

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0450734	(X3) Date Survey Completed 12/30/2020
Name of Provider or Supplier Coffey County Hospital Laboratory	Street Address, City, State 801 N 4th Street, Burlington, 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
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of performance verification documentation for the Siemens Dimension EXL analyzer, non-waived test list and interview, the laboratory failed to verify that the reference intervals (normal values) for 45 of 45 analytes were appropriate for the laboratory's patient population. This is a repeat deficiency from a survey conducted 1/11/2019. See D5421.</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of performance verification documentation for the Siemens Dimension EXL analyzer, non-waived test list, and interview, the laboratory failed to verify that the reference intervals (normal values) for 45 of 45 analytes were appropriate for the laboratory's patient population. Findings: 1. Review of the KS-CLIA-PS01, Laboratory Test List and Annual Volumes dated 12/21/2020 lists 45 analytes are performed on the Siemens Dimension EXL. 1. Review of Siemens Dimension EXL analyzer, S/N DR251762 verification documentation dated 10/5/2020 revealed that reference intervals (normal values) verification studies were not performed for 45 of 45 analytes. 2. Interview with the General Supervisor (GS) on 12/30/2020 at 2:30 p.m. confirmed, the laboratory failed to verify that the reference intervals (normal values) for 45 of 45 analytes were appropriate for the laboratory's patient population.

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 pipette and thermometer function check protocols, records or certificates of accuracy and interview, the laboratory failed to define and perform a function check protocol for the pipettes and thermometers. Findings: 1. No documentation of a function check protocol for the pipettes and thermometers was available at the time of survey. 1. No documentation was available for performance of function checks on 2 of 2 pipettes and 9 of 9 thermometers for a 2 year period. 2. No documentation was available for the certification of accuracy on 2 of 2 pipettes and 9 of 9 thermometers for a 2 year period. 2. Interview with the GS on 12/30/2020 at 11:30 a.m. confirmed, the laboratory failed to define and perform a function check protocol for the pipettes and thermometers.