Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2097188	03/06/2018
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**
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 2016 and 2017 AAB (American Association of Bioanalysts) proficiency testing records and interview with TP (testing personnel) 3/6/18, the laboratory director and testing personnel failed to attest to the integration of proficiency samples into the laboratory's routine patient workload. Review of 2016 and 2017 AAB proficiency testing records revealed the names of the laboratory director and TP who tested the samples were typed on the attestation statement for each event, but the attestation statements had not been signed. During interview at approximately 11:30 a.m., TP #1 stated they were unaware the attestation statements had to be signed.
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 2016 and 2017 AAB (American Association of Bioanalysts) proficiency testing records and interview with the laboratory director 3/6/18, the laboratory failed to document evaluation of all ungraded proficiency testing results. Review of 2016 and 2017 AAB proficiency testing records revealed the key at the

	bottom of the proficiency testing results states "? = This score may not truly evaluate performance for this specimen which was not graded because of lack of participant consensus." Review of 2016 and 2017 AAB proficiency testing records revealed the following ungraded results with no evaluation documented: a. 1 of 2 forward progression samples on the 2016 2nd event; b. 1 of 5 sperm cell identification samples on the 2017 2nd event. During interview at approximately 11:25 a.m., the laboratory director stated they were unaware they needed to evaluate results flagged with "?" (ungraded results).
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: Based on procedure manual review, observation, and interview with TP (testing personnel) 3/6/18, the laboratory's procedure manual was not complete and current for the testing performed. Findings: 1. The procedure manual did not include a procedure for sperm count quality control using QC-Beads. The laboratory obtained two different procedures from their sister facility during the survey: a. The Bioscreen QC-Beads product insert states "... Summary and Explanation: ... It is recommended that the technician perform a quality control check using the two levels of controls each day prior to counting sperm samples. ... Procedure for Manual Counting of QC-Beads: ... 3. Pipette the bead suspension into the counting chamber. ... 6. Count at least 200 beads. 7. Calculate the concentration of beads according to the counting chamber manufacturer's instructions. 8. Repeat steps 1-7 using a fresh aliquot of beads. 9. Compare the two results. If the results are within 10% of each other, then average the two counts. 10. The average count should be within the range of the Expected Values. ..." b. The laboratory's "QC Bead Counts" procedure states "... II. PROCEDURE ... D. Pipette the bead suspension into the counting chamber. ... G. Count the beads in 10 squares. The count should be in the expected range. Repeat above steps if not in range. H. Compare results between two lab personnel. ..." During interview at approximately 12:00 p.m., TP #1 stated that she counts the Lo and Hi QC-Beads in duplicate, but documents only one count. She stated she would repeat the counts if they did not agree. 2. The procedure manual did not include a step-by-step procedure for quality control performed each day of testing for sperm morphology,

	concentration, and motility. During interview at approximately 12:40 p.m., TP #1 stated that the laboratory uses previously tested proficiency samples (videos) for quality control. She confirmed there were no written instructions in the procedure manual for this process. 3. The procedure manual did not include instructions for use of the fertility stuff LeucoScreen Cytochemical Peroxidase Stain observed in the laboratory's refrigerator by the surveyor during a tour of the laboratory at approximately 1:30 p.m. During interview at approximately 1:40 p.m., TP #1 stated that they rarely use it. 4. The procedure manual did not include a step-by-step procedure for intertechnician variability, including the frequency, the criteria for acceptability, and the steps to be taken if the results are unacceptable. The laboratory's "PROFICIENCY TESTING" procedure states "... A. This first testing method, intertechnician variability, is considered an internal monitoring. Much of the semen analysis process is interpretive and can vary from one technician to another. By comparing the results of all the technicians in the laboratory on one sample the lab director can assure consistent reporting from all of the technicians. All results will be kept in the IVF / Andrology Proficiency Testing Manual. ..." 5. The procedure manual did not include instructions for proficiency testing participation, including the correct name of the proficiency testing company (American Association of Bioanalysts {AAB}), evaluation of results (including ungraded), and corrective action. The laboratory's "PROFICIENCY TESTING" procedure states "... The second testing method is an external monitoring system. The laboratory subscribes to the American board of bio analysts (ABB) Proficiency Testing Services. Every six months some samples of dead sperm for concentration evaluation are sent to the lab with some slides for morphology staining and viability staining. Additionally, the lab receives CD's for evaluation of sperm concentration, sperm motility, sperm morphology and embryo morphology. These results are then sent back to ABB and will be compared to all the other participating laboratories. All results will be kept in the ABB binder. ..." 6. The procedure manual did not include the correct acceptable range for refrigerator temperature. The laboratory's "Quality Control Refrigerator" procedure states "... B. Daily Record temperature everyday from the digital max/min thermometer. (-20 degrees C to -25 degrees C) ..." Review of 2018 temperature logs revealed the acceptable range listed at the top of the log was "1-7 degrees C".
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the laboratory director 3/6 /18, the technical supervisor (laboratory director) failed to ensure that 1 of 3 testing personnel (TP #2) was evaluated semiannually during the first year of testing patient specimens. Review of personnel records revealed TP #2 was hired in December 2016 and was trained in December 2016 and January 2017. TP #2 had a competency evaluation documented in November 2017. There were no other records available to document that TP #2's competency was evaluated twice during her first year of testing patient specimens. During interview at approximately 2:55 p.m., the laboratory director confirmed that TP #2 did not have a semiannual competency evaluation during her first year of testing patient specimens. She stated it must have been overlooked.

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 2016, 2017, and 2018 sperm count quality control records, and interview with TP (testing personnel) 3/6/18, testing personnel failed to follow the laboratory's quality control policies and failed to document all quality control activities performed. The procedure manual did not include a procedure for sperm count quality control using QC-Beads. The laboratory obtained two different procedures from their sister facility during the survey: 1. The Bioscreen QC-Beads product insert states "... Summary and Explanation: ... It is recommended that the technician perform a quality control check using the two levels of controls each day prior to counting sperm samples. ... Procedure for Manual Counting of QC-Beads: ... 3. Pipette the bead suspension into the counting chamber. ... 6. Count at least 200 beads. 7. Calculate the concentration of beads according to the counting chamber manufacturer's instructions. 8. Repeat steps 1-7 using a fresh aliquot of beads. 9. Compare the two results. If the results are within 10% of each other, then average the two counts. 10. The average count should be within the range of the Expected Values. ..." b. The laboratory's "QC Bead Counts" procedure states "... II. PROCEDURE ... D. Pipette the bead suspension into the counting chamber. ... G. Count the beads in 10 squares. The count should be in the expected range. Repeat above steps if not in range. H. Compare results between two lab personnel. ..." Review of 2016, 2017, and 2018 sperm count quality control records revealed the laboratory documented one count for the Lo QC-Beads and one count for the Hi QC-Beads each day of testing. There was no documentation that the laboratory tested the QC-Beads in duplicate, evaluated to ensure the results were within 10% of each other, and averaged the counts from 3/1/16 - 3/6/18. During interview at approximately 12:00 p.m., TP #1 stated that she counts the Lo and Hi QC-Beads in duplicate as stated in the Bioscreen QC-Beads product insert, but documents only one count. She stated she would repeat the counts if they did not agree.