Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0924715	03/19/2025
Name of Provider or Supplier	**Street Address, City, State**	
Urology Associates, Pc - Hendersonville	107 Glen Oak Blvd, Suite 100, Hendersonville, TN	

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
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 laboratory observation, a review of laboratory policies, and staff interviews, the laboratory failed to follow its policy for labeling 3 of 4 urinalysis specimens. The findings include: 1. Observation of the laboratory on 03/19/2025 at 9:30 a.m. revealed the laboratory performing testing on four urine specimens. Three specimens were labeled with the last name only. 2. A review of the laboratory's "Collection, Handling, and Processing Laboratory Specimens" policy (Policy: PP6) revealed the following statements: - "The below procedure must be followed to ensure the proper identification of every specimen." - "3. Write the patient's name, MR number and can add the date of birth on the container before the patient leaves the room or before you go to the next patient." 3. An interview with the technical consultant on 03/19/2025 at 1:00 p.m. confirmed the laboratory requires two specimen identifiers for specimen labeling and did not follow its policy for labeling three of the four urine specimens observed.
D5393	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(b)(c) (b) The preanalytic systems 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 preanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document

	all preanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on a review of quality assurance (QA) records, staff interviews, and lack of documentation, the laboratory failed to document discussions with all appropriate staff (2 of 2) responsible for entering test orders when the laboratory's quarterly QA review identified missing post-vasectomy qualitative semen analysis. The findings include: 1. A review of the laboratory's 2024 fourth-quarter QA documents revealed no documented orders for the post-vasectomy qualitative semen analysis for patient 1899330. 2. In an interview with the technical consultant on 03/19/2025 at 1:00 p.m., the technical consultant revealed that the laboratory requires the provider or the provider's nurse to enter orders "on behalf" of the provider when given verbally. 3. The laboratory did not have documentation showing that it had discussed the unacceptable QA event with the provider or the provider's nurse responsible for entering test orders for patient 1899330.