

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0452770	(X3) Date Survey Completed 09/16/2020
Name of Provider or Supplier Edwards County Medical Center	Street Address, City, State 620 West 8th Street, Kinsley, 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
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records from American Proficiency Institute (API) and staff interview, the laboratory failed to evaluate its proficiency testing results. Findings: 2019 Hematology/Coagulation - 1st Event PT. 1. Four analyte/method scores of Unacceptable, 2. Eight analyte/method scores of Not Graded 3. No evidence of evaluation was available at the time of survey. 2019 Microbiology 3rd Event PT. 1. All results scored acceptable. 2. No evidence of evaluation was available at the time of survey. Interview with General Supervisor (GS) on September 16, 2020 at 12:30 p.m. confirmed, the laboratory failed to evaluate its proficiency testing results.</p>
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>

This STANDARD is not met as evidenced by:

Based on an absence of thermometer function check records or certificates of accuracy and interview, the laboratory failed to define a function check protocol for the thermometers. Findings include: 1. No documentation was available for function checks on 4 of 4 thermometers for a 2 year period. 2. No documentation was available for the certification of accuracy (NIST traceable) on 4 of 4 thermometers for a 2 year period. 2. Interview with GS on 9/16/2020 at 3:10 p.m. confirmed, the laboratory failed to define a function check protocol for the thermometers.