Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D1046666	(X3) Date Survey Completed 11/08/2023
Name of Provider or Supplier Main Line Fertility West Chester	**Street Address, City, State** 915 Old Fern Hill Road, West Chester, PA	

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 review of the American Association of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records and interview with the technical consultant (TC), the laboratory director (LD)/designee and testing personnel (TP) failed to sign 2 of 2 AAB-MLE PT attestation statement documents for semen analysis examinations performed in 2022. Findings include: 1. On the day of the survey, 11/08/2023 at 09:28 am, review of AAB-MLE PT records revealed the following 2 of 2 AAB-MLE PT attestation statements were not signed by the LD /designee and TP for semen analysis examinations performed in 2022 : - AAB-MLE Embryology Andrology Fetal S2 2022 - AAB-MLE Embryology Andrology Fetal S1 2022 2. The TS confirmed the findings above on 11/08/23 at 11:00 am.
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 of the laboratory, lack of documentation and interview with the technical consultant (TC), the laboratory failed to monitor and document the room temperature to ensure operating conditions were met for the proper storage of reagents from 01/15/2022 to 11/08/2023. Findings Include: 1. On the day of the survey, 11/08 /2023 at 10:53 am, observation of the laboratory revealed the laboratory failed to monitor and document room temperature for the proper storage of QC reagents (accu-beads+) used for semen analysis examinations from 01/15/2022 to 11/08/2023. 2. The manufacturer's instructions states, "accu-beads+ are packaged in 5 ml aliquots and are stable at room temperature for up to 2 years." 3. The laboratory could not provide documentation of room temperatures from 01/15/2022 to 11/08/2023. 4. The TC confirmed the findings above on 11/08/2023 at 11:00 am.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on observation of the laboratory, lack of documentation, and interview with the technical consultant (TC), the laboratory failed to assess the maintenance/ function checks for 1 of 1 pipette used for semen analysis examinations in the laboratory from 1 /15/2022 to the day of the survey. Findings Include: 1. On the day of survey, 11/08 /2023 at 10:53 am, during a tour of the laboratory the surveyor observed the following 1 of 1 pipettes were due for calibration: - VWR Ergonomic High Performance Pipette SN # 942730792 exp: 02/25/2022. 2. The laboratory could not provide maintenance /function check records for the VWR Ergonomic High Performance Pipette. 3. The laboratory performed 165 semen analysis examinations in 2022 (CMS 116 annual volume). 4. TP #1 confirmed the findings above on 03/23/2023 around 2:30 pm.
D5463	CONTROL PROCEDURES CFR(s): 493.1256(d)(7)(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-- Over time, rotate control material testing among all operators who perform the test. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records and interview the technical consultant (TC), the laboratory failed to over time rotate control material testing between 2 of 6 TP who performed semen analysis examinations from 01/15/2022 to 11 /08/2023. Findings include: 1. On the date of the survey, 11/08/2023 at 09:30 am, review of the laboratory's QC records revealed that 2 of 6 TP (CMS 209 TP #3, and #6) failed to perform QC for semen analysis examinations performed from 01/15 /2022 to 11/08/2023. 2. The TC confirmed the findings above on 11/08/2023 at 11:00 pm.