Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D1012476	(X3) Date Survey Completed 06/28/2022
Name of Provider or Supplier Fertility Institute Of New Orleans, Apc	**Street Address, City, State** 4770 South I-10 Service Road Suite 201, Metairie, 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 performed on June 28, 2022 at Fertility Institute of New Orleans, APC, CLIA ID # 19D1012476. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of laboratory policies, quality control (QC) records, and interview with personnel, the laboratory failed to retain QC acceptability ranges for at least two (2) years as required for the Roche Cobas e411 analyzer. Findings: 1. Review of the laboratory's "Chemistry Controls" policy revealed "Daily and Monthly Quality Control results/graphs are filed in a readily available location and reatained for the appropriate time period. Control values can be affected by a lot number change of reagent. Before the values can be put into use, the controls are printed for the month up to the point of change." 2. Review of Chemistry controls for April 2021, March 2022, and May 2022 revealed the laboratory did not include the acceptable ranges for the QC. 3. In interview on June 28, 2022 at 1:50 pm, the Technical Consultant stated the ranges for QC listed in the instrument is 3 SD; not their acceptable limit of +/- 2 SD. The Technical Consultant further stated he does not keep documentation of the laboratory's calculated +/-2 SD acceptable limits for previous QC, just while currently in use.
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 policies, personnel training records, and interview with personnel, the laboratory failed to follow their policy related to initial training for three (3) of three (3) Testing Personnel reviewed. Findings: 1. Review of the laboratory's "New Technologist Training" policy, effective date "4/20/2020" revealed "Proper initial training of testing personnel is critical and required before beginning to work in the laboratory. Successful completion of the mock Competency Assessment for each work area (Chemistry, Andrology, Urinalysis) clears the trainee to work independently in the lab, following a sign-off by the Trainer and Laboratory Director. " 2. Review of the laboratory's personnel records revealed the laboratory did not have documentation of the Laboratory Director's sign-off prior to testing for the following three (3) Testing Personnel: a) Technical Consultant (who also serves as Testing Personnel): initial training for the Roche Cobas e411 completed March 8, 2021 b) Testing Personnel 1: Hired June 28, 2021: initial training completed July 9, 2021; initial training for Roche Cobas e411 completed July 30, 2021 c) Testing Personnel 2: Hired July 2021: initial training completed July 13, 2021; initial training for Roche Cobas e411 completed July 19, 2021 3. In interview on June 28, 2022 at 9:30 am, the Technical Consultant confirmed the Laboratory Director did not sign-off on the initial trainings for the identified personnel.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, proficiency tests records, and interview with personnel, the laboratory failed to verify the accuracy of Anti-Mullerian Hormone (AMH) at least twice annually in 2021. Findings: 1. Review of the laboratory's "Proficiency Testing" policy revealed "Proficiency testing (PT) samples are received two or three times a year for all tests performed..." 2. In interview on June 28, 2022 at 8:55 am, the Technical Consultant stated the laboratory added AMH testing in March 2021. 3. Review of the laboratory's proficiency testing records revealed the laboratory did not verify the accuracy of the AMH analyte until 2022. 4. In interview on June 28, 2022 at 9:48 am, the Technical Consultant stated the laboratory went live with AMH testing at the same time the Roche Cobas e411 did. The Technical Consultant stated the laboratory enrolled with the American Proficiency Institute (API) in 2022 for proficiency testing of the AMH analyte. The Technical Consultant confirmed the laboratory did not verify the accuracy of AMH since the instrument's validation in 2021.
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 by surveyor, review of the laboratory's policies, performance verification studies, test menu, and interview with personnel, the laboratory failed to have complete verification studies for Endocrinology testing. Findings: 1. In interview on June 28, 2022 at 8:55 am, the Technical Consultant stated the laboratory added the Roche Cobas e411 instrument and Anti-Mullerian Hormone (AMH) test in March 2021. 2. Observation by surveyor during the laboratory tour on June 28, 2022 at 9:14 am revealed the laboratory utilizes the Roche Cobas e411 for endocrinology testing of the following analytes: estradiol, LH, progesterone, FSH, beta HCG, prolactin, TSH, and AMH. 3. Review of the laboratory's "Test Method Verification" policy revealed the following: a) "According to CLIA regulations, before reporting patient results, laboratories need to verify or establish the performance specifications of all non-waived tests added to the laboratory menu." b) "Start with PRECISION. 20 data points is a standard but minimum is two samples with two different known values, five repetitions. Do not use sample that value is zero. Two repetitions in same run is performed. In a different run on same day the 3rd repetition is performed. On different days, run the 4th and 5th repetition. If possible, have different staff perform the 3rd, 4th, 5th repetitions to check for operator variance." c) Reportable Range: "If samples with very low and very high values were used for precision and accuracy and the results were acceptable, then the reportable range has been verified. If not, use a sample at the low end, one in the middle and one on the higher end of linearity." d) Reference Range: "Lab is required to monitor the applicability of this normal range and make adjustments when necessary. Collect specimens from
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 by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure performance verification studies were complete. Refer to D5421.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii)

	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)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5217.
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 record review and interview with personnel, the Laboratory Director failed to ensure that a quality control program was maintained to assure quality laboratory services were provided. Refer to D3031.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) 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 policies, personnel training records, and interview with personnel, the Laboratory Director failed to ensure three (3) of three (3) Testing Personnel reviewed had appropriate training documentation prior to patient testing. Refer to D5209.
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 record review and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Refer to D3031.
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 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. Refer to D3031.
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 policies, personnel training records, and interview with personnel, the Laboratory Director failed to ensure three (3) of three (3) Testing Personnel reviewed had appropriate training documentation prior to patient testing. Refer to D5209.