

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D1066515	(X3) Date Survey Completed 08/30/2018
Name of Provider or Supplier Novant Health Lakeside Family	Street Address, City, State 269 Gillman Road, Suite 100, Denver, NC	
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 laboratory records and technical consultant (TC) interview 8/30/18, the laboratory failed to perform and verify the accuracy and precision performance standards of microalbumin and creatinine prior to resuming patient testing after relocation of laboratory in September of 2017. The laboratory performs urine microalbumin and creatinine testing on the Alere Afinion AS-100 chemistry analyzer. The laboratory relocated in September of 2017. Review of laboratory records failed to reveal documentation the laboratory performed accuracy and precision performance standards for microalbumin and creatinine testing after relocation of laboratory and prior to beginning patient testing on the Alere Afinion AS-100 chemistry analyzer in September of 2017. Interview with TC at approximately 11:30 a.m. confirmed the laboratory had not performed accuracy and precision studies for microalbumin and creatinine testing as required after relocation of laboratory and prior to resuming patient testing in September of 2017.</p>