Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D0250876	(X3) Date Survey Completed 07/10/2024
Name of Provider or Supplier Lowcountry Urology Clinics Pa	**Street Address, City, State** 2687 Lake Park Drive, 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 CLIA recertification survey was conducted on July 10, 2024 at the clinical laboratory of Lowcountry Urology Clinics by the South Carolina Department of Public Health's Bureau of Healthcare Systems and Services. The laboratory was found to be out of compliance with 42 CFR Part 493, CLIA Requirements for Laboratories. The following is a description of the CONDITION and STARDARD level deficiencies:
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: D2000 Based on the lack of documentation and staff interview, the laboratory failed to enroll in a proficiency testing (PT) program approved by Health and Human Services (HHS). Findings included: 1. No documentation of PT enrollment was available at the time of survey. 2. In an interview on July 10, 2024, at 11:30am in the laboratory breakroom with the office manager (OM), the findings were confirmed.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a

	proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: D2016 Based on the lack of documentation and staff interview, the laboratory failed to successfully participate in a PT program approved by HHS. Findings included: 1. No documentation of successful participation in a PT program approved by HHS. 2. In an interview on July 10, 2024, at 11:30am in the laboratory breakroom with the OM, the findings were confirmed.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: D5209 Based on the lack of documentation and staff interview, the laboratory failed to establish and follow written policies and procedures to assess employee competency. Findings included: 1. No documentation of employee competencies was available for review at the time of the survey. 2. In an interview on July 10, 2024, at 11:30am in the laboratory breakroom with the OM, the findings were confirmed.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: D5291 Based on the lack of documentation and staff interview, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism of quality assessment. Findings included: 1. No documentation of quality assessments was available for review at the time of the survey. 2. No written quality assessment

	policy and procedure was available for review at the time of the survey. 3. In an interview on July 10, 2024, at 11:30am in the laboratory breakroom with the OM, the findings were confirmed
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: D5413 Based on direct observation, lack of documentation, and staff interview, the laboratory failed to monitor the temperature and humidity of the laboratory environment. Findings included: 1. During a tour of the laboratory on July 10, 2024, at 11:40am, the surveyor observed no device for monitoring room temperature and humidity was in use in the laboratory. 2. Document review revealed no records monitoring room temperature and humidity of the laboratory. 3. Document review reveals a policy "TEMPERATURE AND HUMIDITY CONTROL" indicating "The temperature and humidity of the laboratory and the temperatures of the refrigerator and freezer are recorded daily." 4. Tolerance limits for room temperature and humidity are listed as "15-30 degrees Celsius (C)" and "Humidity Tolerance Limits" are listed as "0-95%". 5. In a staff interview with the OM and TP1 on July 10, 2024, at 11:30am in the laboratory breakroom, the findings were confirmed.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: D5441 Based on direct observation, staff interview and document review, the laboratory failed to have control systems that monitor the accuracy and precision of the complete analytic process. Findings included: 1. During a tour of the laboratory on July 10, 2024, at 11:40am, the surveyor observed TP1 performing urine dipstick testing. 2. TP1 was asked how frequently quality control samples were performed. TP1 indicated no quality control samples were performed. 3. In an interview with the OM at 12:00pm on July 10, 2024 in the laboratory breakroom, the findings were

	confirmed. 4. Document review of the package insert for the Chemstrip 10 MD urine test strip indicates "Each laboratory should establish its own goals for adequate standards of performance. Commercially prepared control solutions should be used on a regular basis, as established by the institution's quality control protocols." 5. Document review reveals a lack of quality control protocol.
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: D6004 Based on record review and staff interview, the LD failed to ensure the competency of testing staff. Findings included: 1. No documentation of employee competencies was available for review at the time of the survey. 2. In an interview on July 10, 2024, at 11:30am in the laboratory breakroom with the OM, the findings were confirmed.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director (LD) failed to ensure the laboratory's enrollment in PT program approved by HHS. Findings included: 1. No documentation of PT enrollment was available at the time of survey. 2. In an interview on July 10, 2024, at 11:30am in the laboratory breakroom with the OM, the findings were confirmed.