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.

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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		

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	17D2056639	A. BUILDING _____ B. WING _____	09/09/2020

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
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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

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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 (b) (6), (b) (7)(C) t 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		

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D5411	Continued From page 1 manufacturer's insert, review of the patient log and interview with (b) (6), (b) (7)(C) 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 (b) (6), (b) (7)(C) 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		