Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0459459	02/23/2023
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 February 23, 2023 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.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS-209 (Laboratory Personnel Report) form, personnel records, proficiency testing (PT) records, policies, and interview with personnel, the laboratory failed to ensure that proficiency testing for Hematology and Chemistry testing were performed by personnel who routinely perform laboratory testing for three (3) of six (6) events reviewed. Findings: 1. Review of the laboratory's CMS-209 form and personnel records revealed the following: a) The Technical Consultant does not serve as testing personnel b) No record of Personnel 5 serving as testing personnel at the laboratory 2. Review of the laboratory's "Proficiency Testing" policy 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. Review of the laboratory's American Proficiency Institute (API) proficiency testing results revealed personnel not designated as testing personnel performed proficiency testing for the following three (3) events: a) 2021 Hematology/Coagulation 3rd Event: Technical Consultant (the laboratory did not document the specific samples tested) b) 2022 Chemistry-Core 1st Event: Technical Consultant and Personnel 5 (the laboratory did not document the

	specific samples tested) c) 2022 Chemistry-Core 2nd Event: Technical Consultant and Personnel 5 (the laboratory did not document the specific samples tested) 4. In interview on February 23, 2023 at 10:06 am the Technical Consultant stated he does not serve as testing personnel at the laboratory. The Technical Consultant further stated at 11:51 am that Personnel 5 never served as testing personnel at the laboratory. The Technical Consultant confirmed the laboratory had documentation of non-testing personnel performing proficiency testing.
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 policies, proficiency testing (PT) records, and interview with personnel, the laboratory failed to document the sample sets tested by each testing personnel for three (3) of six (6) testing events reviewed. Findings: 1. Review of the laboratory's "Proficiency Testing" policy revealed "Each step of handling, preparation, processing, and examination of the PT specimens is documented." 2. Review of the laboratory's American Proficiency Institute (API) records for 2021 and 2022 revealed the testing personnel did not document the specific sample set(s) tested for the following events: a) 2021 Hematology /Coagulation 3rd Event: three (3) personnel tested samples on November 18, 2021 b) 2022 Chemistry-Core 1st Event: four (4) personnel tested samples on February 1, 2022 c) 2022 Chemistry-Core 2nd Event: three (3) personnel tested samples on June 6, 2022 3. In interview on February 23, 2023 at 11:51 am, the Technical Consultant confirmed the laboratory did not document the specific proficiency testing samples tested by personnel.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual and interview with personnel, the laboratory failed to have the policies and procedures for testing utilizing the Cobas e411 approved and signed by the current Laboratory Director. Findings: 1. Review of the laboratory's policies for the Cobas e411 analyzer revealed the policies did not include the Laboratory Director's approval/signature for Estradiol (E2), Follicular Stimulating Hormone (FSH), Luteinizing Hormone (LH), Human

	Chorionic Gonadotropin plus Beta (BHCG), Progesterone, Prolactin (PRL), and Thyroid Stimulating Hormone (TSH). 2. In interview on February 23, 2023 at 12:24 PM, the Technical Consultant confirmed that the laboratory director did not approve or sign the policies.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observation, review of test menu and validation records, as well as interview with personnel, the laboratory failed to document complete performance specification verifications for the Cobas e411 Analyzer. Findings: 1. Observation by surveyors on February 23, 2023 at 10:12 a.m. revealed the laboratory utilized the Cobas e411 analyzer. 2. Review of the laboratory test menu revealed the laboratory utilized the Cobas e411 for Estradiol (E2), Follicular Stimulating Hormone (FSH), Luteinizing Hormone (LH), Human Chorionic Gonadotropin plus Beta (BHCG), Progesterone, Prolactin (PRL), and Thyroid Stimulating Hormone (TSH) testing. 3. Review of the "Chemistry Analyzer Validation Summary" revealed the laboratory did not include the following: a) Precision studies with documentation and explanation of exclusion of data points and a summary that matched performance of studies. b) Reportable range with raw data to support verification of lowest achievable value for Estradiol. 4. Further review of the "Chemistry Analyzer Validation Summary" revealed a description of accuracy and between-run precision studies that utilized twenty-four points and between-day precision studies that used "Three levels with different analyte concentrations over at least a 30 day period." This description differed from another document labeled "Precision Study" which stated "Precision was determined by 24 to 30 measurements of different analyte concentrations in control media (Level 1 Level 2, and Level 3),on different days, by three technicians..." The laboratory's "Precision Study" chart included twenty-nine (29) points for level 1, twenty-six (26) points for level 2, and twenty-four (24) points for level 3, except for the analyte LH which had twenty-three (23) points. 5. Further review of the "Chemistry Analyzer Validation Summary" section "Analytical Measuring Range" revealed the laboratory's minimum reportable value for Estradiol was 5.00 pg/mL which is the lowest detectable value according to the manufacturer; however, review of the raw data revealed the laboratory detected 119 pg/mL as the minimum value for Estradiol. 6. In interview February 23, 2023 at 11:51 AM, the Technical Consultant stated he was unable explain why some data was excluded and why some data did not match the studies. He also confirmed the lowest value achieved by the laboratory did not correlate with the lowest value achieved by the manufacturer.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory

	must perform and document 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 by surveyors, review of the laboratory's maintenance logs, and interview with personnel, the laboratory failed to perform weekly maintenance as required by the manufacturer for two (2) of fifty two (52) weeks in 2022 for Chemistry testing. Findings: 1. Observation by surveyors during the laboratory tour on February 23, 2023 at 10:14 am revealed the laboratory utilizes the Cobas e 411 analyzer for Chemistry testing. 2. Review of the laboratory "cobas e 411 analyzer Maintenance Log" revealed the following weekly tasks: a) clean incubator and aspiration station b) clean sipper probe 3. Further review of the Cobas maintenance logs revealed weekly maintenance was not documented for the following: a) February 2022: missing the week of February 7, 2022 b) November 2022: missing the week of November 28, 2022 4. In interview on February 23, 2023 at 3:12 pm, the Technical Consultant confirmed the laboratory did not have documentation of maintenance for the identified weeks.
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, review of the laboratory's policy and procedure manual, test menu, quality control records, and quality control package inserts; as well as interview with laboratory personnel, the laboratory failed to establish their own mean and ranges for chemistry Quality Control (QC) material as required by the manufacturer for twenty-two (22) of twenty-three (23) months. Findings: 1. Observation by surveyors during the tour of the laboratory on February 23, 2023 at 10:12 AM revealed the laboratory maintained a Cobas e411 analyzer. 2. Review of the test menu revealed the laboratory used the Cobas e411 for testing of Estradiol (E2), Follicular Stimulating Hormone (FSH), Luteinizing Hormone (LH), Human Chorionic Gonadotropin plus Beta (BHCG), Progesterone, Prolactin (PRL), and Thyroid Stimulating Hormone (TSH). 3. Review of the laboratory policy "Quality Controls" revealed the laboratory used "Biorad Lyphochek Assayed Immunoassay Levels 1, 2, and 3" for chemistry quality control. 4. Further review of the "Quality Controls" policy revealed "When a new lot number of control is put into use, the new control is run between 15 and 30 days along with the current lot number of control to verify that the values are falling within then (sic) stated values of the package insert for the

	appropriate control. A new mean and standard deviation is calculated. These values are then used to replace the stated values in the package insert for all chemistry test except AMH. AMH control range from the manufacturer is used as laboratory range because of the cost of Testing (Reagent, Calibrator, and Control) and infrequency of testing." 5. Review of the "Bio-Rad Lyphochek Immunoassay Plus Control Levels 1, 2, and 3" package insert section "Assignment of Values" revealed "It is recommended that each laboratory establish its own acceptable ranges and use those provided only as a guide." 6. Review of the laboratory's quality control records revealed that the laboratory used BioRad's lot specific mean and acceptable range and did not have documentation of establishing its own lot specific mean and range until February 2, 2023. a) Bio-Rad Lyphochek Immunoassay Plus Control, Lot # 40390, Expiration 12 /31/2022, Laboratory put in use 3/20/2021 b) Bio-Rad Lyphochek Immunoassay Plus Control, Lot #40410, Expiration 9/30/2024, Laboratory put in use 5/2/2022 7. In interview on February 23, 2023 at 1:20 PM, the Technical Consultant confirmed the laboratory did not have raw data demonstrating the laboratory's established their own quality control mean and acceptable range prior to February 2023.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on observation, review of the laboratory's policy and procedure manual, test menu, quality control records, and problem logs; as well as interview with laboratory personnel, the laboratory failed to evaluate patient test results since the last acceptable run after quality control failure to determine an adverse effect for five (5) out of six (6) months reviewed for chemistry testing. Findings: 1. Observation by surveyors during the tour of the laboratory on February 23, 2023 at 10:12 a.m. revealed the laboratory maintained a Cobas e411 analyzer. 2. Review of the laboratory's test menu revealed the laboratory used the Cobas e411 for testing of Estradiol (E2), Follicular Stimulating Hormone (FSH), Luteinizing Hormone (LH), Human Chorionic Gonadotropin plus Beta (BHCG), Progesterone, Prolactin (PRL), and Thyroid Stimulating Hormone (TSH). 3. Review of the "Chemistry Controls" and "Quality Controls" policies revealed the laboratory failed to include criteria for review of patients after quality control failure. 4. Review of the laboratory's problem logs revealed recalibration of the following analytes after quality control failures as determined by the testing personnel: 08/10/2021 - Prolactin 08/16/2021 - Prolactin 08 /17/2021 - Prolactin 09/28/2021 - Prolactin 10/29/2021 - Prolactin 06/27/2022 - Follicle Stimulating Hormone 01/05/2023 - Luteinizing Hormone 01/09/2023 - Estradiol 01/31/2023 - Thyroid Stimulating Hormone 5. In interview on February 23, 2023 at 3:00 PM, the Technical Consultant confirmed no patient result look back was performed for dates identified above. He also confirmed the laboratory did not have criteria for patient look backs.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that complete verification procedures were performed. Refer to D5421.
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 samples were tested as required. Findings: 1. The laboratory failed to ensure that proficiency testing for Hematology and Chemistry testing were performed by personnel who routinely perform laboratory testing for three (3) of six (6) events reviewed. Refer to D2007. 2. The laboratory failed to document the sample sets tested by each testing personnel for three (3) of six (6) testing events reviewed. Refer to D2015.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. 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 quality control program was maintained to assure quality laboratory services were provided. Findings: 1. The laboratory failed to establish their own mean and ranges for chemistry Quality Control (QC) material as required by the manufacturer for twenty-two (22) of twenty-three (23) months. Refer

	to D5469. 2. The laboratory failed to evaluate patient test results since the last acceptable run after quality control failure to determine an adverse effect for five (5) out of six (6) months reviewed for chemistry testing. Refer to D5783.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(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 by surveyors, 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) 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 record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D6053.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the Laboratory

	Director failed to ensure that an approved procedure manual for chemistry testing was available to all personnel. Refer to D5407.
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. Findings: 1. The laboratory failed to perform weekly maintenance as required by the manufacturer for two (2) of fifty two (52) weeks in 2022 for Chemistry testing. Refer to D5429.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Technical Consultant failed to ensure performance specification verification studies were complete. Refer to D5421.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Technical Consultant failed to ensure the quality control program was maintained to assure the quality of laboratory testing. Findings: 1. The laboratory failed to establish their own mean and ranges for chemistry Quality Control (QC) material as required by the manufacturer for twenty-two (22) of twenty-three (23) months. Refer to D5469. 2. The laboratory failed to evaluate patient test results since the last acceptable run after quality control failure to determine an adverse effect for five (5) out of six (6) months reviewed for chemistry testing. Refer to D5783.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)

	The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate 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 the laboratory's policies, personnel records, and interview with personnel, the Technical Consultant failed to perform a semi-annual competency assessment as required for one (1) of four (4) testing personnel reviewed. Findings: 1. Review of the laboratory's "Laboratory Personnel Competency" policy revealed "Each new employee will be assessed initially, at six months, 12 months, and then annually on all procedures for which they will be responsible." 2. Review of personnel records revealed Testing Personnel 3 was hired February 1, 2021 and no longer employed as of April 7, 2022. 3. Further review of personnel records for Testing Personnel 3 revealed the laboratory had documentation of an assessment performed April 1, 2021, two months after her initial training, not six months as required. 4. In interview on February 23, 2023 at 11:00 am, the Technical Consultant stated the assessment performed April 1, 2021 was the semi-annual assessment and is unsure why it was performed two months after training, instead of six months. The Technical Consultant confirmed the laboratory did not have documentation of a six month assessment for Testing Personnel 3 as required.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure 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 samples were tested as required. Findings: 1. The laboratory failed to ensure that proficiency testing for Hematology and Chemistry testing were performed by personnel who routinely perform laboratory testing for three (3) of six (6) events reviewed. Refer to D2007. 2. The laboratory failed to document the sample sets tested by each testing personnel for three (3) of six (6) testing events reviewed. Refer to D2015.
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 record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D6127.

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 the laboratory's policies, personnel records, and interview with personnel, the Technical Supervisor failed to ensure performance of a semi-annual competency assessment as required for one (1) of four (4) testing personnel reviewed. Findings: 1. Review of the laboratory's "Laboratory Personnel Competency" policy revealed "Each new employee will be assessed initially, at six months, 12 months, and then annually on all procedures for which they will be responsible." 2. Review of personnel records revealed Testing Personnel 3 was hired February 1, 2021 and no longer employed as of April 7, 2022. 3. Further review of personnel records for Testing Personnel 3 revealed the laboratory had documentation of an assessment performed April 1, 2021, two months after her initial training, not six months as required. 4. In interview on February 23, 2023 at 11:00 am, the Technical Consultant stated the assessment performed April 1, 2021 was the semi-annual assessment and is unsure why it was performed two months after training, instead of six months. The Technical Consultant confirmed the laboratory did not have documentation of a six month assessment for Testing Personnel 3 as required.