

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2011373	(X3) Date Survey Completed 06/30/2026
Name of Provider or Supplier Reproductive Medicine Institute	Street Address, City, State 233 East Erie Street, Chicago, IL	
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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the CMS-209 (Laboratory Personnel Report) Form, laboratory policies and procedures, American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records, and interview with the laboratory director (LD); the laboratory failed to ensure two of three testing personnel (TP) who routinely performed semen analysis testing in the specialty of hematology participated in four of four PT events reviewed. Findings include: 1. Review of the CMS-209 (Laboratory Personnel Report) Form revealed three TP (TP #1, TP #2, and TP #3) authorized to perform semen analysis testing in the specialty of hematology. 2. Review of laboratory policies and procedures revealed the procedure titled "8.4 Procedure: Proficiency Testing for Andrology Procedures", which stated, under "Quality Control:", "5. Technicians performing PT are rotated if applicable." 3. Review of AAB-MLE PT records for semen analysis testing over the past two years found that two of three TP listed on the CMS-209 had not participated in semen analysis PT. Year/Event: TP: 2024 - Event 2 1 2025 - Event 1 1 2025 - Event 2 1 2026 - Event 1 1 4. Interview with the LD on 06/30/2026, at 11:38 am, confirmed the laboratory failed to ensure two of three TP who routinely performed semen analysis testing in the specialty of hematology participated in four of four PT events reviewed.