

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 28D2150840	(X3) Date Survey Completed 11/28/2018
Name of Provider or Supplier Northpointe Family Medicine	Street Address, City, State 5901 N 27th Street, Lincoln, NE	
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 the demonstration of performance specifications and an interview with the technical consultant at 2:45 PM on 11/28/2018, the laboratory failed to demonstrate the accuracy for 3 new instruments used for hematology, routine chemistry and special chemistry/endocrinology. Findings are: 1. Review of the validation of performance specifications for the 3 new instruments, a hematology instrument, a chemistry instrument and a special chemistry instrument (all 3 put in use in late September 2018), revealed a failure to check for accuracy. 2. Interview with the technical consultant confirmed a test comparison with another laboratory or instrument had not been performed prior to patient testing on any of these instruments.</p>