

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0453069	(X3) Date Survey Completed 02/21/2019
Name of Provider or Supplier Decatur Health System Inc	Street Address, City, State 810 W Columbia St, Oberlin, 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
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 package insert instructions and interview with the General Supervisor #1 the laboratory failed to store quality control (QC) reagents under conditions consistent with the manufacturer's instructions. Findings include: 1. Review of the Bio-Rad Liquichek Immunoassay Plus Control package insert indicated that the storage temperature range was -20 degrees Centigrade to -70 degrees Centigrade. 2. Review of the freezer temperature logs revealed 2 occurrences in February 2019 in which the temperature did not meet the manufacturer's storage range. On February 3, 2019 and Feb 21, 2019 the temperature of freezer was documented as -19 degrees Centigrade. 3. Interview with the General Supervisor #1 confirmed that the laboratory failed to follow manufacturer instructions for storing Bio-Rad Liquichek Immunoassay Plus Control on February 21, 2019 @ 1135 AM.</p>