CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) APPLICATION FOR CERTIFICATION

ALL APPLICABLE SECTIONS OF THIS FORM MUST BE COMPLETED.

I. GENERAL INFORMATION

☐ Initial Application Anticipated Start Date _____
☐ Survey
☐ Change in Certificate Type
☒ Other Changes (Specify) New Director
Effective Date _____

CLIA IDENTIFICATION NUMBER
17 D 2056639
(If an initial application leave blank, a number will be assigned)

FACILITY NAME
SOUTH WIND WOMENS CENTER (DBA TRUST WOMEN)

FEDERAL TAX IDENTIFICATION NUMBER
(b)(4)

EMAIL ADDRESS abrink@itrustwomen.org
☐ RECEIVE FUTURE NOTIFICATIONS VIA EMAIL

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

FAX NO. *(Include area code)*
(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 address is specified*

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

CITY	STATE	ZIP CODE
WICHITA	KS	67218

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

NUMBER, STREET

CITY	STATE	ZIP CODE

SEND FEE COUPON TO THIS ADDRESS
PICK ONE:
☒ Physical
☐ Mailing
☐ Corporate

SEND CERTIFICATE TO THIS ADDRESS
PICK ONE:
☒ 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)*
BOURNE, CHRISTINA M.

Laboratory Director's Phone Number
(316) 260-6934

CREDENTIALS
M.D.

FOR OFFICE USE ONLY
Date Received 11/18/21

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)*

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.

☐ Certificate for Provider Performed Microscopy Procedures (PPM) *(Complete Sections I-VII and IX-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 ☐ AAHHS/HFAP ☐ 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.

PRA Disclosure Statement

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. Expiration Date: 03/31/2024. The time required to complete this information collection is estimated to average one hour 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 comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850. *****CMS Disclaimer*****Please do not send applications, claims, payments, medical records or any documents containing sensitive information to the PRA Reports Clearance Office. Please note that any correspondence not pertaining to the information collection burden approved under the associated OMB control number listed on this form will not be reviewed, forwarded, or retained. If you have questions or concerns regarding where to submit your documents, please contact LabExcellence@cms.hhs.gov.

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

- ☐ 01 Ambulance
- ☒ 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
- ☐ 22 Practitioner Other *(Specify)* _____
- ☐ 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)* _____

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

	SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
FROM:	00:00	08:00	08:00	08:00	08:00	08:00	00:00
TO:	00:00	17:00	17:00	17:00	17:00	17:00	00:00

(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 1-3 below)*

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

☐ 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 base, using its address?

   ☐ Yes ☒ 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 waived tests per certificate) public health testing and filing for a single certificate for multiple sites?

   ☒ Yes ☐ No

   If yes, provide the number of sites under the certificate 2 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 ☒ No

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

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

NAME AND ADDRESS/LOCATION		TESTS PERFORMED/SPECIALTY/SUBSPECIALTY
NAME OF LABORATORY OR HOSPITAL DEPARTMENT SOUTH WIND WOMENS CENTER (DBA TRUST WOMEN)		D(RHO)
ADDRESS/LOCATION *(Number, Street, Location if applicable)* 1240 SW 44th STREET		
CITY, STATE, ZIP CODE OKLAHOMA CITY, OK 73109	TELEPHONE NO. *(Include area code)* (405) 429-7940	
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 estimated annual test volume.

VI. WAIVED TESTING *If only applying for a Certificate of Waiver, complete this section and skip sections VII (PPM Testing) and VIII (Non-Waived Testing).*

Identify the waived testing (to be) performed by completing the table below. Include each analyte, test system, or device used in the laboratory.

ANALYTE / TEST	TEST NAME	MANUFACTURER
~~Example: Streptococcus group A~~	~~Ace Rapid Strep Test~~	~~Acme Corporation~~
HEMOGLOBIN	Hemopoint	Stanbio Laboratory
Urine pregnancy Test	OneStep +	Henry Schein

Indicate the **ESTIMATED TOTAL ANNUAL TEST** volume for all waived tests performed 4230

☐ Check if no waived tests are performed

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

VII. PPM TESTING *If only applying for a Certificate for PPM, complete this section and skip section VIII (Non-Waived Testing).*

Listed below are the **only** PPM tests that can be performed by a facility having a Certificate for PPM. Mark the checkbox by each PPM procedure(s) to be performed.

☒ Direct wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements
☒ Potassium hydroxide (KOH) preparations
☐ Pinworm examinations
☐ Fern tests
☐ Post-coital direct, qualitative examinations of vaginal or cervical mucous
☐ Urine sediment examinations
☐ Nasal smears for granulocytes
☐ Fecal leukocyte examinations
☐ Qualitative semen analysis (limited to the presence or absence of sperm and detection of motility)

Indicate the **ESTIMATED TOTAL ANNUAL TEST** volume for all PPM tests performed 100

If also performing waived complexity tests, complete Section VI. 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 Certificate of Accreditation) Complete this section only if you are applying for a Certificate of Compliance or a Certificate of Accreditation.*

Identify the non-waived testing (to be) performed by completing the table below. Be as specific as possible. This includes each analyte test system or device used in the laboratory. Use (M) for moderate complexity and (H) for high complexity.

ANALYTE / TEST	TEST NAME	MANUFACTURER	M or H
~~Example: Potassium~~	~~Quick Potassium Test~~	~~Acme Lab Corporation~~	~~M~~
D(RHO)	ELDON CARDS FOR RH TESTIN(	ELDON CARDS	M

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

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.

If additional space is needed, check here and attach additional information using the same format." Include text box similar to Section VII.

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, AAHHS/HFAP, AABB, A2LA ,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**		1800
MICROBIOLOGY		100	☑ 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:**		1900

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 Nonprofit		☐ 07 State
_____ (Specify)		☐ 08 Federal
		☐ 09 Other Government
		_____ (If 09 is selected, please specify the country or the province.)

Does this facility have partial or full ownership by a foreign entity or foreign government?

☐ Yes ☒ No

If Yes, what is the country of origin for the foreign entity? _____

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.

PRINT NAME OF DIRECTOR OF LABORATORY

BOURNE, CHRISTINA MARIE

PRINT NAME OF OWNER OF LABORATORY

SIGNATURE OF OWNER/DIRECTOR OF LABORATORY *(SIGN IN INK OR USE A SECURE ELECTRONIC SIGNATURE)* DATE 11/9/21

NOTE: Completed 116 applications must be sent to your local State Agency. Do not send any payment with your completed 116 application.

STATE AGENCY CONTACT INFORMATION CAN BE FOUND AT:
https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf

Certificate

this certificate has been awarded to:

Christina Bourne

for completion of the 20 CME credit program:

Laboratory Director CME Course Program

10/17/2021
Completed

COLA Resources, Inc
Leading Excellence in Laboratory Medicine

Kansas State Board of Healing Arts
800 SW Jackson, Lower Level, Suite A
Topeka, Kansas 66612
785-296-7413

This is your wallet card which indicates that you are authorized to practice in the State of Kansas. Please sign the wallet card prior to using. Keep your card in a safe place to prevent loss or theft. You may also access a current copy of your wallet card in the Online Portal.

CHRISTINA MARIE BOURNE
5107 E KELLOGG DR
WICHITA KS 67218

Kansas State Board of Healing Arts

This is to certify that the individual named below is authorized to practice as indicated.

CHRISTINA MARIE BOURNE

Profession:	Medical Doctor (MD)		
License #:	04-42524	Status:	Active
Date Last Renewed:	05/20/2021	Expiration:	07/31/2022
Orig License Date:	08/26/2019	Date This Status:	08/26/2019
CE Due:	06/30/2020		

Signature of Practitioner

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
		☐ 08 Federal
		☐ 09 Other
(Specify)		(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

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) APPLICATION FOR CERTIFICATION

I. GENERAL INFORMATION

☐ Initial Application ☒ Survey
☐ Change in Certificate Type
☐ Other Changes (Specify) _____

Effective Date 9/9/2020

CLIA IDENTIFICATION NUMBER
17 D 2056639
(If an initial application leave blank, a number will be assigned)

FACILITY NAME South Wind Women's Center			FEDERAL TAX IDENTIFICATION NUMBER (b)(4)		
EMAIL ADDRESS wichita@itrustwomen.org			TELEPHONE NO. *(Include area code)* 316.260.6934	FAX NO. *(Include area code)* 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 address is specified* NUMBER, STREET *(No P.O. Boxes)* 5107 E Kellogg Drive			MAILING/BILLING ADDRESS *(If different from facility address) send Fee Coupon or certificate* NUMBER, STREET		
CITY Wichita	STATE Kansas	ZIP CODE 67218	CITY	STATE	ZIP CODE
SEND FEE COUPON TO THIS ADDRESS ☒ Physical ☐ Mailing ☐ Corporate	SEND CERTIFICATE TO THIS ADDRESS ☒ Physical ☐ Mailing ☐ Corporate		CORPORATE ADDRESS *(If different from facility) send Fee Coupon or certificate* NUMBER, STREET		
NAME OF DIRECTOR *(Last, First, Middle Initial)* Marsh, Juliet			CITY	STATE	ZIP CODE
CREDENTIALS MD			**FOR OFFICE USE ONLY** Date Received		

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-VII and IX-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.

PRA Disclosure Statement

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. Expiration Date: 3/31/2021. The time required to complete this information collection is estimated to average one hour 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 comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850. *****CMS Disclaimer*****Please do not send applications, claims, payments, medical records or any documents containing sensitive information to the PRA Reports Clearance Office. Please note that any correspondence not pertaining to the information collection burden approved under the associated OMB control number listed on this form will not be reviewed, forwarded, or retained. If you have questions or concerns regarding where to submit your documents, please contact LabExcellence@cms.hhs.gov.

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

- ☐ 01 Ambulance
- ☒ 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
- ☐ 22 Practitioner Other *(Specify)* _____
- ☐ 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)* _____

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

	SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
FROM:	N/A	08:00	08:00	08:00	08:00	08:00	N/A
TO:	N/A	17:00	17:00	17:00	17:00	17:00	N/A

(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 1-3 below)*

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

☐ 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 base, using its address?

   ☐ Yes ☒ 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 waived tests per certificate) public health testing and filing for a single certificate for multiple sites?

   ☐ Yes ☒ No

   If yes, provide the number of sites under the certificate _____ 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 ☒ No

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

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

NAME AND ADDRESS/LOCATION		TESTS PERFORMED/SPECIALTY/SUBSPECIALTY
NAME OF LABORATORY OR HOSPITAL DEPARTMENT South Wind Women's Center Oklahoma City		Rh testing
ADDRESS/LOCATION *(Number, Street, Location if applicable)* 1240 SW 44th Street		Hgb testing
CITY, STATE, ZIP CODE Oklahoma City, OK 73109	TELEPHONE NO. *(Include area code)* 405.429.7940	Pregnancy testing--urine
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 *If only applying for a Certificate of Waiver, complete this section and skip sections VII (PPM Testing) and VIII (Non-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)

Hgb testing--testing personnel use the Hemocue with microcuvettes as per manufacturer's instructions. All results are recorded in the Lab/Rh log and in the patient's chart in EMR.

Pregnancy testing--testing personnel use the pregnancy test kit as per manufacturer's instructions. All results are recorded in the patient's chart in the EMR.

Indicate the **ESTIMATED TOTAL ANNUAL TEST** volume for all waived tests performed 4091

☐ Check if no waived tests are performed

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

VII. PPM TESTING *If only applying for a Certificate for PPM, complete this section and skip section VIII (Non-Waived Testing).*

Identify the PPM testing (to be) performed. Be as specific as possible.
e.g. (Potassium Hydroxide (KOH) Preps, Urine Sediment Examinations)

Not applicable at this time.

Wet preps

Indicate the **ESTIMATED TOTAL ANNUAL TEST** volume for all PPM tests performed 0 20

If also performing waived complexity tests, complete Section VI. 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) Complete this section only if you are applying for a Certificate of Compliance or a Certificate of Accreditation.*

Identify the non-waived testing (to be) performed. Be as specific as possible. This includes each analyte test system or device used in the laboratory e.g. (Potassium, Acme Chemistry Analyzer).

Rh testing--testing personnel complete Rh testing using the Eldon Card Kit as per manufacturer's instructions. All results are recorded in the Lab/Rh log and the patient's chart in EMR.

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

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, A2LA ,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**		1587
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:**		1587

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 Nonprofit		☐ 07 State
_____ (Specify)		☐ 08 Federal
		☐ 09 Other Government
		_____ (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
MTSC.FS6100 3627	All Women's Health Tacoma, Washington

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.

PRINT NAME OF OWNER/DIRECTOR OF LABORATORY

Juliet Marsh, MD. Laboratory Director

SIGNATURE OF OWNER/DIRECTOR OF LABORATORY *(Sign in ink)*

X [signature]

DATE 9/13/2020

NOTE: Completed 116 applications must be sent to your local State Agency. Do not send any payment with your completed 116 application.

STATE AGENCY CONTACT INFORMATION CAN BE FOUND AT:
http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	17D2056639	A. BUILDING _____ B. WING _____	06/16/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
SOUTH WIND WOMENS CENTER	5107 EAST KELLOGG DRIVE WICHITA, KS 67218

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5411 510M	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under §493.1253. This STANDARD is not met as evidenced by: Review of manufacturer's product instructions and observation of reagents reveals that the laboratory fails to follow manufacturer's instructions for test system operation. The findings: On June 16, 2016 at 4:00 pm, patient testing for the day was finished and the surveyor observed the following: a) A package of Eldon Cards in a drawer in the work area. a) The package was open and contained 28 individual cards for performing Rh typing. b) The "Date of First Opening" was not recorded. The Eldon Card Manufacturer's instructions specify the following storage and handling criteria: a) "Keep bag closed at all times. Do not remove desiccant sachet." b) Record "date of first opening" in box provided on bag. c) "Expires 6 months after first opening and not later than: ....."	D5411		
D6070	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1) Each individual performing moderate complexity	D6070		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE 06/29/2016

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	17D2056639	A. BUILDING _____ B. WING _____	06/16/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
SOUTH WIND WOMENS CENTER	5107 EAST KELLOGG DRIVE WICHITA, KS 67218

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D6070	Continued From page 1 testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Review of laboratory procedures and observation of laboratory reagents reveals that testing personnel fail to adhere to the requirements for test system operation. The Rh typing reagents are not being handled and stored as specified in the laboratory procedure. (See D 5411)	D6070		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	17D2056639	A. BUILDING _____ B. WING _____	09/09/2020

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
SOUTH WIND WOMENS CENTER	5107 EAST KELLOGG DRIVE WICHITA, KS 67218

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D 000	INITIAL COMMENTS South Wind Women's Center's laboratory was found to be in substantial compliance with 42 CFR Part 493, Requirements for Laboratories as a result of an onsite survey on 9 September 2020.	D 000		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients . (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	17D2056639	A. BUILDING _____ B. WING _____	11/09/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
SOUTH WIND WOMENS CENTER	5107 EAST KELLOGG DRIVE WICHITA, KS 67218

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of personnel documentation and interview with the technical consultant, the laboratory failed to perform and document a competency for the technical consultant for moderate complexity testing. Findings: 1. Review of 2017, 2018 competency documentation showed the laboratory failed to perform a competency on the technical consultant for moderate complexity immunohematology testing. 2. Interview with the technical consultant on November 9, 2018 at 10:00 AM confirmed the laboratory failed to perform a competency for the technical consultant for 2017, 2018.	D5209		
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under §493.1253. This STANDARD is not met as evidenced by: Based on review of Eldoncard RhD	D5411		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	17D2056639	A. BUILDING _____ B. WING _____	11/09/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
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D5411	Continued From page 1 manufacturer's insert, review of the patient log and interview with testing personnel #1, the laboratory failed to follow the manufacturer's requirements for storage and stability. Findings: 1. Review of the Eldoncard manufacturer's insert revealed "An EldonBag can be opened for removal of cards at least 50 times during the six months period." 2. Review of the patient log showed the laboratory opened the bag more than 50 times since September 20, 2018. 3. Interview with testing personnel #1 on November 9, 2018 at 10:00 AM confirmed the laboratory failed to follow the manufacturer's guidelines for storage and stability of Eldoncards for Rh testing.	D5411		