Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0459459	08/22/2024
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 Recertification Survey was conducted on August 22, 2024 at Fertility Institute of New Orleans CLIA # 19D0459459. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
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 proficiency testing records and laboratory policies as well as interview with personnel, the laboratory failed to ensure the Testing Personnel and Laboratory Director signed the attestation statement for one (1) of six (6) proficiency testing (PT) events reviewed. Findings: 1. Review of proficiency testing records from 2023 and 2024 revealed the Laboratory Director and Testing Personnel did not sign the attestation statement for American Proficiency Institute (API) 2023 Chemistry - Core - 1st Event. 2. Review of the laboratory's "Proficiency Testing" policy under section "Documentation" revealed "The individual testing the PT specimens and the laboratory director or designee will sign the attestation statement that the PT specimens are tested under the same conditions as patient specimens." 3. In interview on August 22, 2024 at 10:44 a.m., the Technical Supervisor stated the Laboratory Director and Testing Personnel sign the attestation form generated once the results are input and transmitted to API, but the results were not transmitted and an attestation form was not generated. He confirmed the attestation statement for the event identified above was not signed by the Laboratory Director and Testing Personnel.

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, review of manufacturers' storage requirements and the laboratory's temperature records, as well as interview with personnel, the laboratory failed to define acceptable room temperature limits within the manufacturers' required ranges for laboratory supplies and reagents for two (2) of two (2) rooms where supplies were stored. Findings: 1. Observation by the surveyor during the laboratory tour on August 22, 2024 at 9:13 a.m. revealed supplies stored in the laboratory and phlebotomy room to include, but not limited to, the following: a) Laboratory - BD Vacutainer C&S Preservative Urine Tube - Manufacturer's storage requirements 4 - 25 degrees Celsius - Copan Transystem sterile transport swab - Manufacturer's storage requirements 5 - 25 degrees Celsius - LeucoScreen Plus - Manufacturer's storage requirements 2 - 25 degrees Celsius - VitalScreen - Manufacturer's storage requirements 2 - 25 degrees Celsius b) Phlebotomy room - BD Vacutainer ACD Solution A Blood Collection Tubes - Manufacturer's storage requirements 4 - 25 degrees Celsius - BD Vacutainer K2EDTA - Manufacturer's storage requirements 4 - 25 degrees Celsius - BD Vacutainer SST Blood Collection Tubes - Manufacturer's storage requirements 4 - 25 degrees Celsius 2. Review of the laboratory's temperature logs from July 2024 revealed the laboratory defined the acceptable room temperature limits for the rooms identified above as 68.0 - 78.8 degrees Fahrenheit (20 - 26 degrees Celsius) which exceeded the manufacturers' upper temperature limits. 3. In interview on August 22, 2024 at 9:20 a.m., the Technical Supervisor confirmed the laboratory's acceptable temperature limits exceeded the manufacturers' requirements as identified above.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure proficiency testing samples are tested as required. Refer to D2009.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413

	The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on observation by surveyors, record review, and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Refer to D2009.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. 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 the laboratory personnel performed test methods as required. Refer to D5413.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS-209 (Laboratory Personnel Report) form, laboratory policies, personnel records, and interview with personnel, the Laboratory Director failed to ensure two (2) of two (2) Testing Personnel had documentation of training prior to patient testing. Findings: 1. Review of the laboratory's CMS-209 revealed the following testing personnel: a) Personnel 2 b) Personnel 3 c) Personnel 4 d) Personnel 5 2. In interview on August 22, 2024 at 10:16 a.m., the Technical Supervisor stated Personnel 4 and Personnel 5 were trained at a sister location in 2023. He further stated they began working at this location in March 2024. 3. Review of personnel records for Personnel 4 and Personnel 5 revealed 2023 training documents with three of the laboratory's locations included at the top of the document but did not indicate which location training occurred. 4. Further review of personnel records for Personnel 4 and Personnel 5 revealed the laboratory did not have documentation of training at this location in 2024. 5. In interview on August 22, 2024 at 10:20 a.m., the Technical Supervisor confirmed the laboratory did not have documentation of training at this laboratory location.
D6112	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451 The technical supervisor is responsible for the technical and scientific oversight of the

	laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Supervisor failed to provide technical and scientific oversight for the laboratory. Refer to D5413.
D6151	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(b)(3)(4) (3) The director or technical supervisor may delegate to the general supervisor the responsiblity for providing orientation to all testing personnel; and (4) Annually evaluating and documenting the performance of all testing personnel. This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS-209 (Laboratory Personnel Report) form and personnel records as well as interview with personnel, the General Supervisor failed to evaluate the competency of one (1) of one (1) testing personnel annually in 2023. Findings: 1. Review of the laboratory's CMS-209 form revealed the Laboratory Director also served as a General Supervisor. 2. Further review of the CMS-209 revealed the following Testing Personnel: a) Personnel 2 - also served as Technical Supervisor, General Supervisor, and Technical Consultant b) Personnel 3 c) Personnel 4 d) Personnel 5 3. Review of personnel records for Personnel 2 revealed he did not have an annual competency performed in 2023. 4. In interview on August 22, 2024 at 12:05 p.m., the Technical Supervisor confirmed he did not have an annual competency performed for his role as Testing Personnel in 2023.