Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0969563	10/07/2020
Name of Provider or Supplier	**Street Address, City, State**	
Fci Hoffmann Estate	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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures manual and interview with the technical supervisor, the laboratory did not have a comprehensive procedure manual that included the following when applicable to each test: * Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. * Step-by-step performance of the procedure, including test calculations and interpretation of results. * Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. * Control procedures. *

	Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. . * The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. * Description of the course of action to take if a test system becomes inoperable. Findings include: 1. The procedure manual for semen analysis was reviewed. 2. The laboratory performs semen analysis for the purpose of evaluating male fertility. 3. The procedures listed the parameters it measures while performing semen analysis in an outline form which included: a. sperm count b. motility c. morphology d. volume e. ph f. color g. liquefaction h. viscosity 4. There were no step by step procedures that identifies how the laboratory measures each of the parameters listed above. 5. There were no procedures that described the laboratory process for quality control of each parameter. 6. There was no current procedure for how the laboratory performs sperm counts. The instructions for performing sperm counts that were in the manual, are no longer in use. 7. There were procedures that the laboratory does not perform included in the lab's procedure manual. 8. There were no procedures that describe which test are referred to other labs and what the names of those reference labs are. 9. There were no procedures that describe the laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life-threatening results, or panic, or alert values. 10. There were no procedures that describe the course of action to take if a test system becomes inoperable. 11. At 1:00 PM on October 7, 2020, the technical supervisor confirmed the surveyor's findings.