Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2255259	(X3) Date Survey Completed 09/09/2024
Name of Provider or Supplier Fairfield Obgyn	**Street Address, City, State** 27150 Highway 290 Ste 500, Cypress, TX	

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 announced survey of the laboratory was conducted on 09/09/2024. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories) for the specialties/subspecialties for which it was surveyed. STANDARD LEVEL DEFICIENCIES were cited.
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 review of laboratory's policies/procedures, personnel records and staff interview, the laboratory failed to follow its own policy to document annual competency assessment for 1 of 3 testing personnel performing testing in 2023, testing person number one (TP1). Findings included: 1. Review of laboratory's policy "Initial Training &(and) Competency Assessment" (effective May 2024), revealed: "Evaluating and documenting competency of personnel responsible for testing is required at least semiannually during the first year the Testing Personnel tests patient specimens. Thereafter, Competency Assessment (CA) must be performed at least annually unless test methodology or instrumentation changes." 2. Review of laboratory's personnel records revealed TP1's last competency assessment as testing personnel was documented on 09/26/2022. There was no competency assessment documented for 2023. 3. In an interview on 09/09/2024 at 0915 hours in the office, the laboratory's Technical Consultant, who also holds the TP1 position (as indicated on submitted Form CMS 209) stated that she does testing but has not had her competency as testing personnel assessed in 2023. This confirmed the findings.
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 review of manufacturer's instructions, laboratory's environmental temperature logs and staff interview, the laboratory failed to ensure room temperature ranges were within manufacturer's specifications for 37 of 41 days reviewed from July and August 2024. Findings included: 1. Review of the "BD MicroProbe Processor Instrument User Manual" (document number MA0106, 2016-04 [08]) revealed: "Environmental Indoor Use Ambient Temperature: 22-28C (Degrees Celsius)" 2. Review of the laboratory's "Temperature Log" from 2024 revealed the laboratory had an established acceptable environmental temperature range for the laboratory of 15-30C or 59-86F (Degrees Fahrenheit). The laboratory failed to ensure room temperature ranges were within manufacturer's specifications of 22-28C or 71.6-82.4 F. 3. Further review of the laboratory's environmental logs revealed the following 37 of 41 days reviewed from July and August 2024 the indoor use temperature was out of the manufacture's acceptable range of 22-28C or 71.6-82.4F: Date: Temperature (F): 07/01/2024 70 07/02/2024 70 07/03/2024 71 07/10/2024 71 07/11/2024 70 07/12 /2024 70 07/15/2024 70 07/16/2024 70 07/17/2024 71 07/18/2024 70 07/19/2024 71 07/22/2024 68 07/23/2024 67 07/24/2024 71 07/25/2024 69 07/29/2024 71 07/30 /2024 70 07/31/2024 68 08/01/2024 67 08/02/2024 67 08/05/2024 65 08/06/2024 65 08/07/2024 68 08/08/2024 68 08/09/2024 68 08/12/2024 69 08/13/2024 68 08/14 /2024 69 08/15/2024 69 08/16/2024 69 08/19/2024 69 08/20/2024 69 08/21/2024 68 08/22/2024 68 08/23/2024 67 08/26/2024 70 08/29/2024 71 4. In an interview on 09 /09/2024 at 1000 hours in the office, the laboratory's Technical Consultant (as indicated on submitted Form CMS 209) confirmed the findings. Key: CMS - Centers for Medicare and Medicaid