

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0969563	(X3) Date Survey Completed 05/29/2024
Name of Provider or Supplier Fci Hoffmann Estate	Street Address, City, State 2260 W Higgins Rd, Ste 200, Hoffman Estates, 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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation and interview with the general supervisor (GS); the laboratory failed to follow the written procedure for reporting specimen quality for the hematology analysis of semen specimens for five of five final patient reports reviewed in 2022 through 2024. Findings include: 1. Review of the laboratory's "Standard Operation Procedure for Sperm Processing for Semen Analysis (SA)" revealed the following information: "6.4 Quality Control for Semen Analysis Processing ...Analysis Quality: ...Use the following chart to determine the specimen quality and record in ArtWorks: # of Criteria Met: Quality 3 Good 2 Fair 1 Poor". 2. Review of laboratory records and patient test reports revealed no documentation for the determination of semen specimen quality in ArtWorks for five of five final patient test reports reviewed in 2022 through 2024. Report A: Patient ID: 47020763 Date: 05/24/2022 No documentation of semen specimen quality. Report B: Patient ID: 47017711 Date: 09/20/2022 No documentation of semen specimen quality. Report C: Patient ID: 47024160 Date: 02/14/2023 No documentation of semen specimen quality. Report D: Patient ID: 47030386 Date: 12/26/2023 No documentation of semen specimen quality. Report E: Patient ID: 47034962 Date: 04/18/2024 No documentation of semen specimen quality. 3. On 05/29/2024, at 11:46 a. m., the GS confirmed the above findings.</p>