Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	08D0691598	05/30/2024
Name of Provider or Supplier	**Street Address, City, State**	
Urology Associates Of Delaware, P A	200 Banning Street, Suite 250, Dover, DE	

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	A Recertification survey was conducted on May 30, 2024 at approximately 1:00 pm at Urology Associates of Delaware, PA. The laboratory was surveyed according to 42 CFR par 493 Clinical Laboratory Improvement Ammendments (CLIA) requirements. Specific deficiencies are as follows:
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Interview and document review. The laboratory failed to have a quality improvement process in place. Findings include: 1. At approximately 2:00 pm on May 30, 2024 during document review, there was no evidence of internal audits to monitor and assess problems in the laboratory to include quality control, equipment maintenance, temperature logs and similar daily laboratory quality assurance activities. 2. At approximately 2:05 pm the LD confirmed that no internal audits were documented, but that they were performed on an informal basis. 3. By the end of the interview at approximately 2:46 pm no internal audit documentation was provided.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system

	performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: interview, observation and document review. The laboratory failed to ensure that all pipette in use had a current calibration. Findings include: 1. At approximately 2:30 pm on May 30, 2024 during observation in the laboratory, the pipette in use, Integra Multiplex 7021980 was noted to have an expired calibration which occured on January 24, 2024. 2. At approximately 2:35 pm, during interview and document review, the Laboratory Director (LD) could not provide current calibration documentation for that pipette but stated that two other pipettes were sent out for calibration. 3. At the end of the interview at approximately 2:46 pm no documentation was provided for the expired pipette and the LD confirmed that it was expired.