Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0291948	05/12/2025
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Urology Institute	1401 Pasadena Avenue South Suite 4, Saint Petersburg, FL	

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 Advanced Urology Institute on 05/12/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to maintain documentation of weekly eyewash station checks for two (06/2024, 10/2023) of three months (03/2025, 06/2024, 10/2023) selected for review. Findings included: Review of the "Eye Wash Station Log" showed "flush and check eye wash stations weekly." No documentation was available for review for 06/2024 and 10/2023 to reflect safety checks on the eye wash station were completed. Interview with Testing Person H on 05/12/2025 at 12:05 p.m. confirmed the lack of documentation.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by:

	Based on record review and interview, the laboratory failed to verify the accuracy of urine microscopic twice a year for two of two years (June 2023 through December 2024). Findings included: "Split Sample Reporting" (SSR) forms from June 2023 through December 2024 were reviewed. SSR was the method used to verify the accuracy of the urine microscopic testing. There was one report for 2024, dated 02/05 /2024, and no reports for June 2023 to December 2023. Interview with Testing Person H on 05/12/2025 at 11:35 a.m. confirmed the above.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (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 perform and maintain a Quality Assessment Program as evidenced by no documented Monthly Quality Assurance for 11 months (06/2023 - 11/2023, 03/2024, 05/2024 - 08/2024) of 18 months (06/2023-08/2024, 02/2025 - 04/2025) reviewed, failure to verify the accuracy of urine microscopic testing twice a year for two of two years (06/2023 - 12 /2024), failure to identify 3 testing persons (#B, C, and E) of 8 testing persons (#A - H) lacked competencies for 2024, and failure to identify weekly eyewash station checks for two (06/2024, 10/2023) of three months (03/2025, 06/2024, and 10/2023) selected for review. Findings included: 1) Quality Assurance Checklists were reviewed. No Monthly Quality Assurance Checklists were signed as completed by the Laboratory Director for 06/2023 - 11/2023 and 05/2024 - 08/2024. Monthly Quality Assurance Checklists signed by the Laboratory Director for 02/2025 -04/2025, 01 /2024 - 04/2024, and 12/2023 failed to identify any issues. Interview with Testing Person (TP) H on 05/12/2025 at 12:15 p.m. confirmed the above. 2) "Split Sample Reporting" (SSR) forms for 2024 and 2023 were reviewed. SSR was the method used to verify the accuracy of the urine microscopic testing. There was one report dated 02 /05/2024 and no reports for 06/2023- 12/2023. Interview with TP H on 05/12/2025 at 11:35 a.m. confirmed the above. See D5217. 3) The CMS-209 Laboratory Personnel Report, signed and dated by the Laboratory Director on 5/8/2025 showed 8 TP's would require competencies (A - H). TP file reviews for TP B, C, and E lacked documentation of annual competencies for 2024. Interview with TP H on 05/12/2025 at 12:15 p.m. confirmed the annual competencies were not present. See D6030. 4) The "Eye Wash Station Log" for 06/2024 and 10/2023 showed no documentation to reflect safety checks on the eye wash station were completed. Interview with TP H on 05/12 /2025 at 12:05 p.m. confirmed the lack of documentation. See D3011.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

	This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director (LD) failed to ensure three testing persons (B, C, and E) of 8 testing persons (A - H) had competencies completed for one (2024) of two years reviewed (06/2023-12/2023 and 2024). Findings included: The CMS-209 Laboratory Personnel Report, signed and dated by the LD on 5/8/2025, documented 8 testing persons (TP) would require competencies (A - H). TP file reviews for TP B, C, and E revealed no annual competencies for 2024. Interview with TP H on 05/12/2025 at 12:15 p.m. confirmed annual competencies were not present and were required for 2024.