

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  49D0225848	<b>(X3) Date Survey Completed</b>  07/18/2024
<b>Name of Provider or Supplier</b>  Urological Associates, Ltd	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA recertification survey was conducted at Urological Associates, LTD on July 18, 2024 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiency cited is as follows:
<b>D6029</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(11)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, the laboratory's policies and procedures, lack of documentation and interviews, the laboratory director failed to follow the laboratory's established policy to ensure two of two new TP had documented training /competency assessments prior to performing patient testing procedures utilizing the Qualigen FastPack IP System for prostatic specific antigen (PSA) and testosterone (Testo) analysis on the date of survey on July 18, 2024. The findings include: 1. Review of CLIA CMS-209 form revealed TP A and TP B listed as performing patient testing utilizing the Qualigen FastPack IP System. (See attached TP Code Sheet.) 2. Review of TP records and an interview with the primary TP on July 18, 2024 at 10:15 AM revealed TP A was hired/began patient testing utilizing the FastPack System in April 2024 and TP B was hired/began patient testing utilizing the FastPack System in</p>

May 2024. Further review of the TP A and TP B's personnel records revealed a lack of documentation of the training/initial competency of TP A and TP B. The inspector requested to review training/initial competency assessment documents for TP A and TP B. The laboratory provided no documentation for review. 3. Review of the laboratory's policies and procedures revealed a checklist, "FastPack IP Training Checklist", with the following statement, "Complete this information for any person who will perform tests on the FastPack IP System." 4. In an exit interview with the primary TP on July 18, 2024 at 12:30 PM, the above findings were confirmed.