Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D2176715	03/13/2024
Name of Provider or Supplier	**Street Address, City, State**	
Ohio Fertility Providers Llc	2401 Terra Crossing Blvd Ste 325, Louisville, KY	

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 03/13/2024. The facility was found to not be in compliance with the laboratory requirements of 42 CFR Part 493 with standard deficiencies cited.
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 laboratory policy, College of American Pathologists (CAP) proficiency testing (PT) events (2022 Semen Analysis Events A and B, 2023 Semen Analysis Event A and B), and confirmed in interview, the laboratory failed to have documentation of attestation forms for three (3) of four (4) PT events. Findings include: 1. The laboratory policy titled "Proficiency Testing" stated, "Physical signatures must appear on a paper version of the attestation form. A listing of typed names on the attestation statement does not meet the intent of the requirement. The signature of the laboratory director or designee need not be obtained prior to reporting results to the proficiency testing provider however the testing personnel must obtain the director's signature immediately after submission. In the absence of the director, testing personnel should retain all forms until the director's return." 2. Review of the

	laboratory PT events revealed the following: a. 2022 Event A - No attestation form was provided for review. b. 2022 Event B - No attestation form was provided for review. c. 2023 Event B - No attestation form was provided for review. 3. In an interview on 3/13/2024 at 12:10 PM in the break room, The Laboratory Director (LD) was asked to provide attestation documentation. No documentation was provided. This confirmed the findings.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on review of laboratory policy, College of American Pathologists (CAP) proficiency testing (PT) events (2022 Semen Analysis Event A and B, 2023 Semen Analysis Event A and B), and confirmed in interview, the laboratory director (LD) failed to review Proficiency testing (PT) events for two (2) of four (4) testing events. Findings include: 1. The laboratory policy titled "Proficiency Testing" stated, "The laboratory director must review the results to verify that testing was performed in the same fashion as patient samples, i.e., in singleton , with dilution where required." 2. Review of the laboratory PT events revealed the following: a. 2022 Event A - No LD signature b. 2023 Event A - No LD signature 3. In an interview on 3/13/2024 at 12:10 PM in the break room, the laboratory director (LD) was asked if a review was performed for the PT events. The LD confirmed the PT events were not reviewed for the two (2) testing events. This confirmed the findings.