Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0452333	08/27/2018
Name of Provider or Supplier	**Street Address, City, State**	
Mowery Clinic, Llc	655 South Santa Fe, 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	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. This STANDARD is not met as evidenced by: Based on review of the manufacturer's package insert instructions and interview with the Laboratory Director (LD), the laboratory failed to define criteria for storage conditions that were essential for the proper storage of quality control (QC) reagents that were consistent with the manufacturer's instructions. Findings Include: 1. Review of the manufacturer's package insert instructions for the hCG serum QC material found the following directions: KIT STORAGE AND STABILITY Do Not Freeze. 2. The LD stated that hCG serum QC material was shipped frozen from a sister laboratory for use in this laboratory. The interview occurred 08/27/2018 at 11:08 AM.