

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D2193615	(X3) Date Survey Completed 05/07/2026
Name of Provider or Supplier Rejuvenating Fertility Center, PLLC	Street Address, City, State 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
D0000	An on-site validation survey was conducted on May 07, 2026 with the following standard level deficiencies cited.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form Centers for Medicare and Medicaid Services (CMS) 209, written policies and procedures, and interview with the Clinical Consultant (CC), the laboratory failed to establish written policies and procedures to assess consultant competency for 2 of 2 consultants (TS & CC). Findings Included: 1) Review of the laboratory's Form CMS 209 revealed 1 Technical Supervisor (TS) and 1 CC listed in consultant/supervisory roles. 2) Review of the laboratory's policy titled 'Rejuvenating Fertility Clinic Personnel Competency SOP' did not contain established policy and procedural components to assess consultant competency. 3) In an interview on 5/07/2026 at 10:13 AM, the CC confirmed the laboratory policies and procedures for consultant competencies were not established.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(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: (b)(1) Water quality. (b)(2) Temperature. (b)(3)</p>

Humidity. (b)(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:

I. Based on direct observation, manufacturer's instructions, review of the laboratory's temperature logs, and interview with the Clinical Consultant (CC), the laboratory failed to define room temperature in accordance with manufacturer instructions for the Tosoh Bioscience AIA-Pack Multi-Analyte Controls for 2 of 2 years (2024 and 2025). Findings Included: 1) In direct observation on 5/7/2026 at 10:45 AM in the laboratory, one Tosoh Bioscience Analyzer was observed in use in the testing of Estradiol, Progesterone, Follicle-stimulating hormone (FSH), Luteinizing Hormone (LH), Human chorionic gonadotropin (hCG). 2) Review of the manufacturer's instructions for the Tosoh Bioscience AIA-Pack Quality Control (QC) titled 'AIA-Pack Multi-Analyte Control MAC' stated the following: "Preparation of Reagents ...Add exactly 3.0mL of reagent grade water, put the stopper back on the vial and allow the reconstituted material to stand for at least 30 minutes at 18 to 25 degrees Celsius." 3) Review of the laboratory's temperature logs for 2024 and 2025 titled 'Rejuvenating Fertility Center Quality Control Sheet' revealed a defined acceptable temperature range of 16 to 33 degrees Celsius, with the following dates where recorded temperatures exceeded the manufacturer's upper threshold (June 2025 random review): 6/4/2025, 26 degrees Celsius; 6/5/2025, 27 degrees Celsius; 6/6/2025, 27 degrees Celsius. 4) In an interview on 5/07/2026 at 10:48 AM, the CC confirmed the defined acceptable laboratory room temperature ranges for 2024 and 2025 did not adhere to manufacturer instructions. II. Based on direct observation, manufacturer's instructions, review of the laboratory's freezer temperature logs, and interview with the Clinical Consultant (CC), the laboratory failed to define freezer temperature ranges in accordance with manufacturer instructions for 2 of 2 packages of Bio-Rad Liquicheck Immunoassay Plus Controls. Findings Included: 1) In direct observation on 5/7/2026 at 12:09 PM in the laboratory two packages of Bio-Rad Liquicheck Immunoassay Plus Controls were observed (Lot Number 1003960) in the freezer (Serial Number #VSA0950766), with manufacturer storage temperature requirements of -70 to -20 degrees Celsius. 2) Review of the laboratory's freezer temperature logs within the document titled 'Rejuvenating Fertility Center Quality Control Sheet' revealed a defined acceptable temperature range of -20 to -5 degrees Celsius for the Freezer. During a random review, in June 2025, all 23 testing days the laboratory was open, the temperature range was recorded less than -20 degrees Celsius (ranging from -16.8 to -13.3 degrees Celsius). 3) In an interview on 5/07/2026 at 12:10 PM, the CC confirmed the defined acceptable freezer temperature ranges were not in accordance with manufacturer storage requirements.