Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D2068667	09/13/2021
Name of Provider or Supplier	**Street Address, City, State**	
Labette Health Frozen Lab	1902 S Hwy 59, Parsons, 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 a review of the manufacturer's operation manual, a lack of documentaion for the room temperature and humidity, and interview with the operations manager, the laboratory failed to monitor and document the humidity and room temperature for the cryostat in histopathology testing. Findings: 1. Review of the maufacturer's manual for the Tissue-Tek Cryo3 cryostat showed to operate in a temperature range of 15 degrees Celsius to 28 degrees Celsius with the humidity range 30% to 85%. 2. Request of the room temperature and humidity documentation for the cryostat was not available at the time of the survey. 3. Interview with operations manager and testing personnel #2 on 9/13/2021 at 12:00 p.m. confirmed the laboratory failed to monitor and document the humidity and room temperature for the cryostat in histopathology testing.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a

	function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on an absence of thermometer function check records or certificates of accuracy, protocols for the cyrostat thermometer and interview, the laboratory failed to define and perform a function check protocol for 1 of 1 cryostat thermometer. Findings: 1. No documentation was available for function checks on 1 of 1 cryostat thermometer at the time of survey. 2. No documentation was available for the certification of accuracy (NIST traceble) on the 1 of 1 cryostat thermometer at the time of survey. 3. Proctocols for the function check of the thermometer was not made available at the time of survey. 4. Interview with the operations manager and testing personnel #2 on 9/13/2021 at 12:00 p.m. confirmed, the laboratory failed to define and perform a function check protocol for 1 of 1 cryostat thermometer.