Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2062280	08/27/2019
Name of Provider or Supplier	**Street Address, City, State**	
Conceptions Fertility Laboratories Llc	4425 Ponce De Leon Blvd Suite 110, Miami, 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 conducted, 8/27/2019 found the Conceptions Fertility Laboratories LLC clinical laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with staff, the laboratory failed to document the review of the PT results for 2 out 2 years reviewed for the specialties of Endocrinology and Hematology. Findings include: 1- Endocrinology Specialty -Review of College of American Pathologists (CAP) PT Evaluation and Comparative Method Statistics, showed a grade code [20] for 5 out of 5 events (2017 3rd event, 2018 1, 2 and 3rd event and 2019 1st event) for Human chorionic gonadotropin (hCG) serum quantitative test. Code [20]= No appropriate target/response can not be graded. As per CAP "Actions Laboratories Should Take when a PT Result is not graded". Code 20. Action required: Applies to a response that is not formally evaluated when a peer group is not established due to fewer than 10 laboratories reporting. Document that a laboratory performed a self-evaluation using the data presented in the Participant Summary. Review of the results for the events of reference revealed that, the self-grading performed did not fulfill the requirements. Hematology Specialty -Review of CAP PT results for Sperm Morphology and Motility for 2017 (2nd event), 2018 and 2019 (1st event), revealed: a) 2nd event of 2017 had a clerical error for the sperm counts and sperm motility results. No corrective action documented for the clerical error. b) Results for Sperm motility and forward progression had a code 26. Code 26: Action required: Laboratory should document the review. Review of the peer results, with the value of reference provided

	by CAP PT organization, revealed that for PT sample # 6, the peer review showed a higher consensus different from the laboratory result. No documentation of the review and evaluation of results found. During an interview on 08/27/2019 at 2:30 PM, the TP # A confirmed that the laboratory had incomplete documentation of the self-evaluation for the results for the events of reference.
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 proficiency testing (PT) records and interview with staff, the laboratory failed to ensure the twice a year accuracy verification testing for Luteinizing hormone (LH) and Progesterone hormone for 1 out of 2 years reviewed. Findings include: Review of College of American Proficiency (CAP) PT 1st event 2018 for Estradiol, Follicle-stimulating hormone (FSH), Luteinizing hormone (LH), Progesterone, revealed no report of test results of LH and Progesterone to the PT event of reference. No documentation of the self-evaluation. During an interview on 08/27/2019 at 2:30 PM, the TP # A confirmed that the laboratory had no documentation of the self-evaluation for the results for the event of reference.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on analyzer user manual review and interview with testing personnel (TP)A, the laboratory failed to document room humidity requirement to ensure optimal operation of the Automated Immunoassay Analyzer (AIA-360) analyzer for 2 out 2 years reviewed. Findings include: Review of AIA-360 analyzer manual revealed a room humidity requirement not greater than 80 %. No documentation of the room humidity found for 2017, 2018 and 2019 (January to August). During an interview on 08/27/2019 at 2:30 p.m., the TP A confirmed that there was no record of room humidity control check.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The

	laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation, lack of documentation and staff interview, the facility failed to maintain daily quality control (QC) documentation for Giemsa stain for 2 out of 2 years reviewed. Findings include: The laboratory performs daily quality control slides for the Giemsa stain used for semen morphology analysis. No records available found to support this activity. During an interview on 8/27/2019 at 2:30 pm the TP # A confirmed that laboratory failed to keep records of the QC stain slide.
D6144	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463 The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have documentation that the General Supervisor (GS) provided a day to day supervision of laboratory operation and personnel performing testing and reporting results. Findings include: Review of CMS 209 Laboratory Personnel Report dated and signed by the Laboratory Director (LD) on 8/28/2019 revealed: LD as a Clinical Consultant (CC), Technical Supervisor (TS) and GS; and 2 testing personnel (TP # A and TP # B). - Review of GS job description, stated that the GS had to provide a day to day supervision of laboratory operation and personnel performing testing and reporting results. -The GS does not reside in Florida and visits the laboratory every 3 months. No documentation of the daily review by the GS of laboratory activity found during the visit. During an interview on 8/28/2019 at 2:30 pm with TP # A, she confirmed that that the GS is not daily based in the laboratory and no documentation of the daily supervision provided.