

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0911305	(X3) Date Survey Completed 06/28/2024
Name of Provider or Supplier Novant Health Walkertown Family Medicine	Street Address, City, State 2800 Darrow Road, Walkertown, 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
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's IQCP (Individualized Quality Control Plan) and review of 2022, 2023 and 2024 ACR (Albumin Creatinine Ratio) quality control and patient records 6/28/24, the laboratory failed to perform quality control testing as required before reporting patient test results. 11 patients were tested from 6/13/24 to 6/19/24 when quality control material was not tested as specified in the laboratory's IQCP. Findings: Review of the laboratory's IQCP for the Afinion Urine Albumin /Creatinine Ratio revealed "... External controls will be tested with each new lot number or shipment of test materials, when training new employees, anytime an unexpected result is obtained, and once weekly, on the first day of patient testing. ..." Review of 2022, 2023, and 2024 ACR quality control records revealed the laboratory tested Level I and Level II controls on 6/6/24, but the controls were not tested again until 6/20/24, a period of approximately two weeks. Review of patient records revealed 11 patients were tested from 6/13/24 to 6/19/24 during the week when controls were not tested.</p>