

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D0969574	(X3) Date Survey Completed 06/09/2026
Name of Provider or Supplier Lowcountry Urology Clinics Pa	Street Address, City, State 641 St Andrews 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 onsite announced CLIA recertification survey was conducted at Lowcountry Urology Clinics PA on June 9, 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 Condition 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 June 9, 2026:
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on direct observation, lack of documentation, and staff interview, the laboratory failed to establish and/or follow written policies and procedures that ensure optimum integrity of a patient's specimen form the time of collection or receipt of the specimen through completion of testing and reporting of results. Findings included: 1. During a tour of the laboratory on June 9, 2026, at 3:36 pm the surveyor directly observed urines on the counter next to the Clarity urine analyzer. 2. Review of the urine labels reveals no time of collection was written on any of the urine containers. 3. In an interview on June 9, 2026, at 4 pm in the conference room with office manager and assistant office manager the above 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 record review, lack of documentation for urological sediments and semen analysis testing, and staff interview, the laboratory failed to document twice annually the accuracy of all testing personnel performing microscopic examination for moderately complex testing for 4 out of 4 testing personnel (Providers Performing microscopic examination). Findings included: 1. Review of American Proficiency Institute (API) records reveal the following: a. 2024 Hematology/Coagulation-3rd Event: Andrology Sperm (presence/absence) (PMO) score 100% Sperm Motility (pres/abs)(PMO) score 100% Microscopy Urine Sediment score 100% b. 2025 Hematology/Coagulation-2nd Event: Andrology Sperm (presence/absence) (PMO) No score documented Sperm Motility (pres/abs)(PMO) No score documented Microscopy Urine Sediment score 0% c. 2025 Hematology/Coagulation-3rd Event: Andrology Sperm (presence/absence) (PMO) score 50% Sperm Motility (pres/abs)(PMO) 100% Microscopy Urine Sediment score 100% d. 2026 Hematology/Coagulation-3rd Event: Andrology Sperm (presence/absence) (PMO) score 0% Sperm Motility (pres/abs) (PMO) score 0% Microscopy Urine Sediment score 0% The laboratory lacked twice annual verification of accuracy for 3 out of 3 years reviewed (2024, 2025, and 2026). 2. The surveyor requested and the laboratory failed to provide documentation of urine sedimentation and qualitative semen analysis accuracy verification on the day of inspection for the following testing personnel: a. TP1 b. TP2 c. TP3 d. TP4 3. In an interview on June 9, 2026, at 4 pm in the conference room with office manager and assistant office manager the above findings were confirmed.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observation, lack of documentation, and staff interviews, the laboratory failed to ensure thermometers (equipment) did not exceed their expiration date. Manufacturers require specific storage and operating temperatures to operate efficiently. Findings included: 1. During a tour on June 9, 2026, at 3:36 pm the surveyor directly observed thermometers used to record room and refrigerator temperatures. 2. The surveyor requested and the laboratory failed to provide the verification of thermometers calibrations and/or documentation of the calibration expiration date. a. ThermPro thermometer expired April 31, 2024 b. Refrigerator thermometer no calibration information available. 3. In an interview on June 9, 2026, at 4 pm in the conference room with office manager and assistant office manager the above findings were confirmed.
D5777	COMPARISON OF TEST RESULTS CFR(s): 493.1281(b)(c) (b) The laboratory must have a system to identify and assess patient test results that appear inconsistent with the following relevant criteria, when available: (b)(1) Patient age. (b)(2) Sex. (b)(3) Diagnosis or pertinent clinical data. (b)(4) Distribution of

	patient test results. (b)(5) Relationship with other test parameters. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and staff interview, the laboratory failed to document all test result comparison activities for 3 out of 3 years reviewed (2024, 2025, and 2026). Findings included: 1. Review of policy and procedure titled "Quality Assurance Plan", section D. Comparison of Test Results: Reference 493.1709, Method: States "In an office with more than 1 physician or physician extender, those personnel reading urine macroscopics, wet preps and KOH preps should, twice annually, read the same specimen in order to determine if the practitioners are reporting the results in the same manner. 2. The surveyor request and the laboratory failed to provide documentation of urine microscopy sediment comparison count between the following testing personnel: a. TP1 b. TP2 c. TP3 d. TP4 3. In an interview on June 9, 2026, at 4 pm in the conference room with office manager and assistant office manager the above findings were confirmed.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and staff interview, the laboratory failed to follow written policies and procedures for an ongoing assessment and or correct problems identified in the analytic systems for 3 out of 3 years reviewed (2024, 2025, and 2026). Findings included: 1. Review of CMS 116 application reveals moderately complex test qualitative semen analysis are performed by 4 out of 4 testing personnel: a. TP1 b. TP2 c. TP3 d. TP4 2. The surveyor requested and the laboratory failed to provide the established and /or communicated revised policies and procedures to prevent recurrence of the identified problem. The laboratory lacks documentation of the procedure used to prevent proficiency test failures. 3. In an interview on June 9, 2026, at 4 pm in the conference room with office manager and assistant office manager the above findings were confirmed.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on record review (American Proficiency Institute), lack of documentation, and staff interview, the laboratory failed to provide a quality assessment of the effectiveness of corrective actions taken to resolve problems and/or any revised

policies and procedures necessary to prevent recurrence of problems and/or discussion of analytic systems quality assessment reviews with appropriate staff for 3 out of 3 years reviewed (2024, 2025, and 2026). Finding included: 1. Review of American Proficiency Institute (API) records reveal the following: a. 2025 Hematology/Coagulation-2nd Event: Andrology Sperm (presence/absence) (PMO) No score documented Sperm Motility (pres/abs)(PMO) No score documented Microscopy Urine Sediment score 0% b. 2025 Hematology/Coagulation-3rd Event: Andrology Sperm (presence/absence) (PMO) score 50% Sperm Motility (pres/abs)(PMO) 100% Microscopy Urine Sediment score 100% c. 2026 Hematology/Coagulation-3rd Event: Andrology Sperm (presence/absence) (PMO) score 0% Sperm Motility (pres/abs) (PMO) score 0% Microscopy Urine Sediment score 0% 3. The surveyor requested and the laboratory failed to provide an assessment of the effectiveness of the corrective action (Corrective Action Checklist) and/or any policies and procedures that were put in place as of 2025 Hematology/Coagulation 2nd-Event. 4. In an interview on June 9, 2026, at 4 pm in the conference room with office manager and assistant office manager the above findings were confirmed.

D6003

LABORATORY DIRECTOR QUALIFICATIONS
CFR(s): 493.1405 AND 493.1406

The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have had laboratory training or experience consisting of: (b)(2)(ii)(A) At least one year directing or supervising non-waived laboratory testing; and (b)(2)(ii)(B) Have at least 20 CE credit hours in laboratory practice that cover the laboratory director responsibilities defined in 493.1407; or (b)(3)(i)(A) Hold an earned doctoral degree in a chemical, biological, clinical or medical laboratory science or medical technology from an accredited institution; or (b)(3)(i)(B) Hold an earned doctoral degree; and (b)(3)(i)(B)(1) Have at least 16 semester hours of doctoral level coursework in biology, chemistry, medical technology (MT), clinical laboratory science (CLS), or medical laboratory science (MLS); or (b)(3)(i)(B)(2) An approved thesis or research project in biology/chemistry/MT/CLS/MLS related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and (b)(3)(ii) Have at least 20 CE credit hours in laboratory practice that cover the laboratory director responsibilities defined in 493.1407; and (b)(3)(ii)(A) Be certified and continue to be certified by a board approved by HHS; and (b)(3)(ii)(B) Have had at least 1 year of experience directing or supervising nonwaived laboratory testing; or (b)(4)(i)(A) Have earned a master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B)(1) Meet bachelor's degree equivalency; and (b)(4)(i)(B)(2) Have at least 16 semester hours of additional graduate level coursework in biology, chemistry, medical technology, clinical or medical laboratory science; or (b)(4)(i)(C)(1) Meet bachelor's degree equivalency; and (b)(4)(i)(C)(2) Have at least 16 semester hours in a

combination of graduate level coursework in biology, chemistry, medical technology, clinical or medical laboratory science coursework and an approved thesis or research project related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and (b)(4)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing; and (b)(4)(iii) Have at least 1 year of supervisory laboratory experience in nonwaived testing; and (b)(4)(iv) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in 493.1407; or (b)(5)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(5)(i)(B) At least 120 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either- (b)(5)(i)(B)(1) 48 semester hours of medical laboratory science or medical laboratory technology courses; or (b)(5)(i)(B)(2) 48 semester hours of science courses that include- (b)(5)(i)(B)(2)(i) 12 semester hours of chemistry, which must include general chemistry and biochemistry or organic chemistry; and (b)(5)(i)(B)(2)(ii) 12 semester hours of biology, which must include general biology and molecular biology, cell biology or genetics; and (b)(5)(i)(B)(2)(iii) 24 semester hours of chemistry, biology, or medical laboratory science or medical laboratory technology in any combination; and (b)(5)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing; and (b)(5)(iii) Have at least 2 years of supervisory laboratory experience in nonwaived testing; and (b)(5)(iv) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in 493.1407. (b)(6) Notwithstanding any other provision of this section, an individual is considered qualified as a laboratory director of moderate complexity testing under this section if they were qualified and serving as a laboratory director of moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

This STANDARD is not met as evidenced by:

Based on record review, lack of documentation, and staff interviews, the laboratory director failed to operate the laboratory as required and was of such quality as to provide the physician with education equivalent to the experience described in 493.1405(b)(2)(ii)(A). And ensure the overall operation and administration of the laboratory, to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with applicable regulations for the 3 out of 3 years reviewed (2024, 2025, and 2026). Findings included: 1. Review of CMS 209 list one laboratory director and four testing personnel. 2. Review of policies and procedures, API PT results, and previous deficiency reports reveal the laboratory director lack the education and/or experience needed to meet the requirements as set by the Center of Medicare and Medicaid (CMS) 493.1405(b)(4)(iv) and defined in 493.1407. 3. In an interview on June 9, 2026, at 4 pm in the conference room with office manager and assistant office manager the above findings were confirmed.

D6007

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(1)

(e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:

Based on record review, the lack of documentation, and staff interview, the laboratory director failed to ensure that testing systems developed and used for each of the tests performed in the laboratory services for all aspects of test performance, which includes the preanalytical, analytical, and postanalytical phases of testing for 3 out of 3 years reviewed (2024, 2025, and 2026). Findings included: 1. Review of the following records for moderately complex testing a. Quality Assurance Plan b. Urine Sediment Examination c. Qualitative Semen Analysis Microscopic Examination revealed policies and procedures were established, however these policies and procedures were not followed by staff. 2. The surveyor requested but the laboratory lack sufficient documentation demonstrating quality laboratory services for all aspects of the test(s) performance as required 493.1232, 493.1252, 493.1281, and 493.1289 and to include preanalytic, analytic, and postanlytic phases of testing. 3. In an interview on June 9, 2026, at 4 pm in the conference room with office manager and assistant office manager the above findings were confirmed.