Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D0704883	06/24/2026
Name of Provider or Supplier	**Street Address, City, State**	
Lowcountry Urology Clinics Pa	1470 Tobias Gadson Blvd, 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 announced onsite CLIA recertification survey was conducted on June 24, 2026, at the laboratory of Lowcountry Urology Clinics at the Tobias Gadson location 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, CLIA requirements for laboratories. The following is a list of STANDARD LEVEL deficiencies cited as a result of the recertification survey on June 24, 2026:
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on records review, lack of documentation, and staff interview, the laboratory failed to document the review and evaluation of accuracy of testing and /or PT results for 3 out of 3 years reviewed (2024, 2025, 2026). Findings included: 1. Review of CMS 116 form reveals that the lab performed semen analysis. 2. Review of American Proficiency Institute testing records reveal the following results: a. 2024 Hematology /Coagulation- 3rd event result 100% (Lab Reported test problem) b. 2025 Hematology /Coagulation- 3rd event test results were not reeived by API. The laboratory lacks documentation of evaluation of profificency testing of 2024,2025, and 2026. 3. Laboratory provided the results and attestation form for American Proficiency Institute (API) 2026 1st event Hematology /Coagulation Post-Vasectomy Sperm Motility which lacked the signature and date reviewed by the LD. 4. In an interview with the practice manager on June 24, 2026, at 12:30pm in the laboratory office, the findings were confirmed.
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 records review, lack of documentation, and staff interview, the laboratory failed to have documentation of twice annual verification of qualitative semen analysis for 2 out of 2 years (2024, 2025). Findings included: 1. Review of American Proficiency Institute Andrology testing Scores reveal the laboratory for semen analysis as follows: a. 2024 Lacks PT results b. 2025 Lacks PT results 2. No other documentation was a vailable on the day of the survey to document twice annual verification of accuracy for qualitative semen analysis. 2. In an interview with the practice manager on June 24, 2026 at 12:30pm in the laboratory office, the findings were confirmed.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on records review, lack of documentation, and staff interview, the laboratory director (LD) failed to document the approval, signing, and dating of the laboratory's procedure manual for 2 out of 2 years reviewed (2024, 2025). Findings included: 1. A review of the procedure manual reveals on the day of survey the following procedures: a. Quality Assurance Plan b. Qualitative Semen Analysis Both lack laboratory director's signature of approval and date signed. 2. The laboratory was using the owner's manual for the Clarity Urinalysis device as a procedure manual. The manual lacked documentation of approval, signature, and date by the LD. 3. In an interview on June 24, 2026, at 12:30pm in the laboratory office with the practice manager, the findings were confirmed.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Based on records review, lack of documentation, and staff interview, the LD failed to document the evaluation of the laboratory's proficiency testing performance for 3 out of 3 years reviewed (2024,2025, and 2026) Findings included: 1. A review of API PT attestation statement from 2026 Hematology/ Coagulation 1st event reveals a lack of the signature and date of the LD. 2. The surveyor requested, but no other documentation of proficiency testing was available for review at the time of the survey. 3. In an interview with the practice manager on June 24, 2026, at 12:30pm in the laboratory office, the findings were confirmed.

D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on records review, lack of documentation, and staff interview, the technical consultant (TC) failed to ensure that testing personnel (TP)receive proper training for the type and complexity of the services offered to include evaluation of performance for individuals responsible for moderate complexity testing at least semiannually during the first year of empolyment in 2 out of 2 years reviewed (2024, 2025) Findings included: 1. Review of the CMS 209 presonnel report reveals 3 TP. 2. Review of the QA plan reveals annual competency assessment, but lacks a requirement for initial and 6 month competency assessments for new hires. 3. In an interview with the practice manger on June 24, 2026, at 12:30pm in the laboratory office, the findings were comfirmed.