

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0450734	(X3) Date Survey Completed 01/11/2019
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
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: Based on review of performance verification procedures for the Biofire microbiology analyzer and interview with the general supervisor, the laboratory failed to verify reference intervals (normal values). Findings: 1. Review of the verification procedures for the Biofire analyzer for respiratory and gastrointestinal panels showed no verification of normal values. 2. Interview with the general supervisor on January 11, 2019 at 11:30 AM confirmed the laboratory failed to ensure the verification procedures for normal values for the Biofire analyzer were appropriate for the laboratory's patient population.</p>