

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0891794	(X3) Date Survey Completed 06/14/2024
Name of Provider or Supplier Andrology Institute Of America	Street Address, City, State 181 Collins Lane, Lexington, KY	
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	A Recertification Survey was conducted on 06/14/2024. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) documents, and confirmed in staff interview, the facility failed to document corrective actions taken for events that were unacceptable for 4 of 5 PT reports reviewed. Findings included: Review of the PT report dated 05/19/2022, revealed the sperm count, sperm motility, and sperm viability had a reported value that was of the grading range or had an incorrect response. Review of the PT report dated 04/04/2023, revealed the sperm count had a reported value that was out of the grading range or had an incorrect response. Review of the PT report dated 10/25/2023, revealed the sperm viability and sperm mobility reported value was out of the grading range or had an incorrect response. Review of the PT report dated 04/10/2024, revealed the sperm morphology had a reported value that was out of the grading range or had an incorrect response. Review of the PT reports revealed no evidence to indicate corrective action for the reported values found out of the grading range or that had an incorrect response. During an interview on 06/14/2024 at 12:19 PM, the Laboratory Director (LD) confirmed that although he reviewed the PT failures, he did not document any corrective actions.</p>