Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0459459	02/11/2021
Name of Provider or Supplier	**Street Address, City, State**	
Fertility Institute Of New Orleans	800 North Causeway Boulevard, Suite 2c, Mandeville, LA	

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	A Certification survey was performed on February 11, 2021 at Fertility Institute of New Orleans, CLIA ID # 19D0459459. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, 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 direct observation by surveyor, review of personnel records, CMS-209 form, and interview with personnel, the laboratory failed to evaluate competency in 2019 and 2020 for one (1) of three (3) Testing Personnel reviewed per laboratory policy. Findings: 1. Review of the laboratory's "Laboratory Personnel Competency" policy revealed "Each new employee will be assessed initially after training, at six months, 12 months, and then annually on all procedures for which they will be responsible." 2. Direct observation by surveyor on February 11, 2021 at 9:08 am, revealed the Technical Consultant performed laboratory testing. The Technical Consultant served as the testing personnel on the day of the survey. 3. Review of the laboratory's previous CMS-209 form (Laboratory Personnel Report) dated May 14, 2018 revealed the current Technical Consultant was listed as Testing Personnel. 4. Review of personnel records for the Technical Consultant revealed the laboratory did not have documentation of annual competency assessment for his Testing Personnel duties in 2019 and 2020 for endocrinology, urinalysis, and semen analysis testing. 5. In interview on February 11, 2021 at 9:49 am, the Technical Consultant stated he rarely comes to this facility; he was testing due to a loss of employees. The Technical

	Consultant confirmed the laboratory did not perform competency for his duties as Testing Personnel for 2019 and 2020.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of the laboratory's policies, quality control (QC) records, and interview with personnel, the laboratory failed to verify acceptability of new lot numbers and/or shipments of quality control materials utilized for semen analysis. Findings: 1. Observation by surveyor during laboratory tour on February 11, 2021 at 9:08 am revealed the laboratory utilizes Accu-beads as the QC material for semen analysis. 2. Review of the laboratory's "Establishing QC Ranges for Sperm Counting effective 2/9/2020" policy revealed "The Laboratory must verify that the test performance is similar to the control values provided with the external control. The Laboratory must also develop methods of Internal Quality Control to monitor precision for test procedures to determine when testing procedures are outside control limits and not producing acceptable results." 3. Further review of the "Establishing QC Ranges for Sperm Counting" policy revealed a written procedure for establishing bead lot mean and ranges that included a comparison between the laboratory's different locations. Step "n" included the following statement: "Perform the above testing when acquiring a new lot of Accubeads and/or Cell Vision Slides. It is advisable to begin this testing at least a month before a new bead lot or slide lot is put into use." 4. Review of the laboratory's QC records for the Accu-beads revealed the laboratory did not have documentation of performance of the identified QC verification studies for the lot in current use. 5. In interview on February 11, 2021 at 12:06 pm, the Technical Consultant stated the laboratory does not perform the identified procedure. The Technical Consultant further stated he was unaware of the identified procedure. The Technical Consultant confirmed the laboratory did not verify the Accu-bead QC performance of new lots/shipments prior to use.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for

	monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on observation by surveyor, record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures were maintained for assessing personnel competency. Refer to D5209.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that a quality control program was maintained to assure the quality of laboratory testing. Refer to D5469.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on observation by surveyor, record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures were maintained for assessing personnel competency. Refer to D5209.