

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0969550	(X3) Date Survey Completed 08/26/2025
Name of Provider or Supplier Fertility Centers Of Illinois	Street Address, City, State 19065 Hickory Creek Dr - Ste 115, Mokena, 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE 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 review of laboratory records, College of American Pathologists (CAP) proficiency testing (PT) records, lack of documentation, and interview with the laboratory representative; the laboratory failed to perform bi-annual method accuracy evaluations for one of two semen analysis measurements performed, sperm motility, in the specialty of hematology from 2023 through the date of survey, 08/26/2025. Findings include: 1. Review of laboratory records revealed the laboratory performing semen analysis measurements including sperm count and sperm motility 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. Interview with the laboratory representative on 08/26/2025, at 2:42 pm, confirmed the laboratory failed to perform bi-annual method accuracy evaluations for one of two semen analysis measurements performed, sperm motility, in the specialty of hematology from 2023 through the date of survey, 08/26/2025.</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of documentation, and</p>

inter with the laboratory representative; the laboratory failed to have two of two semen analysis policies and procedures reviewed, approved, signed, and dated by the laboratory director (LD) in the specialty of hematology. Findings include: 1. Review of laboratory policies and procedures revealed no LD approval, including signature and date, by the LD on two of two semen analysis policies and procedures: a. "Subject: Quality Control" b. "Subject: Semen Analysis" 2. Interview with the laboratory representative on 08/26/2025, at 2:42 pm, confirmed the laboratory failed to have two of two semen analysis policies and procedures reviewed, approved, signed, and dated by the LD in the specialty of hematology.

D5433

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(1)

(b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section.

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures, laboratory records, lack of documentation, and interviews with the laboratory representative and testing personnel (TP) #1; the laboratory failed to perform and document STAT III stain maintenance each day of semen analysis patient testing in the specialty of hematology for six of six testing dates reviewed from 2023 through the date of survey, 08/26/2025. Findings include: 1. Review of laboratory policies and procedures revealed the procedure titled "Quality Control", which stated, under "Quality Control to be performed weekly:", "iii. Directions: 2. Monitoring of the stains is required every day. These results must be logged appropriately." 2. Review of "Daily STAT III Stain Quality Control" log revealed STAT III stain maintenance lacked daily maintenance for six of six testing dates reviewed from 2023 through the date of survey, 08/26/2025. Testing Date: Maintenance Performed: 08/30/2023 No 12/15/2023 No 04/10/2024 No 10/23/2024 No 03/19/2025 No 06/11/2025 No 3. Interviews with the laboratory representative and TP #1 on 08/26/2025, at 2:42 pm, confirmed the laboratory failed to perform and document STAT III stain maintenance each day of semen analysis patient testing in the specialty of hematology for six of six testing dates reviewed from 2023 through the date of survey, 08/26/2025.

D6091

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(iii)

(e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures, College of American Pathologists (CAP) proficiency testing (PT) records, lack of documentation, and interview with the laboratory representative; the laboratory director (LD) failed to ensure review of four of four PT results received for semen analysis in the specialty of hematology from 2023 through the date of survey, 08/26/2025. 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"; and "E. Reviewing Results: a. Several weeks after you have submitted your testing, you should receive your Evaluation results. b. Have the Director/Supervisor /FCI Physician sign off on the Evaluation and file it in the appropriate year's CAP binder." 2. Review of CAP PT records for semen analysis revealed a lack of LD review of received PT scores from 2023 through the date of survey, 08/26/2025. CAP PT Event: Scores Received: LD Review: 2023 SEM-B 12/12/2023 No 2024 SEM-A 05/22/2024 No 2024 SEM-B 11/21/2024 No 2025 SEM-A 05/15/2025 No 3. Interview with the laboratory representative on 08/26/2025, at 2:42 pm, confirmed the LD failed to ensure review of four of four PT results received for semen analysis in the specialty of hematology from 2023 through the date of survey, 08/26/2025.