

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0665215	(X3) Date Survey Completed 03/05/2019
Name of Provider or Supplier Lucas County Health Center	Street Address, City, State 1200 North Seventh Street, Chariton, IA	
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 Sysmex XN-550 performance specification records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 2:15 pm on 03/05/2019, the laboratory failed to perform the performance specification of accuracy for one out of one new test system (Sysmex XN-550) implemented in 2017. The findings include: 1. The laboratory began performing patient testing on the Sysmex XN-550 in November 2017. 2. The laboratory performed and documented the performance specifications of precision, reportable range, and verification of reference intervals for the Sysmex XN-550. 3. At the time of the survey, personnel identifier #2 confirmed that the laboratory did not perform and document the performance specification of reportable range for the Sysmex XN-550 hematology instrument.</p>