Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D1064020	03/20/2024
Name of Provider or Supplier	**Street Address, City, State**	
Fertility Institute Of New Orleans, Apc	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 Recertification survey was performed at Fertility Institute of New Orleans, CLIA ID 19D1064020 on March 20, 2024. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and proficiency testing (PT) records as well as interview with personnel, the laboratory failed to maintain a complete policy for proficiency testing. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not include instructions for review and documentation of PT evaluation results that are ungraded. 2. Review of the laboratory's American Proficiency Institute (API) PT records revealed the following events had ungraded results that were not reviewed by the laboratory: a) 2022 Hematology/Coagulation - 3rd event b) 2023 Hematology/Coagulation - 1st event c) 2023 Hematology/Coagulation - 3rd event 3. In interview on March 20, 2024 at 11:50 a.m., the Technical Supervisor confirmed the laboratory did not include review of ungraded proficiency testing results.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are

	established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. 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 assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D5291.