Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0924702	06/03/2024
Name of Provider or Supplier	**Street Address, City, State**	
Urology Associates, Pc -Gallatin	405 Steam Plant Road, Gallatin, 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
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 a review of the laboratory's procedure manual and staff interview, the laboratory failed to follow its policy for procedure review in 2023. The findings include: 1. A review of the laboratory's policy titled "Addendum to CLIA procedure" revealed the following statements: - "This Policy and Procedure Manual is located on the shared drive (L:) in the Laboratory folder, can be accessed from all computers at Urology Associates, and will be reviewed and signed by the Director(s) annually." - "Below is the signature(s) attesting to the policy review:" There was no signature present in the space provided for 2023. 2. An interview with the Technical Consultant on 06/03/2024 at 10:30 a.m. confirmed the laboratory did not follow their policy for annual procedure review in 2023.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other

	materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of the laboratory's procedure manual and staff interview, the laboratory's procedure for microscopic exams of urine sediment failed to include reference intervals (normal values) for patient testing. The findings include: 1. A review of the laboratory's procedure manual revealed no reference ranges listed for urine sediment microscopic exams. 2. An interview with the Technical Consultant on 06/03/2024 at 10:30 a.m. confirmed the laboratory's procedure did not include reference ranges.