

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D0301189	<b>(X3) Date Survey Completed</b>  04/25/2024
<b>Name of Provider or Supplier</b>  Urology Centers Of Alabama, Pc	<b>Street Address, City, State</b>  3485 Independence Drive, Birmingham, AL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5445</b>	<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 a review of Policies and Procedures, a review of BioRad CFX96 Quality Control (QC) records, and an interview with the General Supervisor, the laboratory failed to perform Quality Control each day of patient testing or follow an approved Individual Quality Control Plan (IQCP). This was noted for three out of three months reviewed in 2023. The findings include: 1. A review of Policies and Procedures revealed the following under "Quality Control of RT-PCR Molecular Testing Reagents": "...The above controls are performed on any new lots prior to use for any clinical specimens, and on a weekly basis thereafter...". There was no evidence of an implemented IQCP 2. A review of QC records for the BioRad CFX96 revealed controls were run weekly, not daily prior to patient testing, for Urinary Tract Infection (UTI) Panels in March 2023, June 2023, and September 2023. 3. During an interview on 4/25/2024 at 11:54 AM, the General Supervisor confirmed no IQCP was in place for UTI Panels run on the BioRad CFX96 at the time of survey.</p>