

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  08D0691598	<b>(X3) Date Survey Completed</b>  04/22/2026
<b>Name of Provider or Supplier</b>  Urology Associates Of Delaware, P A	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A Recertification Survey was conducted on April 22, 2026 at approximately 10:00 AM. The laboratory was surveyed according to 42 CFR Part 493 Clinical Laboratory Improvement Amendments (CLIA) requirements. Deficiencies were identified as follows:
<b>D6063</b>	<p><b>LABORATORY TESTING PERSONNEL</b> CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.</p> <p>This CONDITION is not met as evidenced by: Based on observation, interview, and facility document review, and United States (U. S.) Food and Drug Administration (FDA) guidelines, the laboratory failed to ensure all individuals performing patient testing met the qualification requirements. Findings included: The facility failed to ensure Testing Personnel (TP) #2 met the qualification requirements to perform moderate complexity testing. (Refer to D6065 for details.)</p>
<b>D6065</b>	<p><b>TESTING PERSONNEL QUALIFICATIONS</b> CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p> <p>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or</p>

(b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on observation, interview, facility document review, and United States (U.S.) Food and Drug Administration (FDA) guidelines, the laboratory failed to ensure all individuals performing patient testing met the qualification requirements. Findings included: A tour of the laboratory, on 04/22/2026 at 11:00 AM, revealed Testing Personnel (TP) #2 testing patient samples using an automated urinalysis analyzer. During a concurrent interview, TP #2 described the sample handling process for the urinalysis analyzer. The U.S. FDA public database "CLIA [Clinical Laboratory Improvement Amendments]," at [www.accessdata.fda.gov](http://www.accessdata.fda.gov), revealed the automated urinalysis analyzer used for patient testing was categorized as moderate complexity. A facility document titled, "[Name of automated urinalysis analyzer] Training Form," dated 07/01/2024, revealed TP #2 was satisfactorily trained to operate the analyzer. Personnel records revealed a lack of documentation of education qualifications for TP #2. During an interview on 04/22/2026 at 11:40 AM, the Laboratory Director (LD) stated the laboratory did not have documentation that TP #2 met the CLIA qualification requirements for moderate complexity testing personnel. During interview on 04/22/2026 at 3:10 PM, the LD stated that TP #2 had been performing approximately 70 to 80 patients' tests per day, on Mondays through Thursdays, and approximately 40 patients' tests, on Fridays, since July 2024.