

**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
02/28/2019

LABORATORY DIRECTOR
KENNETH H RAND

EXPIRATION DATE
02/27/2021

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.



Karen W. Dyer

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

452 certs2_012919

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:

<u>LAB CERTIFICATION (CODE)</u>	<u>EFFECTIVE DATE</u>	<u>LAB CERTIFICATION (CODE)</u>	<u>EFFECTIVE DATE</u>
HISTOCOMPATIBILITY (010)	09/06/2006	ABO & RH GROUP (510)	11/02/1999
BACTERIOLOGY (110)	11/02/1999	ANTIBODY TRANSFUSION (520)	11/02/1999
MYCOBACTERIOLOGY (115)	11/02/1999	ANTIBODY NON-TRANSFUSION (530)	11/02/1999
MYCOLOGY (120)	11/02/1999	ANTIBODY IDENTIFICATION (540)	11/02/1999
PARASITOLOGY (130)	11/02/1999	COMPATIBILITY TESTING (550)	11/02/1999
VIROLOGY (140)	11/02/1999	HISTOPATHOLOGY (610)	11/02/1999
SYPHILIS SEROLOGY (210)	11/02/1999	CYTOLOGY (630)	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		

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.



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 November 18, 2021 to maintain accreditation.

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

Chair, Accreditation Committee

President, College of American Pathologists

aa BB 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

October 01, 2018 - September 30, 2020



MaryBeth Bassett

President, AABB

Danell J. Truitt MD

Chair, Accreditation Program Committee



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Blood Establishment Registration - Report

Submitted To FDA
Confirmation Number: 56158

Submitted by: Michael Passwater on 11/22/2019

This report has been submitted to the FDA. Report is now in view only mode.

To make changes to this registration, wait until we have accepted this report, then select this establishment and submit a new report with the new changes.

LEGAL NAME AND LOCATION

Central File Number (CFN): 1073823

FDA Establishment Identifier (FEI): 1073823

Applicant License Number:

Parent License Number:

Establishment DUNS: 039183736

Current Status: Active Annual

Applicant Name:

Legal Name: UF Health Shands Medical Laboratories Blood Bank

Address: P. O. Box 100344

Room G110 - Shands Cancer Hospital

Blood Bank Dept.

City: Gainesville

State: Florida

Zip: 32601

Country: United States

Phone: 352-733-0900

District Office: Florida

MAILING ADDRESS OF REPORTING OFFICIAL

Organization: UF Health Shands Medical Laboratories Blood Bank

Reporting Official Name: J. Peter Pelletier

Address: P.O. Box 100344

UF Health Shands Cancer Hospital

Room G110 - Blood Bank Dept.

City: Gainesville

State: Florida

Zip: 32601

Country: United States

Phone: 352-733-0900

Foreign Phone:

Email: pelletierp@ufl.edu

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING FOR MANUFACTURERS OF BLOOD PRODUCTS AND LICENSED DEVICES	FEI: 1073823 DUNS: 039183736 U.S. License Number:	REASON FOR SUBMISSION Annual Registration	DISTRICT OFFICE: Florida VALIDATED BY FDA: 01/01/2019
LEGAL NAME AND LOCATION: UF Health Shands Medical Laboratories Blood Bank P. O. Box 100344 Room G110 - Shands Cancer Hospital Blood Bank Dept. Gainesville, FL 32601 USA 352-733-0900	REPORTING OFFICIAL: J. Peter Pelletier UF Health Shands Medical Laboratories Blood Bank P.O. Box 100344 UF Health Shands Cancer Hospital Room G110 - Blood Bank Dept. Gainesville, FL 32601 USA 352-733-0900 pelletierp@ufl.edu	U.S. AGENT:	
OTHER NAMES USED IN THIS LOCATION:	TYPE OF OWNERSHIP: CORPORATION DONOR/RECIPIENT RELATIONSHIP:	ESTABLISHMENT TYPE: HOSPITAL BLOOD BANK	

PRODUCT	COLLECT	MANUAL APHERESIS	AUTOMATED APHERESIS	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR RETESTED	TEST	STORE AND DISTRIBUTE TO OTHERS	BACTERIAL TESTING	PATHOGEN REDUCED	POOLED
WHOLE BLOOD						X		X				
RED BLOOD CELLS (RBC)						X		X				
RBC DEGLYCEROLIZED						X		X				
RBC WASHED						X						
RBC REJUVENATED						X		X				
RBC REJUVENATED DEGLYCEROLIZED						X		X				
CRYOPRECIPITATED AHF								X				
PLATELETS						X		X				
PLATELETS PAS (PLATELETS ADDITIVE SOLUTION)						X		X				
PLATELETS EXTENDED DATING						X		X				

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING FOR MANUFACTURERS OF BLOOD PRODUCTS AND LICENSED DEVICES	FEI: 1073823 DUNS: 039183736 U.S. License Number:	REASON FOR SUBMISSION Annual Registration	DISTRICT OFFICE: Florida VALIDATED BY FDA: 01/01/2019
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PLATELETS WASHED						X		X				
GRANULOCYTES						X		X				
PLASMA								X				
FRESH FROZEN PLASMA								X				
PLASMA CRYOPRECIPITATED REDUCED								X				
LIQUID PLASMA								X				
RECOVERED PLASMA									X			

***** End Of Report *****