

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0883791	<b>(X3) Date Survey Completed</b>  02/17/2025
<b>Name of Provider or Supplier</b>  Advanced Urology Institute, Llc	<b>Street Address, City, State</b>  5747 38th Ave N, Saint Petersburg, FL	
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 Advanced Urology Institute, LLC on 02/17/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to at least twice annually, verify the accuracy of the urine microscopic testing performed from 5/22/2023 to 2/17/25. Findings include: 1. Policy titled Semi-Annual Maintenance included directions for split samples to be sent to an outside laboratory for the urine microscopic testing performed. 2. The last split sample record which was complete with acceptable comparison was 5/22/23. The next record for split sample was dated 9/6/2024 , sixteen months later, and showed "unable to compare". There was no documentation of any other split samples sent for this timeframe. The next split sample record was dated 2/13/2025, which documented discrepancies. There was no documentation of acceptable comparison of split samples for urine microscopic testing from 5/22/2023 to 2/17/2025 provided for review. 3. Testing Personnel B (TP-B), who is also the Clinical Manager, confirmed on 2/17/2025 at 10:38 AM the laboratory had not verified the accuracy of the urine microscopic testing performed at least twice annually from 5/22/23 to 2/17/25.</p>
<b>D6020</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(5)</p>

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:

Based on record review and interview, the Laboratory Director failed to ensure that the quality assessment program was maintained to assure the quality of laboratory services provided and to identify failures for two of two years (2023-2024). Findings include: 1. The laboratory used a Monthly Quality Assurance Checklist for the quality assurance program. From 11/2022 to 8/24/23 there were no monthly Monthly Quality Assurance Checklists provided for review. There was no documentation as to why the Monthly Quality Assurance Checklist had not been performed for eight months. 2. The Monthly Quality Assurance Checklist from 8/24/2023 to 1/3/2025 did not document the laboratory had identified the failure to at least twice annually, verify the accuracy of the urine microscopic testing performed from 5/22/2023 to 2/17/25. (See D5217). 3. The Monthly Quality Assurance Checklist from 8/24/2023 to 1/3/2025 did not indicate the laboratory had identified the failure of the Technical Consultant to evaluate the competency of eight of eight testing personnel assuring that the staff maintained their competency to perform urine microscopic testing for two of two years (2023-2024). (See D6046). 4. On 2/17/2025 at 10:35 AM, Testing Personnel B confirmed the Monthly Quality Assurance Checklist had not identified the failures as cited at D5217 and D6046, and had no documentation to show why the Monthly Quality Assurance Checklist had not been performed from 11/2022 to 8/24/2023.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)

(b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to--

This STANDARD is not met as evidenced by:

Based on record review and interview, the Technical Consultant failed to evaluate the competency for eight of eight testing personnel TP A-H) assuring competency to perform urine microscopic testing for two of two years (2023-2024). Findings include; 1. CMS-209 Laboratory Personnel Report signed by the Laboratory Director 2/12/25 listed eight Testing Personnel other than himself. (TP-A, TP-B, TP-C, TP-D, TP-E, TP-F, TP-G, and TP-H). The designated duties list showed Employee Competencies were the responsibility of the Medical Director (Lab Director), who is also the Technical Consultant as listed on the CMS-209 Laboratory Personnel Report signed by the Laboratory Director on 2/12/25. 2. Personnel competency records showed: TP-A had an annual competency dated 12/5/23 and 2/3/25 performed by TP-B. There was no documentation of annual competency for 2024. TP-B had an annual competency for 10/12/22 and 2/3/25 performed by TP-C. There was no documentation of annual competency for 2023 or 2024 although TP-B documented performing testing personnel competencies during 2023 and 2024. TP-C had an annual competency dated 12/5/23 and 2/3/25 performed by TP-B. There was no documentation of annual competency for 2024. TP-D had an annual competency dated 12/5/23 and 2/3/25 performed by TP-B. There was no documentation of annual competency for 2024. TP-E had an initial competency dated 7/1/24 and 6 month dated 2/3/25 both performed by

TP-B. TP-F had an annual competency dated 12/5/23 and 2/3/25 performed by TP-B. There was no documentation of annual competency for 2024. TP-G had an initial competency dated 12/14/23, 6 month dated 7/31/24, and an annual dated 2/3/25 all performed by TP-B. TP-H had an annual competency dated 12/5/23 and 2/3/25 performed by TP-B. There was no documentation of annual competency for 2024. 3. On 2/17/2025 at 10:10 AM, TP-B confirmed the Technical Consultant had not evaluated the competencies of laboratory staff from 2023-2024.