Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0459459	06/17/2026
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 June 17, 2026 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.
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 review of the laboratory's CMS 209 form (Laboratory Personnel Report), policies, and personnel records; and interview with personnel, the laboratory failed to establish a complete written competency assessment policy to include competency assessment of the Clinical Consultant. Findings: 1. Review of the laboratory's CMS-209 (Laboratory Personnel Report) form revealed Personnel 5 served as Clinical Consultant. 2. Review of the laboratory's competency assessment policy revealed the laboratory did not include performance of competency assessment for the Clinical Consultant to include frequency of performance. 3. Review of the personnel records for Personnel 5 revealed a competency was not performed for his role as Clinical Consultant. 4. In interview on June 17, 2026 at 11 a.m., the Laboratory Director stated Personnel 5 started in the role of Clinical Consultant in February 2026. He confirmed the laboratory's policy did not include performance of competency assessments for personnel serving as Clinical Consultant and the laboratory did not perform a competency for the Clinical Consultant.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)

	(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on observation, review of the laboratory's maintenance logs and patient test records, and interview with personnel, the laboratory failed to perform maintenance every two (2) weeks on the Cobas e411 analyzer as required by the manufacturer for three (3) of thirteen (13) biweekly weeks reviewed. Findings: 1. Observation by surveyor during the laboratory tour on June 17, 2026 at 9:45 a.m. revealed the laboratory utilized the Cobas e 411 analyzer for Endocrinology testing. 2. Review of the laboratory maintenance logs for the cobas e 411 analyzer from December 2025 through May 2026 revealed the following maintenance tasks due every two (2) weeks: a) "Clean rinse stations" b) "Perform liquid flow cleaning" 3. Further review of the maintenance logs from December 2025 through May 2026 revealed maintenance was not performed when due every two (2) weeks for the following weeks: a) 12/31/2025 - 01/04/2026 b) 04/02/2026 - 04/08/2026 c) 05/07/2026 - 05/11/2026 4. Review of patient test records revealed the laboratory performed the following volume of patient tests on the Cobas e411: a) 12/31/2025 - 01/04/2026 (forty-one (41) tests performed) b) 04/02/2026 - 04/08/2026 (one hundred eighty-eight (188) tests performed) c) 05/07 /2026 - 05/11/2026 (one hundred twenty-five (125) test performed) 5. In interview on June 17, 2026 at 11:45 a.m., the Laboratory Director confirmed the laboratory did not have documentation of maintenance every two weeks for the weeks identified above.
D6003	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1405 AND 493.1406 The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have had laboratory training or experience consisting of: (b)(2)(ii)(A) At least one year directing or supervising non-waived laboratory testing; and (b)(2)(ii)(B) Have at least 20 CE credit hours in laboratory practice that cover the laboratory director responsibilities defined in 493. 1407; or (b)(3)(i)(A) Hold an earned doctoral degree in a chemical, biological, clinical or medical laboratory science or medical technology from an accredited institution; or (b)(3)(i)(B) Hold an earned doctoral degree; and (b)(3)(i)(B)(1) Have at least 16 semester hours of doctoral level coursework in biology, chemistry, medical technology (MT), clinical laboratory science (CLS), or medical laboratory science (MLS); or (b)(3)(i)(B)(2) An approved thesis or research project in biology/chemistry /MT/CLS/MLS related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and (b)(3)(ii) Have at least 20 CE credit hours in laboratory practice that cover the laboratory director responsibilities defined in 493.1407; and (b)(3)(ii)(A) Be certified

	and continue to be certified by a board approved by HHS; and (b)(3)(ii)(B) Have had at least 1 year of experience directing or supervising nonwaived laboratory testing; or (b)(4)(i)(A) Have earned a master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B)(1) Meet bachelor's degree equivalency; and (b)(4)(i)(B)(2) Have at least 16 semester hours of additional graduate level coursework in biology, chemistry, medical technology, clinical or medical laboratory science; or (b)(4)(i)(C)(1) Meet bachelor's degree equivalency; and (b)(4)(i)(C)(2) Have at least 16 semester hours in a combination of graduate level coursework in biology, chemistry, medical technology, clinical or medical laboratory science coursework and an approved thesis or research project related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and (b)(4)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing; and (b)(4)(iii) Have at least 1 year of supervisory laboratory experience in nonwaived testing; and (b)(4)(iv) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in 493.1407; or (b)(5)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(5)(i)(B) At least 120 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either- (b)(5)(i)(B)(1) 48 semester hours of medical laboratory science or medical laboratory technology courses; or (b)(5)(i)(B)(2) 48 semester hours of science courses that include- (b)(5)(i)(B)(2)(i) 12 semester hours of chemistry, which must include general chemistry and biochemistry or organic chemistry; and (b)(5)(i)(B)(2)(ii) 12 semester hours of biology, which must include general biology and molecular biology, cell biology or genetics; and (b)(5)(i)(B)(2)(iii) 24 semester hours of chemistry, biology, or medical laboratory science or medical laboratory technology in any combination; and (b)(5)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing; and (b)(5)(iii) Have at least 2 years of supervisory laboratory experience in nonwaived testing; and (b)(5)(iv) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in 493.1407. (b)(6) Notwithstanding any other provision of this section, an individual is considered qualified as a laboratory director of moderate complexity testing under this section if they were qualified and serving as a laboratory director of moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with personnel, the Laboratory Director failed to meet the qualifications for a Laboratory Director of moderate complexity testing. Findings: 1. In interview on June 17, 2026 at 10:36 a.m., the Laboratory Director stated he started in the role of Laboratory Director in February 2026. 2. Review of personnel records for the Laboratory Director revealed he did not have documentation of 20 continuing education (CE) credit hours that encompass preanalytic, analytic, and postanalytic phases of testing to assure the laboratory director is qualified for the position. 3. In interview on June 17, 2026 at 10:36 a.m., the Laboratory Director confirmed he did not have the CE credit hours as identified above.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) (e)(6) Ensure the establishment and maintenance of acceptable levels of analytical

	performance for each test system; This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed required maintenance. Refer to D5429.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) (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 record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D5209.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's policies and personnel records and interview with personnel, the Laboratory Director failed to define written job responsibilities for the Laboratory Director and Clinical Consultant. Findings: 1. Review of the laboratory's policies and personnel records revealed the laboratory did not include written job responsibilities for personnel serving as Laboratory Director and Clinical Consultant. 2. In interview on June 17, 2026 at 10:36 a.m., the Laboratory Director confirmed the laboratory did not have a policy for job responsibilities for the Laboratory Director and the Clinical Consultant. II. Based on review of the laboratory's CMS 209 form (Laboratory Personnel Report) and personnel records and interview with personnel, the Laboratory Director failed to delegate, in writing, the responsibilities of the Clinical Consultant to one (1) of one (1) personnel serving in the role. 1. Review of the laboratory's CMS-209 (Laboratory Personnel Report) form revealed Personnel 5 serving as Clinical Consultant. 2. Review of personnel records revealed the laboratory did not have documentation of the Laboratory Director delegating the tasks and responsibilities of Clinical Consultant to Personnel 5. 3. In

	interview on June 17, 2026 at 10:36 a.m., the Laboratory Director confirmed the laboratory did not have documentation of the Laboratory Director delegating the tasks and responsibilities to Personnel 5 as identified above.