Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2122277	08/06/2021
Name of Provider or Supplier	**Street Address, City, State**	
Carolinas Fertility Institute	2614 E 7th Street, Suite C, Charlotte, 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**
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, review of the 2019, 2020, and 2021 AAB(American Association of Bioanalysts) PT (proficiency testing) records and interview with the LD(laboratory director) and TP(testing personnel) 8/6/21, the laboratory failed to maintain all PT records and failed to ensure the laboratory director and testing personnel signed the attestation statement. Findings: The laboratory's Proficiency Testing policy states, "7. Primary records related to PT and alternative assessment testing are retained for 2 years. These include all instrument tapes, work cards, computer printouts, evaluation reports, evidence of review, and documentation of followup/corrective action." Review of the 2019, 2020, and 2021 AAB PT records revealed only the PT evaluation reports were available for review. The laboratory failed to maintain the PT report forms used by the laboratory to record PT results and failed to ensure the laboratory director and testing personnel signed the attestation statement for the following: 1. S1 2019 test event; 2. S2 2019 test event; 3. S1 2020

	test event; 4. S2 2020 test event; 5. S1 2021 test event. During interview at approximately 3 p.m., the LD and TP #2 confirmed the PT report forms and attestation statements were not on file for review.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, review of the QC beads manufacturers' instructions, review of QC(quality control) records, and interview with TP(testing personnel) 8/6/21, the laboratory failed to ensure the results of QC testing were acceptable before reporting patient results for 15 days in 2019, 2020, and 2021. Findings: The laboratory's Makler Chamber QC policy states, "...To ensure that all of our makler chambers are reading accurately they will be QC tested once daily. II. Procedure 1. Use QC beads or Accubeads. Use both high and low standards of these. 2. Aliquot beads onto the Makler and count as usual. Count multiple squares on both sides of the chamber each time. 3. Record high and low on Daily Makler QC worksheet." The QC beads manufacturers' instructions under Procedure for Manual Counting of QC-beads states, "Count the beads using a standard counting procedure for counting sperm....10. The average count should be within the range of the Expected Values. If the results are not within this range, then repeat steps 1-9...." Review of QC records revealed the QC beads QC were outside of the expected values for the Makler Chamber- Hi QC-beads(between 53-67 million beads/mL) and Lo QC-beads (between 25-34 million beads/mL) for the following: 1. 4/28/19- QC beads low count 24; 2. 5/6/19 - QC beads low count 24; 3. 5/13/19- QC beads low count 23; 4. 5/20/19- QC beads low count 23; 5. 5/21/19- QC beads high count 48; 6. 10/7/19- QC beads high count 68; 7. 2/13/20- QC beads high count 69; 8. 2/24/20- QC beads high count 69; 9. 8/27/20- QC beads low count 36; 10. 1/8/21- QC beads high count 52; 11. 1/13/21- QC beads high count 51; 12. 1/20/21- QC beads high count 68; 13. 3/1/21- QC beads low count 35; 14. 3/29/21- QC beads high count 50; 15. 6/22/21- QC beads high count 68. At approximately 1 p.m., TP#2 stated that anytime the QC bead counts are outside of expected values, another TP repeats the counts. There was no documentation on file to show the counts were repeated for the above dates.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of laboratory records, review of personnel records, the absence of documentation, and interview with the Technical Supervisor(director) 8/6/21, the

	Technical Supervisor failed to evaluate the competency of 2 of 4 TP(testing personnel). Findings: Review of laboratory records revealed Memo: Policy on Training and Competency Assessments that states, "....2. Documentation of Competency at 6 months: Six months after the completion of training of the new hire must be monitored for the competency. This means that all the procedures listed on the competency assessment(which is in the on-site file) must be reviewed for the new hire. 3. Documentation of Competency at 12 months and then annually thereafter. The same issues apply to the 12-month as to 6-month." Review of personnel records revealed: 1. The competency for TP#2 had not been evaluated since an annual competency assessment completed 3/30/20, a period of 16 months. 2. Training for TP#3 was completed on 8/24/20. There was no semiannual competency assessment completed for TP#3 during the first year of testing patient specimens. At approximately 3 p.m., the Technical Supervisor confirmed the competency assessments were not completed when they were due.