

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0450663	(X3) Date Survey Completed 11/14/2019
Name of Provider or Supplier Yates Center Medical Clinic	Street Address, City, State 1004 E Madison, Yates Center, 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 records and interview with TP #1, the laboratory failed to define a function check protocol for the thermometers. Findings include: 1. No documentation was available for function checks of thermometers for a 14 month period from Aug 2018 to Nov 2019. No documentation was available for the certification of accuracy (NIST traceable) for thermometers. 2. Interview with TP#1 on 11/14/2019 @11:10 am confirmed the laboratory had no records of function checks for the thermometers used in the laboratory during the period of Aug 2018 to Nov 2019.</p>
D5801	<p>TEST REPORT CFR(s): 493.1291(a)</p> <p>The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to</p>

network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's records and electronic final test reports, the laboratory failed to have an adequate data entry system(s) review in place that ensured test results were accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to the electronic medical record (EMR). Findings Include: 1. Review of records from Aug 2018 and Nov 2019, the laboratory failed to perform a system check to ensure test results and other patient specific data are accurately and reliably sent from point of data entry to final destination. 2. During interview on 11/14/2019 @ 1120 , the TP#1 confirmed that no system check verifying accurate result transmission had been performed during the period of Aug 2018 to Nov 2019.