

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0692294	(X3) Date Survey Completed 07/08/2019
Name of Provider or Supplier Atrium Health Navicent Urology Baldwin	Street Address, City, State 1217 N Columbia Drive, Milledgeville, 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 June 8, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5479	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Qualigen FastPack iP analyzer (Qualigen) Quality Control (QC), and the Qualigen Operators Manual, the laboratory failed to perform QC as recommended by the manufacturer for Prostate Specific Antigen (PSA). Findings: 1. Review of the Qualigen QC for the analyte PSA, the Laboratory was performing QC once per week, and or after calibration. 2. Review of the Qualigen Operators Manual, the manufacturer states that: When control testing is performed, two control levels must be used. Qualigen recommends that users run controls whenever: Patient testing is performed.* A calibration is performed. Repair maintenance is performed. Improper storage or handling of FastPacks is suspected. Questionable patient results are obtained. Users should follow proper state and federal quality control guidelines. * Review the Individualized Quality Control Plan (IQCP) Guidelines implemented by CMS. These guidelines are based on individual risk factors involved in the performance of each test run in your laboratory. IQCP is voluntary and provides laboratories with flexibility in customizing QC policies and procedures based on the unique aspects and test systems found in your laboratory and may allow for the reduction in the frequency of control testing required. 3. Interview with staff # 2</p>

(CMS 209 form), on July 8, 2019 at approximately 3 pm, in the breakroom, confirmed that at the time of the survey there was not a copy of an Individual Quality Control Plan available.