Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D2076549	04/24/2025
Name of Provider or Supplier	**Street Address, City, State**	
Auc Urologists, Llc	101 Mcleod Health Boulevard, Suite 202, Myrtle Beach, 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 initial survey was conducted at AUC Urologists, LLC on April 24, 2025 by the South Carolina Department of Public Health's Bureau of Nursing Homes and Medical Services. The facility was found to be out of compliance with Medicare Standards at 42 CFR Part 493..CLIA Laboratory Requirements
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: Based on policies and procedure manual review, testing personnel record review, and staff interview, the laboratory failed to establish and follow written policies and procedures to assess employee competency for 2 of 3 moderate complexity testing personnel listed on the CMS 209 and American Proficiency Institute (API) attestation statement for 3 years reviewed (2023, 2024, and 2025) as required 493.1407(e)(12). Findings included: 1. The laboratory director failed to follow policy titled "AUC Urologists General policies" ensuring employee(s) competency were performed twice a year during the first year. 2. Review of testing personnels' files revealed that two employees (DC, JC) that perform moderately complex urine microscopy did not have competency evaluations available on day of survey. 3. In an interview on April 24, 2025, at 5:10 pm with the general supervisor (GS), 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: During onsite recertification survey on April 24, 2025, based on records review, lack of documentation and staff interview, the laboratory failed to verify the accuracy of histopathology and cytology reports at least twice annually for 3 of 3 years reviewed (2023, 2024, 2025). Findings include: 1. Review of CMS 209 personnel report form, list 1 laboratory director with the specialty and subspeciality of histopathology and cytology. 2. Records review reveals lack of documentation of semi-annual test accuracy verification for histopathology and cytology. 3. General supervisor confirmed during an onsite interview on April 24, 2025, at 5:10 pm that the laboratory had failed to verify reading accuracy of histopathology and cytology slides at least twice annually.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 direct observation, lack of documentation and staff interview, the laboratory failed to define, monitor, and document laboratory conditions including temperature and humidity for 3 of 3years reviewed (2023, 2024, and 2025). Findings included: 1. A tour of the laboratory was conducted by surveyor on April 24, 2025, at 3:28 pm. The surveyor directly observed a thermometer in the laboratory. 2. Records review reveal a lack of documentation ensuring that the reagents were stored at the appropriate room temperature. 3. Review of manufacturer requirements for waived urinalysis testing. a. Review of package insert Siemens Multistix 10 SG reveals store at temperatures between 15-30 degrees C (59-86 degrees F) as required per manufacturer of CLIA-WAIVED laboratory test. b. Review of Quantimetrixr Dropper Plus Point-of-Care Urinalysis Dipstick Control Level 1 & 2 package insert reveals "After the initial use, the opened urinalysis dipstick control bottles can be stored at room temperature. Do not store above 30 degrees C (86 degrees F). When stored at room temperature (18 -25 degrees C), the controls are stable for one month." 4. In an interview with general supervisor (GS) on April 22, 2025, at 5:10 pm in the office, the above findings were confirmed. Units Celsius=C Fahrenheit=F
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) (e)(11) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all

	testing operations reliably to provide and report accurate results; This STANDARD is not met as evidenced by: Based on records review and staff interview, the laboratory director failed to document training provided to personnel prior to testing patients. Two testing personnel identified as new since the last survey. 2 out of 3 personnel records lack training documentation. Findings included: 1. Review of American Proficiency Institute (API) proficiency test (PT) attestation statement reveals two additional person (s) performing microscopy urine sediment of moderately complex testing that are not listed on CMS 209. a. 2023 Hematology/Coagulation 2nd Event, resulted 100%, DC, 07/17/2023 b. 2023 Hematology/Coagulation 3rd Event, resulted 100%, JC, 11/10 /2023 2. In an interview on April 24, 2025, at 5:10 pm in the office with GS the above 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 laboratory director failed to ensure that testing personnel were evaluated at least semiannually during the first year of testing patient specimens for 3 of 3 testing personnel. 1. Records review reveals CMS 209 personnel report form list 1 testing personnel on the day of survey; PT records reveal 2 previous testing personnel in 2023. 2. Documentation of initial training evaluation at least semiannually during the first year of testing was unavailable for review on the day of the survey for 3 of 3 personnel (employees AR, DC, JC). 3. In an interview on April 22, 2025, at 5:10pm in the office with GS the above findings were confirmed.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (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 records review, lack of documentation and staff interview, the laboratory director/technical supervisor failed to ensure that competency assessments were performed annually as required. Reference D5209
D6121	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(i) The procedures for evaluation of the competency of the staff must include, but are not

	limited to-- (b)(8)(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; This STANDARD is not met as evidenced by: Based on records review and staff interview, the technical supervisor failed to ensure all testing personnel had documented competencies for 2 of 3 TPs for three years reviewed (2023, 2024, 2025). Reference D5209 and D6120