Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 19D1064020	**(X3) Date Survey Completed** 04/07/2025
Name of Provider or Supplier Fertility Institute Of New Orleans, Apc	**Street Address, City, State** 8585 Picardy Ave, Ste 418, Baton Rouge, 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 desk review was performed on April 07, 2025 at Fertility Institute of New Orleans, CLIA ID #19D1064020. The following condition level deficiencies were identified: 493.803: Successful Participation 493.1403: Laboratory Director, Moderate Complexity
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of proficiency testing results from the CMS-153D, CMS-155D and American Proficiency Institute (API), the laboratory failed to achieve a score of at least 80% for Endocrinology for two consecutive events, resulting in an initial unsuccessful performance. Refer to D2108.

D2108	ENDOCRINOLOGY CFR(s): 493.843(g) (g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a review of the CASPER 153D & 155D Report and American Proficiency Institute (API) proficiency testing results, the laboratory failed to achieve satisfactory overall score in Endocrinology for two consecutive events, resulting in initial unsuccessful performance. Findings: 1. Review of CASPER 153D & 155D report and proficiency testing results from API revealed the laboratory received an overall score of less than 0% for the following two consecutive events for Endocrinology: a. Event 3 of 2024 received a score of 0% b. Event 1 of 2025 received a score of 0% 2. Further review of PT records revealed the laboratory enrolled in the following Endocrinology analytes: human chorionic gonadotropin (HCG) and thyriod stimulating hormone (TSH).
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to provide overall management and direction. Refer to D6016.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) (e)(4)(i) 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 are tested as required. Findings: 1. The laboratory failed to achieve satisfactory overall score in Endocrinology for two consecutive events, resulting in initial unsuccessful performance. Refer to D2108