

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0453223	(X3) Date Survey Completed 12/03/2020
Name of Provider or Supplier Stanton County Clinic	Street Address, City, State 101 East Greenwood Avenue, Johnson, 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
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on an absence of thermometer function check protocols, records or certificates of accuracy, microscope service records and interview, the laboratory failed to define and perform a function check protocol for the thermometers and microscope. Findings: 1. No documentation of a function check protocol for the thermometers and microscope was available at the time of survey. 2. No documentation was available for performance of function checks on 2 of 2 thermometers for a 2 year period. 3. No documentation was available for the certification of accuracy (NIST traceable) on 2 of 2 thermometers for a 2 year period. 4. No documentation of microscope service records was available for 1 of 1 microscopes for a 2 year period. 5. Interview with the Laboratory Director on 12/3/2020 at 3:05 p.m. confirmed, the laboratory failed to define and perform a function check protocol for the thermometers and microscope.</p>