

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0696591	(X3) Date Survey Completed 03/01/2021
Name of Provider or Supplier Piedmont Endocrinology, Pa	Street Address, City, State 311 9th Avenue Drive Ne, Hickory, 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 2019 and 2020 laboratory records 2/25/21 and interview with TP (testing personnel) 3/1/21, the laboratory failed to demonstrate that they could obtain performance specifications comparable to those established by the manufacturer prior to reporting patient albumin and creatinine test results on 3 of 4 replacement Afinion 2 ACR(albumin/creatinine ratio) analyzers. Review of 2019 and 2020 laboratory records on 2/25/21 revealed the laboratory installed new replacement Afinion 2 ACR analyzers on the following dates: a. 1/10/19(analyzer #4- serial # AF20006032); b. 5/1/19(analyzer #3- serial# AF20006422); b. 11/13/19(analyzer #3-serial# AF20015543); c. 7/9/20(analyzer #4- serial# AF20019586). Review of records revealed the laboratory performed patient correlation studies to verify accuracy for 3 of the 4 replacement analyzers that were approved by the laboratory director on 1/16/19 (Serial# AF20006032), 11/13/19(Serial# AF20015543), and 7/15/20(Serial# AF20019586). There was no documentation to indicate the laboratory verified the precision or reportable range for the 3 Afinion 2 ACR analyzers(serial #AF20006032, #AF2001543, #AF20019586) prior to reporting patient test results. Review of additional records submitted on 3/1/21 and 3/2/21 revealed the laboratory verified accuracy, precision, and the reportable range for only 1 of the 4 analyzers (serial#AF20006422). During interview at approximately 10:15am. 3/1/21, TP#1</p>

confirmed that the laboratory did not verify the precision and reportable range for the replacement Afinion 2 ACR analyzers(serial #AF20006032, #AF2001543, #AF20019586) prior to reporting patient test results. She stated they were told it was not required by the representative who installed the analyzers.