Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D0704883	08/27/2024
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 CLIA Recertification survey was conducted on 8/27/2024. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
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 and interview with staff the laboratory failed to twice annually verify the accuracy of one of one moderately complex tests in 2022 and 2023. a. A review of the CMS-116 revealed the laboratory performed the following moderately complex testing: qualitative semen analysis. b. The laboratory was asked to provide documentation of verification of accuracy. No documentation was provided. c. An interview with the office manager on 8/27/2024 at 2:38 PM in their office confirmed these findings.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on record review, the laboratory's procedures, and interview with staff the

	laboratory failed to establish written policies and procedures for the performance of one of one moderately complex test. a. A review of the CMS-116 revealed the laboratory performed the following moderately complex testing: qualitative semen analysis. b. The laboratory was asked to provide written procedures for the performance of qualitative semen analysis. No documentation was provided. c. An interview with the office manager on 8/27/2024 at 2:15 PM in their office confirmed these findings.
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: Based on record review, direct observations, manufacturer's instructions, and interview with staff the laboratory failed to establish an acceptable room temperature and humidity since 1/1/2022 to 8/27/2024. a. A review of the Daily Temperature Log revealed "Room Temperature should be between 64.4 F and 77 F".(18 degrees to 25 degrees Celsius). The acceptable humidity range was not defined. b. An interview on 8/27/2024 at 1:15 PM in the laboratory the office manger stated the laboratory began monitoring room temperature in August 2024. c. On 8/27/2024 at 1:15 PM the surveyor observed 1 microscope AmScope identification number 2140948 in the laboratory. d. A review of Am Scope 330 Series User's Manual revealed on page 4, "Safety Precautions; 2 ...Keep it indoors in a dry and clean place ...and in maximum relative humidity of 85 [percent]." e. On 8/27/2024 at 1:20 PM the surveyor observed blood collection tubes in the draw station room (sampling): 1 pack of 50 Vacuette tube yellow top serum separator clot activator lot B2312375, Expiration Date 3/1/2025, Storage Temperature 4-25 [degrees Celsius]. 3 packs of 50 Vacuette K3EDTA, lot number B2310357. Expiration Date 1/30/2025, Storage Temperature 4-25 [degrees Celsius]. The room temperature of the draw station room was not monitored, and the defined room temperature range exceeded the manufacturer's storage requirements. f. An interview with the office manager on 8/27/2024 at 1:20 PM and 2:15 PM confirmed these findings.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on record review, the laboratory's policy, and interview with staff the Technical Consultant failed to document competency of 4 of 4 testing personnel in 2022 and 2023. a. A review of the CMS-116 revealed the laboratory performed the following

	moderately complex testing: qualitative semen analysis. b. A review of the laboratory's Quality Assurance Plan provided by the office manager revealed "PERSONNEL ASSESSMENT ...At least annually the laboratory director and/or technical consultant will review the performance of each employee working in the laboratory to assure employee competency. The written result of the review will be filed in the individual's personnel file. Opportunities will be made available to laboratory personnel for continuing education and noted in the record at the time of this review." c. The laboratory was asked to provide competency assessment for testing personnel that perform moderately complex testing. No documentation was provided. d. An interview with the office manager on 8/27/2024 at 2:15 PM in their office confirmed the laboratory did not perform competency on testing personnel that performed moderately complex testing.