

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0452836	(X3) Date Survey Completed 09/14/2020
Name of Provider or Supplier Stafford County Hospital	Street Address, City, State 502 S Buckeye, Stafford, 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 documentation for the Sysmex XN-550 hematology analyzer and interview, the laboratory failed to verify the reference intervals (normal values) were appropriate for the laboratory's patient population. Findings: 1. Review of the verification documentation of the Sysmex XN-550 hematology analyzer, S/N 16079, for the analytes: White Bloodcell Differential, Red Bloodcell Count, Hemoglobin, Hematocrit, White Bloodcell Count, and Platelet testing showed no verification of normal values. Document listed patient testing began January 1, 2019, 2. Interview with general supervisor #1 on September 14, 2020 at 2: 15 p.m. confirmed, the laboratory failed to verify the reference intervals (normal values) were appropriate for the laboratory's patient population.</p>