

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0689588	(X3) Date Survey Completed 03/26/2019
Name of Provider or Supplier Fairview Specialists - Urology - Fairview Park Dr	Street Address, City, State 200 Fairview Park Drive, Dublin, GA	
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
D0000	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on March 26, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiency was cited:
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Environmental Log, consisting of the Refrigerator and Room Temperatures, and Room Relative Humidity, and staff interview the laboratory failed to show corrective action for Refrigerator Temperatures that fell outside the posted temperature range. Findings: 1. Based on the review of the Environmental Log, the Refrigerator Temperature was below the posted acceptable temperature range, 72 times out of a 14 month period, consisting of January 2018 to February 2019. There was no documentation of corrective action and followup temperature checks. 2. Staff interview with the office coordinator, and staff # 1 (CMS form 209), on March 26, 2019 at approximately 11:45am in the front office, confirmed that the laboratory was not documenting corrective action for refrigerator temperatures that fell below the acceptable temperature range that was posted.</p>