Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D2193615	01/19/2022
Name of Provider or Supplier	**Street Address, City, State**	
Rejuvenating Fertility Center, Pllc	225 Main St Ste 101, Westport, CT	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to attest that proficiency testing (PT) samples were performed in the same manner as patient specimens. Findings include: 1. Record review on 1/19/22 of the 2021 American Association of Bioanalysts PT documents for Semen analysis (SA-event 1) and Endocrinology tests (Chemistry/Non-Chemistry-event 2) attestation pages revealed the pages were not signed by the laboratory director (LD). 2. Staff interview with the LD on 1/19/22 at 2:15 PM confirmed the above finding.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to follow its procedure manual for calibration verification for the laboratory tests in the subspecialty of endocrinology. Findings include: 1. Record review of the laboratory's procedure manual for calibration verification on 1/19/22 for the Tosoh analyzer

	revealed the laboratory must perform calibration verification at least semiannually for the endocrinology tests (Follicle stimulating hormone, Luteinizing hormone, Beta human chorionic gonadotropin, Estradiol and Progesterone). 2. The laboratory did not have documentation for the Tosoh analyzer semiannual calibration verification. 3. Staff interview with the laboratory director (LD) and the testing personnel #1 on 1/19 /22 at 11:45 AM confirmed the above findings. 4. The laboratory performs 5,100 endocrinology tests annually.
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: (A) Based on record review and staff interview the laboratory failed to provide a complete procedure manual in the specialty of hematology. Findings include: 1. Record review of laboratory's procedure manual on 1/19/22 for semen analysis (SA) test revealed the lack of the following procedures: a. Quality control (QC) materials. b. Daily QC procedures. c. QC acceptability criteria. d. Remedial action when QC is out of range. 2. Staff interview with the testing personnel #1 on 1/19/22 at 10:30 AM confirmed the above findings. 3. The laboratory performs 100 SA tests annually in the specialty of hematology. (B) Based on record review and staff interview the laboratory failed to establish a step by step procedure for entering patient demographics into the Tosoh analyzer software in the subspecialty of endocrinology. Findings include: 1. Record review of the laboratory's 'Endocrinology Accession Log' on 1/19/22 revealed the following. a. Some testing personnel (TP) enter sample ID number where as some other TP enter patient's first or last name into the Tosoh analyzer software when running patient samples. b. Lack of consistency in entering patient demographics such as name and/or sample ID into the Tosoh analyzer software when running the samples. 2. Record review on 1/19/22 of the the laboratory's procedure manual revealed it did not specify what patient demographics are to be entered into the Tosoh analyzer software when running patient samples. 3. Staff interview with testing personnel#1 on 1/19/22 at 10:45 AM confirmed the above findings.
D5433	MAINTENANCE AND FUNCTION CHECKS

	CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document maintenance(s) for laboratory equipment(s) to ensure accurate and reliable test results. Findings include: 1. Record review on 1/19/22 of the preventive maintenance (PM) log revealed evidence of annual PM for the following three microscopes were not available for 2020 and 2021. a. Olympus CX43RF with SN# OE55739. b. Nikon SM21500 with SN# 1005535. c. Olympus inverted microscope with SN# 7M21014. 2. The laboratory did not have a policy detailing the PM frequency for the microscopes in use. 3. Staff interview with the testing personnel (TP) #1 on 1/19/22 at 2:00 PM confirmed that annual PM and function checks for the above laboratory equipment(s) were overlooked and not performed in 2020 and 2021.
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 record review and staff interview, the laboratory failed to evaluate control results to detect any outliers, shifts or trends in control values due to instrument malfunctions or changes in the analytical system in the sub-specialty of endocrinology. Findings include: 1. Record review of the laboratory's Quality Control (QC) log for endocrinology tests on 1/19/22 revealed the laboratory did not have documentation of QC review by the laboratory director (LD) and/or technical consultant for statistical evaluation to identify trends and/or shifts. 2. The laboratory did not have a policy in place to evaluate and identify trends and/or shifts in QC data. 3. Staff interview with the LD and testing personnel #1 on 1/19/22 at 11:30 AM confirmed the above findings. 4. The laboratory performs 5,100 endocrinology tests (Follicle stimulating hormone, Luteinizing hormone, Beta human chorionic gonadotropin, Estradiol and Progesterone) annually.

D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to establish a mechanism in place to ensure manually transcribed results were reported accurately. Findings include: 1. Record review of the laboratory's 'Endocrinology Accession Log' on 1/19/22 revealed the following. a. Endocrinology test results obtained from Tosoh instrument were manually transcribed into the laboratory's electronic medical record system. b. Lack policy and/or documentation for manual entry audits for verification of the accuracy of the manually transcribed test results. 2. Staff interview with the testing personnel #1 on 1/19/22 at 12:30 PM confirmed the above findings. 3. The laboratory performs 5,100 endocrinology tests (Follicle stimulating hormone, Luteinizing hormone, Beta human chorionic gonadotropin, Estradiol and Progesterone) annually.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory director (LD) failed to review and/or take remedial action when unacceptable Proficiency Testing (PT) scores were received in the subspecialty of endocrinology. Findings include: 1. Record review of American Association of Bioanalysts PT evaluation report on 1/19 /22 revealed the laboratory obtained a 50% score for the analyte Progesterone in the second event (Q2) in 2021. 2. Record review on 1/19/22 of the above PT failure investigation/remedial action report revealed it was not reviewed and/or approved by the LD to prevent recurrence. 3. The laboratory performs 5,100 endocrinology tests (Follicle stimulating hormone, Luteinizing hormone, Beta human chorionic gonadotropin, Estradiol and Progesterone) in the subspecialty of endocrinology. Based on record review and staff interview the laboratory failed to establish a mechanism in place to ensure manually transcribed results were reported accurately. Findings include: 1. Record review of the laboratory's 'Endocrinology Accession Log' on 1/19/22 revealed the following. a. Endocrinology test results obtained from Tosoh

	instrument were manually transcribed into the laboratory's electronic medical record system. b. Lack policy and/or documentation for manual entry audits for verification of the accuracy of the manually transcribed test results. 2. Staff interview with the testing personnel #1 on 1/19/22 at 12:30 PM confirmed the above findings. 3. The laboratory performs 5,100 endocrinology tests (Follicle stimulating hormone, Luteinizing hormone, Beta human chorionic gonadotropin, Estradiol and Progesterone) annually.