Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1014741	(X3) Date Survey Completed 08/19/2025
Name of Provider or Supplier Auc Urologists, Llc	**Street Address, City, State** 3600 Sea Mountain Hwy, Little River, 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 offsite Proficiency Test (PT) Desk survey was conducted at AUC UROLOGISTS, LLC on August 19, 2025. The facility was found to be out of compliance with the Medicare Condition at 42 CFR 493 CLIA Laboratory Requirements. The following is a list of CONDITION LEVEL DEFICIENCIES were found to be out of compliance: D2016-42 CFR. 493.803 Condition: Successful participation [proficiency testing] D6000 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director
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: Based on a proficiency testing desk review of Certification and Survey Provider

	Enhancement Report (CASPER)-0155D report and College of American Pathologist (CAP) 2025 records, the laboratory had not successfully participated in a proficiency testing program approved by (HHS), for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. The laboratory failed to successfully participate in the specialty Hematology for the analyte Hemoglobin (HGB). Refer to D2130.
D2130	HEMATOLOGY CFR(s): 493.851(f) (f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a proficiency testing desk review of CASPER 0155D report and graded proficiency reports from CAP 2025 records (Events 1, 2), the laboratory failed to achieve a satisfactory performance (80% or better) for the same analyte in two consecutive testing events in the specialty and subspecialty of Hematology for the analyte HGB. Findings included: 1. A review of the CAPSER 0155 report revealed the following scores for the laboratory's Hemoglobin: a. FH3-A 2025, Event 1: 60% b. FH3-B 2025, Event 2: 60% 2. The scores were confirmed by review of the graded CAP results. Scores less than 80% for the analyte indicate failure or unsatisfactory performance. A failure of the analyte for two out of three testing events is scored as unsuccessful.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on proficiency testing desk review of CASPER 0155D report and CAP 2025 records, the laboratory director failed to provide overall management and direction of the laboratory services. Refer to D6016
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on proficiency testing desk review of CASPER 0155D report and CAP Proficiency Testing 2025 records, the laboratory director failed to ensure that the overall quality of the laboratory services provided. The laboratory director failed to ensure successful participation in an HHS approved proficiency testing program. Refer to D2130