Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0237367	(X3) Date Survey Completed 08/27/2019
Name of Provider or Supplier Novant Health Forsyth Endocrine Consultants	**Street Address, City, State** 755 Highland Oaks Drive, Suite 201, Winston Salem, 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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of 2017, 2018, and 2019 ACR (microalbumin/creatinine) quality control logs, and interview with TP (testing personnel) 8/27/19, the laboratory failed to discard control material that exceeded its expiration date. The Abbott Afinion ACR Control product insert states "... Opened control vials Opened control vials are stable for 8 weeks when stored refrigerated at 2-8 degrees C (36-46 degrees F). ..." Review of 2017, 2018, and 2019 ACR quality control logs revealed the following statement: "Controls are good for 8 weeks once opened." The logs also included a section for documenting the date quality control material was opened, and a section for documenting the open expiration date. Review of 2017, 2018, and 2019 ACR quality control logs revealed lot number 10198798 CI (low control) and lot number 10198799 CII (high control) were opened 3/4/19. The open expiration date for both controls was listed as 5/30/19, approximately 13 weeks after the open date. The controls were tested by the laboratory after the open expiration date on 5/6/19, 5/13/19, 5/20/19, and 5/28/19, and patient testing continued during this time. During interview at approximately 10:40 a.m., TP #1 stated that she also documents the open date and the open expiration date on the end of the ACR Control box, but she had discarded the box end for lot numbers 10198798 and 10198799.