Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2097188	03/25/2024
Name of Provider or Supplier	**Street Address, City, State**	
Carolinas Fertility Institute Pa	1002 N Church Street, Suite 200, Greensboro, NC	

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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of 2022 and 2023 AAB (American Association of Bioanalysts) proficiency testing records, and interview with TP (testing personnel) #1 on 3/25/24, the laboratory failed to document evaluation of ungraded and unacceptable proficiency testing results for 3 of 4 test events. Findings: Review of the laboratory's "Proficiency Testing" policy revealed "... m. ...a) All data is reviewed by the Lab Director. Any results not in agreement with correct PT outcomes as communicated by the testing entity upon conclusion of the cycle of national testing for that period are discussed. ... b) All comments and reviews are to be documented in writing and added to the PT evaluation, which will be signed by the Laboratory Director. ... f) If PT challenges are not graded for reasons including (but not restricted to): Lack of consensus or 'educational challenge' Corrective Action - We use +/- 3 S.D. from the survey peer group mean, as used in some CAP PTS Evaluation Criteria, to assess PT performance anytime an acceptable range not established by CAP. ..." Review of 2022 and 2023 AAB proficiency testing events revealed the laboratory failed to document evaluation of unacceptable and ungraded results (coded with a ?) on the following events: 1. 2022 S2 event - sample #7 unacceptable for sperm motility - forward progression and ungraded for sperm morphology 2. 2023 S1 event - sample #2 ungraded for sperm motility - forward progression and sample #3 ungraded for sperm morphology 3. 2023 S2 event - sample #7 ungraded for sperm morphology During interview at approximately 10:40 a.m., TP #1 stated he was not aware they needed to evaluate results coded with a ?.
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 the laboratory's policies and procedures, review of 2021, 2022, 2023, and 2024 temperature logs and interview with TP #1 on 3/25/24, the laboratory failed to monitor and document room, refrigerator, and incubator temperatures daily as specified by their procedure. Findings: Review of the laboratory's "Quality Control" procedure revealed "... II. Procedure ... a) Incubator (HERATHERM) Record temperatures daily from thermometer. (Reading: 35-38 degrees C) b) Refrigerator Record temperature everyday. Refrigerator (2-8 degrees C). ... d) Lab Note the room temperature and record on log. (20-25 degree C) ...". Review of 2021, 2022, 2023, and 2024 temperature logs revealed: 1. No documentation of incubator, refrigerator, and room temperatures for the months of May, June, and July 2021 and no documentation of incubator, refrigerator, and room temperatures August 12-31, 2021. 2. No documentation of incubator, refrigerator, and room temperatures in March 2022. During interview at approximately 12:45 p.m., TP #1 stated that he was not employed here during that time. He stated that based on a timeline provided by former employees, the laboratory was performing patient testing during May, June, July, and August 2021 and March 2022.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with TP #1, the laboratory director failed to ensure that the annual competency assessment for 1 of 1 testing personnel was performed by personnel who met the qualification requirements for technical supervisor. Findings: Review of personnel records revealed the annual competency assessment for TP #1 was not performed by the laboratory director who also serves as technical supervisor and general supervisor for the laboratory. Review of personnel records revealed there was no delegation of duties from the laboratory director to other personnel. During interview at approximately 10:35 a.m., TP #1

	confirmed the competency evaluation was not performed by the laboratory director. He stated that one of the testing personnel in a sister facility performed his competency evaluation.
D6177	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3) Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of 2021, 2022, and 2023 logs, and interview with TP #1 on 3/25/24, TP failed to follow the laboratory's procedure for performing quality control on the Makler Chamber. Findings: A. Review of the "Semen Analysis" procedure revealed "... 9. QUALITY CONTROL ... e. Sperm motility, counts, and morphology QC should be performed each day by using the QC videos from AAB. Each day that sperm are counted QC should be performed. ... All QC must be performed prior to testing and releasing the results for patient samples. ..." Review of 2021, 2022, 2023, and 2024 daily quality control logs revealed there was no documentation of daily quality control for June, July, and August 2021. During interview at approximately 12:45 p.m., TP #1 stated that he was not employed here during that time. He stated that based on a timeline provided by former employees, the laboratory was performing patient testing during June, July, and August 2021. B. Review of the "QC Bead Counts" procedure revealed "... II. PROCEDURE ... F. Calculate the concentration of beads according to the counting chamber manufacturer's instructions. G. Repeat steps A-F using a fresh aliquot of beads. H. Compare the two results. If the results are within 10% of each other, then average the two counts. I. The average count should be within the range of the expected values. ... V. QUARTERLY QC Beads should be read on each Makler Chamber on a quarterly basis in order to ensure accuracy of each chamber. Log results into QC logsheet on a quartley basis. ..." Review of the 2023 Quarterly QC Beads logsheets revealed: a. Chamber L - 1/6/23 QC Beads low control readings of 25 and 31, and high control readings of 58 and 66. Both the low and high control readings were not within 10% of each other. b. Chamber J - 12/15/23 QC Beads low control readings of 25 and 30. The low control readings were not within 10% of each other. During interview at approximately 12:55 p.m., TP #1 confirmed that the TP did not make sure the results obtained agreed within 10% of each other before they were averaged.