

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2322415	(X3) Date Survey Completed 07/22/2025
Name of Provider or Supplier Fertility Centers Of Illinois	Street Address, City, State 361 W Chestnut, Ste 100, 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
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) (b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, College of American Pathologist (CAP) proficiency testing (PT) records, lack of documentation, and interview with the laboratory director (LD); the laboratory failed to ensure accuracy of four of twelve samples not evaluated by the PT provider for two of two PT events in the specialty of hematology since the beginning of testing in August of 2024. Findings include: 1. Review of laboratory policies and procedures revealed the procedure titled "Quality Control", which stated, under "Quality Control to be Performed Semi-Annually:", "The Supervisor or designee will evaluate the results provided by the agency [CAP] and take corrective action to correct any deficiencies with the approval of the Laboratory Director." 2. Review of CAP comparative evaluation summaries for the following PT events of 2024 and 2025 revealed the following un-graded PT samples: PT Event: Analyte: Sample: 2024 Event B Sperm Count SEM-19 2024 Event B Sperm Count SEM-20 2025 Event A Sperm Count SEM-09 2025 Event A Sperm Count SEM-10 3. Review of laboratory records found no documented review of the ungraded PT samples in the specialty of hematology in 2024 and 2025. 4. Interview with the LD on 07/22/2025, at 2:35 pm, confirmed the laboratory failed to ensure accuracy of four of twelve PT samples not evaluated by the PT provider for two of two PT events in the specialty of hematology since the beginning of testing in August of 2025.
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 review of laboratory records, College of American Pathologist (CAP) proficiency testing (PT) records, lack of documentation, and interviews with the laboratory director (LD) and testing personnel (TP) #4; the laboratory failed to perform bi-annual method accuracy evaluations for one of three semen analysis measurements performed, sperm motility, in the specialty of hematology since the beginning of testing in August of 2025. Findings include: 1. Review of laboratory records revealed the laboratory performing semen analysis measurements including sperm count, sperm motility, and sperm morphology in the specialty of hematology. 2. Review of CAP PT records revealed a lack of bi-annual method accuracy evaluations for the semen analysis measurement of sperm motility. 3. Interviews with the LD and TP #4 on 07/22/2025, at 2:33 pm, confirmed the laboratory failed to perform bi-annual method accuracy evaluations for one of three semen analysis measurements performed, sperm motility, in the specialty of hematology since the beginning of testing in August of 2025.