Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D0250964	05/20/2026
Name of Provider or Supplier	**Street Address, City, State**	
Palmetto Adult And Children's Urology, Pa	2890 Tricom Street, North Charleston, 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 onsite announced recertification survey was conducted at Palmetto Adult and Children's Urology May 20, 2026, by the South Carolina Department of Public Health (SC DPH), Bureau of Nursing Homes and Medical Services. The facility was found to be out of compliance with the Medicare Conditions 42 CFR Part 493. CLIA laboratory requirements. The following STANDARD LEVEL DEFICINCIES were found to be out of compliance as a result of the recertification survey on May 20, 2026:
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on record review, lack of documentation and staff interview, the laboratory failed to verify the accuracy of the tests twice annually as required for high complexity not enrolled for proficiency testing (PT) 493.1236 for 3 out of 3 years reviewed (2023, 2024, and 2025). Findings included: 1. Review of CMS 116 application reveals specialty/subspecialty histopathology testing performed. 2. Review of "Peer to Peer Case Review" dated Jan-June 2024 reveals lack of documentation for accuracy verification. On the day of inspection, the document lacked the following information: a. Lack of reviewer's name b. Lack documentation of reviewer's signature c Lack date reviewed d. Lack identification of initials e. Lack the credentials of the reviewer's 3. The surveyor requested and the laboratory failed to provide verification of accuracy for histopathology slide reading and qualitative semen analysis for 3 out of 3 years on the day of inspection. 4. In an interview on May 20, 2026, at 2:27 pm in the breakroom with office manager the above findings were confirmed.

D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on record review, lack of documentation and staff interview, the laboratory director failed to provide overall guidance for the administrative operation of the laboratory for 1 out of 3 years reviewed (2023, 2024, and 2025). Findings included: 1. Review of the CMS 096D report reveals American Proficiency Institute (API) proficiency testing scores for the following analyte were as follows: a. 0005 Bacteriology, resulted in 0 score b. 0025 Mycology, resulted in 0 score c. 0045 Virology, resulted in 0 score 2. Review of API records reveal lack of documentation to notify CLIA and proficiency testing company of the change in testing status. 3. In an interview on May 20, 2026, at 2:27 pm in the breakroom with office manager the above findings were confirmed.