Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2176775	02/22/2022
Name of Provider or Supplier	**Street Address, City, State**	
Conceptions Fertility Laboratories Llc	2750 Sw 145th Ave Suite 103, Miramar, FL	

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
D0000	A recertification survey was conducted on February 22, 2022. Conceptions Fertility Laboratories LLC clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories. D 5200- General Laboratory Systems - Condition level Deficiency cited.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory failed to monitor and evaluate the overall quality of the general laboratory system and correct identified problems. Findings: Cross Reference D5209: Based on record review and interview, the laboratory failed to document the initial and annual competency assessment for one out of one Technical Supervisor (TS) from 08/10/2020 to 02/22/2022, and the annual competency of one out of one General Supervisor (GS) for 2021. This is a repeat deficiency from the initial survey on 08/10/2020.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

	This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document the initial and annual competency assessment for one out of one Technical Supervisor (TS) from 08/10/2020 to 02/22/2022, and the annual competency of one out of one General Supervisor (GS) for 2021. This is a repeat deficiency from the initial survey on 08/10 /2020. Findings: Review of the Laboratory Personnel Report dated and signed by the Laboratory Director on 08/07/2020 for the initial survey on 08/10/2020 and the Laboratory Personnel Report dated and signed by the same Laboratory Director on 02 /22/2022 for the recertification survey on 02/22/2022, showed the TS on both of the Laboratory Personnel Reports were the same person. Review of personnel folder for the TS revealed that there were no competency evaluations in the folder. Review of personnel folder for the GS revealed that there was no competency evaluations in the folder for 2021. On 02/22/2022 at 2:05 PM, Technical Supervisor stated that there was no competency evaluation performed on herself. On 0222/2022 at 2:02 PM, General Supervisor stated that the competency evaluation for 2021 was not done.
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 record review and interview, the laboratory's procedure titled "Semen Sample Collection Instructions" was incomplete from 08/13/2021 to 02/22/2022. Findings: Review of the laboratory's procedure titled "Semen Sample Collection Instructions"signed and dated by the Technical Supervisor on 08/13/2021 revealed that the procedure failed to have instructions on labeling the specimen container collected by the patient. On 02/22/2022 at 4:08 PM, General Supervisor acknowledged the specimen collection instructions policy given to patients did not mention labeling the specimen container.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(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 record review and interview, the laboratory failed to document that the Laboratory Director approved, signed and dated the procedure manual from 08/13/21 to 02/22/2022 Findings: Review of the online procedure manual showed the Laboratory Director had not approved, signed or dated the procedure manual. Review of the online procedure manual showed that all procedures were signed and dated on 8 /13/21 by the Technical Supervisor. On 02/22/2022 at 3:53 PM, Technical Supervisor stated she did not know the Laboratory Director had to sign the procedure manual.