Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2062280	08/14/2023
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 from 08/08/2023 to 08/14/2023 found the CONCEPTIONS FERTILITY LABORATORIES LLC clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories.
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 test menu review and staff interview, the laboratory failed to verify the accuracy of testing methods at least twice annually for four out of five analytes tested in fertility hormone serum for two out of two years reviewed. Findings included: -Review of the test menu provided with the Clinical Laboratory Improvement Amendment (CLIA) Application for Certification indicated the following tests: Follicle Stimulating Hormone (FSH), Luteinizing Hormone (LH), Progesterone Hormone (P4), Estradiol Hormone (E2) and Human Chorionic Gonadotropin Hormone (hCG). Review of College of American Pathologists (CAP) proficiency testing (PT) records showed that the laboratory failed to enroll the following tests: FSH, LH, P4 and E2 from 2021 to 2023 and failed to perform twice a year accuracy verification. -The laboratory performed the following tests from 09/01/2021 to 08/08/2023: FSH performed 358 tests, LH performed 1062 tests, P4 performed 6533 tests and E2 performed 7033 tests. During an interview on 08/08/2023 at 12:00 pm with General Supervisor, she confirmed that the laboratory failed to do twice a year verification for the analytes listed above for the period 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 observation, record review and interview, the laboratory failed to follow manufacturer's instructions for storage temperature of the Immunoassay Controls for two out of two years reviewed. Findings included: During the laboratory tour on 08/08 /2023 at 10:30 AM, the surveyor found stored in the freezer compartment of the refrigerator three opened box with opening date of 08/01/2023 of Biorad Liquicheck Immunoassay Plus Control: Level 1, Level 2 and Level 3 each one. Also found stored two sealed box of each level for the controls of reference, the lot number for the controls was 85320 with expiration date of 05/31/2024. Review of the required storage temperatures as per manufacturer showed a storage requirement freezer at -20 to -70 Celsius Degrees (C). -Review of the Daily Temperature log revealed an acceptable temperature range of -5 to -20 C. The range does not meet the storage requirement. -Review of documented temperature logs from 09/01/2021 to 08/08 /2023 revealed that the temperature has not reached the requirement of -20 or colder. The freezer temperatures were documented at levels of -13 C to -19 C. During an interview on 08/08/2023 at 10:30 AM, the General Supervisor confirmed that the controls listed above were stored outside of the acceptable range as per manufacturer instructions in the years of reference.