Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2213498	05/24/2023
Name of Provider or Supplier	**Street Address, City, State**	
Rejuvenating Fertility Li Pllc	380 North Broadway, Jericho, NY	

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
D2105	ENDOCRINOLOGY CFR(s): 493.843(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on the review of proficiency testing (PT) records, the laboratory failed to perform corrective action for PT scores less than 100%. Confirmed findings on an interview with the operation manager on 5/24/2023, at approximately 12:30 P.M. Findings: 1. 2022 event Q1 HCG 80%. 2. 2023 event M1 TSH 80%.
D2107	ENDOCRINOLOGY CFR(s): 493.843(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on the review of PT records, the laboratory failed to achieve satisfactory performance, perform corrective action for two consecutive events, and perform

	subsequent remedial specimen PT action. Confirmed findings on an interview with the operation manager on 5/24/2023, at approximately 11:00 A.M. Findings: 1. 2022 event Q1 Estradiol 50%. 2. 2022 event Q2 Estradiol 0%.
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 the review of laboratory's training assessment policy as well as the training and competency documentation, the laboratory failed to establish frequency of personnel training and competency. Confirmed findings on an interview with the operation manager on 5/24/2023, at approximately 10:30 A.M.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on the review of standard operating procedures, the laboratory failed to establish written policies and procedures for specimen transportation. The practice transported specimens to Rejuvenating Fertility, 315 West 57th Street, Suite 208, New York, New York, CLIA: 33D2200675. Confirmed findings on an interview with the technical consultant on 5/23/2023, at approximately 12:00 P.M.
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 the review of TOSOH AIA 360 manufacturer's requirements, the laboratory failed to maintain humidity range of 40-80% as per operator's manual. Confirmed findings on an interview with the operation manager on 5/24/2023, at approximately 11:15 A.M. Findings: 1. In January 2022, humidity was out of range for twenty days.

	2. February 2022 humidity documentation was not available. 3. In March 2022, humidity was out of range for ten days. 4. In November 2022, humidity was out of range for nine days. 5. In December 2022, humidity was out of range for fifteen days. 6. In January 2023, humidity was out of range for sixteen days.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on the direct observation of aliquoted vials of diluent and alcohol in laboratory, the laboratory failed properly label identification, concentration, storage, expiration date, lot number, and preparation date. Confirmed findings on an interview with the operation manager on 5/24/2023, at approximately 11:45 A.M.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of laboratory's standard operating procedures, the laboratory failed to establish written policies and procedures for validation of new lot Quality Control materials TOSOH AIA 360. Confirmed findings on an interview with technical consultant on 5/23/2023, at approximately 12:00 P.M.