

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D2283013	(X3) Date Survey Completed 06/04/2025
Name of Provider or Supplier Urology Associates Of Charleston, Llc	Street Address, City, State 1122 Chuck Dawley Blvd, Suite 200, Mount Pleasant, SC	
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	An announced initial CLIA survey was conducted on June 4, 2025, at the laboratory of Urology Associates of Charleston, LLC in Mt. Pleasant by the South Carolina Department of Public Health (SC DPH) Bureau of Nursing Homes and Medical Services. The laboratory was found to be out of compliance with Medicare condition 42 CFR Part 493, CLIQ Requirements for Laboratories. The following is a list of deficiencies cited as a result of the initial CLIA survey on June 4, 2025.
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on records review and staff interview, the laboratory failed to document the twice annual Quality Assurance for accuracy of test results. Findings included: 1. Review of the laboratory policy and procedure manual reveals a written Quality Assurance Plan. 2. Review of the Quality Assurance Plan reveals 7 indicators for monitoring and evaluating quality processes in the laboratory. 3. Review of Quality Assurance documentation reveals a lack of twice annual verification of accuracy of test results. 4. In an interview with the office manager on June 4, 2025, at 1:20pm, the findings were confirmed.</p>
D6020	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;</p>

This STANDARD is not met as evidenced by:

Based records review, and staff interview, the laboratory director failed to ensure quality assessment programs were established and maintained to assure the quality of laboratory services provided. Findings included: 1. Review of records reveals a lack twice annual quality assessments for test result accuracy. 2. Review of Quality Assessment records reveals a lack of documentation for the laboratory director's review and approval. 3. In an interview with the office manager on June 4, 2025, at 1: 20 pm, the findings were confirmed.