DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

Form Approved
OMB No. 0938-0581

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) APPLICATION FOR CERTIFICATION

I. GENERAL INFORMATION

☐ Initial Application ☒ Survey
☐ Change in Certificate Type
☐ Closure/Other Changes (Specify) _____
Effective Date _____

CLIA IDENTIFICATION NUMBER
17D2056639
(If an initial application leave blank, a number will be

FACILITY NAME
SOUTH WIND WOMEN'S CENTER

FEDERAL TAX IDENTIFICATION NUMBER
(b) (4)

EMAIL ADDRESS
admin@southwindwomenscenter.org

TELEPHONE NO. (Include area code)
(316) 425-3215

FAX NO. (Include area
(316) 425-3451

FACILITY ADDRESS - Physical Location of Laboratory (Building, Floor, Suite if applicable.) Fee Coupon/Certificate will be mailed to this Address unless mailing or corporate

MAILING/BILLING ADDRESS (If different from facility address) send Fee Coupon or certificate

NUMBER, STREET (No P.O. Boxes)
5107 EAST KELLOGG DRIVE

NUMBER, STREET

CITY	STATE	ZIP CODE
WICHITA	KS	67218

CITY	STATE	ZIP CODE

SEND CERTIFICATE TO THIS ADDRESS
Physical ☐
Mailing ☐
Corporate ☐

SEND FEE COUPON TO THIS ADDRESS
Physical ☐
Mailing ☐
Corporate ☐

CORPORATE ADDRESS (if different from facility) send Fee Coupon or certificate
NUMBER, STREET

CITY	STATE	ZIP CODE

NAME OF DIRECTOR (Last, First, Middle Initial)
PAGE DO, LESLIE, F

CREDENTIALS
DIRECTOR

FOR OFFICE USE ONLY
Date Received 04/01/2013

II. TYPE OF CERTIFICATE REQUESTED ((Check only one) Please refer to the accompanying instructions for inspection and certificate testing requirements)

☐ Certificate of Waiver (Complete Sections I - VI and IX - X)
☐ Certificate for Provider Performed Microscopy Procedures (PPM) (Complete Sections I - X)
☒ Certificate of Compliance (Complete Sections I - X)
☐ Certificate of Accreditation (Complete Sections I - X) and indicate which of the following organization(s) your laboratory is accredited by for CLIA purposes, or for which you have applied for accreditation for CLIA purposes .

☐ The Joint Commission ☐ AOA ☐ AABB ☐ A2LA
☐ CAP ☐ COLA ☐ ASHI

If you are applying for a Certificate of Accreditation, you must provide evidence of accreditation for your laboratory by an approved accreditation organization as listed above for CLIA purposes or evidence of application for such accreditation within 11 months after receipt of your Certificate of Registration.

NOTE: Laboratory directors performing non-waived testing (including PPM) must meet specific education, training and experience under subpart M of the CLIA regulations. Proof of these qualifications for the laboratory director must be submitted with this application.

III. TYPE OF LABORATORY (Check the one most descriptive of facility type)

- [ ] 01 Ambulance
- [X] 02 Ambulatory Surgery Center
- [ ] 03 Ancillary Testing Site in Health Care Facility
- [ ] 04 Assisted Living Facility
- [ ] 05 Blood Bank
- [ ] 06 Community Clinic
- [ ] 07 Comp. Outpatient Rehab Facility
- [ ] 08 End Stage Renal Disease Dialysis Facility
- [ ] 09 Federally Qualified Health Center
- [ ] 10 Health Fair
- [ ] 11 Health Main. Organization
- [ ] 12 Home Health Agency
- [ ] 13 Hospice
- [ ] 14 Hospital
- [ ] 15 Independent
- [ ] 16 Industrial
- [ ] 17 Insurance
- [ ] 18 Intermediate Care Facilities for Individuals with Intellectual Disabilities
- [ ] 19 Mobile Laboratory
- [ ] 20 Pharmacy
- [ ] 21 Physician Office
- [X] 22 Practitioner Other (Specify) HEALTH CLINIC
- [ ] 23 Prison
- [ ] 24 Public Health Laboratories
- [ ] 25 Rural Health Clinic
- [ ] 26 School/Student Health Service
- [ ] 27 Skilled Nursing Facility/ Nursing Facility
- [ ] 28 Tissue Bank/Repositories
- [ ] 29 Other (Specify) _____

Is this a shared [ ] Yes [ ] No

IV. HOURS OF LABORATORY TESTING (List times during which laboratory testing is performed in HH:MM format) If testing 24/7 [ ]

	SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
FROM	:	08:00	08:00	08:00	08:00	08:00	:
TO	:	05:00	05:00	05:00	05:00	05:00	:

(For multiple sites, attach the additional information using the same format.)

V. MULTIPLE SITES (must meet one of the regulatory exceptions to apply for this provision in 1-

Are you applying for a single site CLIA certificate to cover multiple testing locations?

[X] No. If no, go to section VI [ ] Yes. If yes, complete remainder of this section

Indicate which of the following regulatory exceptions applies to your facility's operation.

1. Is this a laboratory that is not at a fixed location, that is, a laboratory that moves from testing site to testing site, such as mobile unit providing laboratory testing, health screening fairs, or other temporary testing locations, and may be covered under the certificate of the designated primary site or home

[ ] Yes [X] No

If yes and a mobile unit is providing the laboratory testing, record the vehicle identification number(s) (VINs) and attach to the application.

2. Is this a not-for-profit or Federal, State or local government laboratory engaged in limited (not more than a combination of 15 moderate complexity or

[ ] Yes [X] No

If yes, provide the number of sites under the _____ and list name, address and test performed for each site below.

3. Is this a hospital with several laboratories located at contiguous buildings on the same campus within the same physical location or street address and under common direction that is filing for a single certificate for these locations?

[ ] Yes [X] No

If yes, provide the number of sites under this _____ and list name or department, location within hospital and specialty/subspecialty areas performed at each site below.

If additional space is needed, check [ ] and attach the additional information using the same format.

NAME AND ADDRESS / LOCATION		TESTS PERFORMED / SPECIALTY / SUBSPECIALTY
NAME OF LABORATORY OR HOSPITAL DEPARTMENT		
ADDRESS/LOCATION (Number, Street, Location if Applicable)		
CITY, STATE, ZIP CODE	TELEPHONE NO.(Include area code)	

In the next three sections, indicate testing performed and annual test volume.

VI. WAIVED TESTING

Identify the waived testing (to be) performed. Be as specific as possible. This includes each analyte test system or device used in the laboratory.

e.g. (Rapid Strep, Acme Home Glucose Meter)

Indicate the **ESTIMATED TOTAL ANNUAL TEST** volume for all waived tests performed _____

☐ Check if no waived tests are performed

VII. PPM TESTING

Identify the PPM testing (to be) performed. Be as specific as possible.

e.g. (Potassium Hydroxide (KOH) Preps, Urine Sediment Examinations)

Indicate the **ESTIMATED TOTAL ANNUAL TEST** volume for all PPM tests performed _____

For laboratories applying for certificate of compliance or certificate of accreditation, also include PPM test volume in the specialty/subspecialty category and the "total estimated annual test volume" in section VIII.

☐ Check if no PPM tests are performed

If additional space is needed, check here ☐ and attach additional information using the same format.

VIII. NON-WAIVED TESTING *(Including PPM testing if applying for a Certificate of Compliance or Accreditation)*

If you perform testing other than or in addition to waived tests, complete the information below. If applying for one certificate for multiple sites, the total volume should include testing for ALL sites.

Place a check (✓) in the box preceding each specialty/subspecialty in which the laboratory performs testing. Enter the estimated annual test volume for each specialty. Do not include testing not subject to CLIA, waived tests, or tests run for quality control, calculations, quality assurance or proficiency testing when calculating test volume. (For additional guidance on counting test volume, see the instructions included with the application package.)

If applying for a Certificate of Accreditation, indicate the name of the Accreditation Organization beside the applicable specialty/subspecialty for which you are accredited for CLIA compliance. (The Joint Commission, AOA, AABB, CAP, COLA or ASHI)

SPECIALTY / SUBSPECIALTY	ACCREDITING ORGANIZATION	ANNUAL TEST VOLUME	SPECIALTY / SUBSPECIALTY	ACCREDITING ORGANIZATION	ANNUAL TEST VOLUME
HISTOCOMPATIBILITY 010			**HEMATOLOGY 400**		
☐ Transplant			☐ Hematology		
☐ Nontransplant			**IMMUNOHEMATOLOGY**		1812
MICROBIOLOGY			☑ ABO Group & Rh Group 510		
☐ Bacteriology 110			☐ Antibody Detection (transfusion) 520		
☐ Mycobacteriology 115			☐ Antibody Detection (nontransfusion) 530		
☐ Mycology 120			☐ Antibody Identification 540		
☐ Parasitology 130			☐ Compatibility Testing 550		
☐ Virology 140			**PATHOLOGY**		
DIAGNOSTIC IMMUNOLOGY			☐ Histopathology 610		
☐ Syphilis Serology 210			☐ Oral Pathology 620		
☐ General Immunology 220			☐ Cytology 630		
CHEMISTRY			**RADIOBIOASSAY 800**		
☐ Routine 310			☐ Radiobioassay		
☐ Urinalysis 320			**CLINICAL CYTOGENETICS 900**		
☐ Endocrinology 330			☐ Clinical Cytogenetics		
☐ Toxicology 340			**TOTAL ESTIMATED ANNUAL TEST VOLUME:**		1,812

IX. TYPE OF CONTROL (Check the one most descriptive of ownership type)

VOLUNTARY NONPROFIT	FOR PROFIT	GOVERNMENT
☐ 01 Religious Affiliation	☐ 04 Proprietary	☐ 05 City
☒ 02 Private Nonprofit		☐ 06 County
☐ 03 Other		☐ 07 State
_____ (Specify)		☐ 08 Federal
		☐ 09 Other
		_____ (Specify)

X. DIRECTOR AFFILIATION WITH OTHER LABORATORIES

If the director of this laboratory serves as director for additional laboratories that are separately certified, please complete the following:

CLIA NUMBER	NAME OF LABORATORY

ATTENTION: READ THE FOLLOWING CAREFULLY BEFORE SIGNING APPLICATION

Any person who intentionally violates any requirement of section 353 of the Public Health Service Act as amended or any regulation promulgated thereunder shall be imprisoned for not more than 1 year or fined under title 18, United States Code or both, except that if the conviction is for a second or subsequent violation of such a requirement such person shall be imprisoned for not more than 3 years or fined in accordance with title 18, United States Code or both.

Consent: The applicant hereby agrees that such laboratory identified herein will be operated in accordance with applicable standards found necessary by the Secretary of Health and Human Services to carry out the purposes of section 353 of the Public Health Service Act as amended. The applicant further agrees to permit the Secretary, or any Federal officer or employee duly designated by the Secretary, to inspect the laboratory and its operations and its pertinent records at any reasonable time and to furnish any requested information or materials necessary to determine the laboratory's eligibility or continued eligibility for its certificate or continued compliance with CLIA requirements.

SIGNATURE OF OWNER/DIRECTOR OF LABORATORY (Sign in ink)	Date
	06/16/16

NOTE: Completed 116 applications must be sent to your local State Agency.
SEE ATTACHED LIST OF STATE AGENCY CONTACT INFORMATION.

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0581. The time required to complete this information collection is estimated to average 30 minutes to 2 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection.If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, Attn: PRA Reports Clearance Officer, 7500 Security