

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0663012	(X3) Date Survey Completed 11/12/2021
Name of Provider or Supplier Mowery Clinic Llc	Street Address, City, State 737 E Crawford St, Salina, 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, freezer temperature logs for the time period of 7/1/2021 - 11/11/2021, and interview with the Technical Consultant #1 (TC#1) and General Supervisor #1 (GS#1) on 11/12/2021 at 0840, the laboratory failed to store quality control (QC) materials under conditions consistent with the manufacturer's instructions on two of two freezers for 202 days out of 240 days. The laboratory failed to document corrective actions on temperatures out of the control's required range on two of two freezers for 199 days of 202 days. Findings: 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 Freezer temperature log for "Freezer Back Kenmore" from 7/1/2021 to 11/11/2021 revealed: a. Temperatures were out of the control's required range (> -20 degrees Centigrade) for 104 days out of 120 days reviewed. b. No documentation of corrective actions on temperatures out of control's required range for 104 days out 104 days reviewed were made available at the time of survey.. 3. Review of Freezer temperature log for "Freezer Front Sanyo" from 7/1/2021 to 11/11/2021 revealed: a. Temperature was out of the control's required range (> -20 degrees Centigrade) for 98 days out of 120 days reviewed. b. No documentation of corrective actions on temperatures out of control's required range for 95 days out 98 days</p>

reviewed were made available at the time of survey. 4. Interview with the TC#1 and GS#1 on 11/12/2021 at 0840 confirmed that the laboratory failed to follow manufacturer instructions for storing Bio-Rad Liquichek Immunoassay Plus Controls for 202 days of 240 days and failed to document corrective actions for 199 days of 202 days on two of two freezers for the time period of 7/1/2021 - 11/11/2021.