

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D2056639	(X3) Date Survey Completed 11/09/2018
Name of Provider or Supplier South Wind Womens Center	Street Address, City, State 5107 East Kellogg Drive, Wichita, KS	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>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.</p>
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of Eldoncard RhD 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</p>

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.