

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  14D0969917	<b>(X3) Date Survey Completed</b>  08/26/2025
<b>Name of Provider or Supplier</b>  Fertility Centers Of Illinois	<b>Street Address, City, State</b>  907 N Elm St, Hinsdale, IL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2009</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>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 failed to ensure attestation statements were signed by the laboratory director (LD) on four of four events and by the testing personnel (TP) on two of four events from 2023 through the date of survey, 08/26/2025, in the specialty of hematology. 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:", "Proficiency testing samples must be tested with the laboratory's regular patient workload by personnel who routinely perform testing in the laboratory using routine methods of the laboratory (the individual performing testing on the samples must attest to this policy)"; and "Each step in the handling, preparation, processing and testing of the samples must be documented and a copy maintained with the report for those results as provided by the agency. These records will be kept along with the attention statement, signed by the laboratory director ...." 2. Review of CAP PT attestation forms revealed a lack of LD signatures on four of four events and a lack of TP signatures on two of four events. CAP PT Event: LD Signature: TP Signature: 2023 SEM-B No No 2024 SEM-A No Yes 2024 SEM-B No No 2025 SEM-A No Yes 3. Interview with the laboratory representative on 08/26/2025, at 10:55 am, confirmed the laboratory failed to ensure attestation statements were signed by the LD on four of four events and by the TP on two of four events from 2023 through the date of survey, 08/26/2025, in the specialty of hematology.</p>

**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 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 08:59 am, 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.

**D5407**

**PROCEDURE MANUAL**

CFR(s): 493.1251(d)

(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, lack of documentation, and 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 09:21 am, 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.

**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 11/21/2023 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 09:24 am, 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.