

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0225848	(X3) Date Survey Completed 11/15/2022
Name of Provider or Supplier Urological Associates, Ltd	Street Address, City, State 155 Riverbend Drive, Charlottesville, VA	
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 announced CLIA recertification survey was conducted at Urological Associates, LTD on November 15, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows and include one Condition under 42 CFR part 493 CLIA Regulation: D6063 -42 CFR. 493.1421 Condition Testing Personnel.
D6063	<p>LABORATORY TESTING PERSONNEL 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 a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form, testing personnel records, lack of documentation, and interview, the laboratory failed to retain documentation of education qualifications for one of six testing personnel responsible for reporting moderate complexity endocrinology chemistry patient test results during the review timeframe of December 2020 to the date of the inspection on November 15, 2022. See D6065.</p>
D6065	<p>TESTING PERSONNEL QUALIFICATIONS 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 have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a</p>

chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), personnel records, lack of documentation, and an interview, the laboratory director (LD) failed to retain documentation of education qualifications for one (1) of six (6) chemistry testing personnel (TP) noted on the date of the inspection, November 15, 2022. Findings include: 1. Review of the CMS 209 form revealed the LD identified 6 personnel as qualified to perform moderate complexity endocrinology chemistry Prostate Specific Antigen and Testosterone patient testing on the Qualigen FastPack analyzer during the twenty-three months of review (December 2020 up to 11/15/22). 2. Review of the available laboratory personnel records for evaluation of education documentation revealed no records of education for TP A. *See Personnel Code Sheet. 3. The inspector requested to review the documentation of education for the TP outlined above. The records were not available for review. The office manager stated on 11/15/22 at approximately 1:30 PM, "This staff member has been attempting to get an official transcript from the school and we hope to have it soon." 4. An exit interview with the office manager on 11/15/22 at approximately 3:00 PM confirmed the above findings.