS

The College of American Pathologists
certifies that the laboratory named below

UF Health Shands Hospital
UF Health Medical Labs-Shands Hospital
Gainesville, Florida
Kenneth H. Rand, MD

CAP Number: 1482301
AU-ID: 1180674
CLIA Number: 10D0665884

has met all applicable standards for accreditation and is hereby accredited by the College of American Pathologists' Laboratory Accreditation Program. Reinspection should occur prior to December 8, 2017 to maintain accreditation.

Accreditation does not automatically survive a change in director, ownership, or location and assumes that all interim requirements are met.

Chair, Commission on Laboratory Accreditation

President, College of American Pathologists

AABB Accreditation

Shands Hospital at the University of Florida

having been assessed by AABB, has been found to meet the requirements of applicable Standards of this organization and therefore is granted this

CERTIFICATE OF ACCREDITATION

for the following activities:

Transfusion Activities

In Witness whereof the undersigned, being duly authorized, have caused this Certificate to be issued and the AABB Corporate Seal to be affixed.

Effective Dates

January 01, 2016 - December 31, 2017

ADVANCING TRANSFUSION AND CELLULAR THERAPIES WORLDWIDE • AABB Est. 1947

President, AABB

Chair, Accreditation Program Committee

FORM APPROVED: OMB No. 0910-0052. Expiration Date: May 31, 2018. See instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING

1. REGISTRATION NUMBER
FEI: 1073823
CFN: 1073823

2. U.S. LICENSE NUMBER

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

FOR FDA USE ONLY 1

DISTRICT OFFICE: Florida
VALIDATED BY FDA: 21-NOV-2015
PRINTED BY FDA: 10-DEC-2015

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)).

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)

UFHEALTH-Shands Medical Laboratories Blood Bank
P. O. Box 100344
Room G 110 - Shands Cancer Hospital
Blood Bank Dept.
Gainesville, FL 32601

4.1 PHONE 352-733-0900

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)

UFHEALTH-Shands Medical Laboratories Blood Bank
ATTN: Peter Pelletier
P.O. Box 100344
UF Health-Shands Cancer Hospital
Room G 110 - Blood Bank Dept.
Gainesville, FL 32601

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 Peter Pelletier
8.2 E-MAIL ADDRESS pelletierp@ufl.edu
8.3 PHONE 352-733-0900 8.4 DATE

9. TYPE OF OWNERSHIP
.1 [ ] SINGLE PROPRIETORSHIP
.2 [ ] PARTNERSHIP
.3 [x] CORPORATION profit___ non-profit[x]
.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 [x] 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
U.S. LICENSE NUMBER OF PARENT FIRM
.9 [ ] BROKER/WAREHOUSE
.10 [ ] OTHER (Specify) : _____

11. PRODUCTS
[ ] ALLOGENEIC [ ] 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	1						X		X	
RED BLOOD CELLS (RBC)	2						X		X	
RBC FROZEN	3									
RBC DEGLYCEROLIZED	4						X		X	
RBC REJUVENATED	5						X		X	
RBC REJUVENATED FROZEN	6									
RBC REJUVENATED DEGLYCEROLIZED	7						X		X	
CRYOPRECIPITATED AHF	8								X	
PLATELETS	9						X		X	
LEUKOCYTES/GRANULOCYTES	10						X		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									
SOURCE PLASMA	17									
RECOVERED PLASMA	18									X
BLOOD PRODUCTS FOR DIAGNOSTIC USE	19									
BLOOD BANK REAGENTS	20									
OTHER	21									