

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0652191	(X3) Date Survey Completed 07/10/2018
Name of Provider or Supplier Southeast Health Center Of Ripley County	Street Address, City, State 109 Plum Street, Doniphan, MO	
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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on review of the manufacturer's inserts and interview with technical supervisor, the laboratory failed to monitor and document the humidity of the laboratory for proper operation of the Sysmex KX 21N. 1. Review of the manufacturer's product insert for performance specifications revealed to operate the analyzer in relative humidity of 30-85 percent. 2. Review of the room temperature documentation logs showed the laboratory failed to document humidity. 3. Interview with the technical supervisor on July 10, 2018 at 12:00 PM confirmed the laboratory failed to document the room humidity in the laboratory where the Sysmex KX 21N hematology analyzer was in operation.</p>