Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0863212	09/11/2024
Name of Provider or Supplier	**Street Address, City, State**	
Institute Of Reproductive	94 Old Short Hills Rd, Livingston, NJ	

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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: A) Based on surveyor review of Proficiency Testing (PT) records and interview with the General Supervisor 1 (GS1), the laboratory failed to evaluate coded results obtained from the College of American Pathologists (CAP) for Sperm Morphology & Motility Online events A and B in calendar year 2023. The finding includes: 1. The laboratory failed to evaluate Code 26 (Educational Challenge) response from CAP for Sperm Morphology & Motility Online in events A and B of 2023. 2. The CAP reports were written "See attached" but no evaluation was attached. 3. The GS1 as stated on the CMS 209 form confirmed on 9/11/24 at 11:00 am that the laboratory failed to evaluate coded results for Sperm Morphology & Motility. B) Based on surveyor review of PT records and interview with the GS1, the laboratory failed to evaluate coded results obtained from the CAP for Semen Analysis for event A in calendar year 2024. The finding includes: 1. The laboratory failed to evaluate Code 26 (Educational Challenge) response from CAP for Semen Analysis 2. The GS confirmed on 1/30/24 at 11:00 am that the laboratory failed to evaluate coded results for Sperm Morphology & Motility. Note: The laboratory was previously cited for this deficiency on 2/7/23.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4)

	The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on surveyor review of the Accession Log (AL), and interview with the General Supervisor 1 (GS1), the laboratory failed to maintain an accurate record system for Semen Analysis from 11/10/23 to 9/11/24. The findings include: 1. Review of the semen analysis AL revealed that the following samples had no times processed entered on the AL: a) S24-0906-3 b) S23-0827-4 c) S23-1007-4 d) S24-0911-11 2. The GS1 as listed on CMS form 209 confirmed on 9/11/24 at 11:25 am, the laboratory did not maintain an accurate record system.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that 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 surveyor review of the Performance Specification (PS) records and interview with the General Supervisor (GS1) the LD failed to ensure that PS were adequate to perform Endocrinology tests performed on the Cobas Pro-e88 analyzer from 11/1/23 to 9/11/24. The findings include: 1. There was no documented evidence the LD approved and signed the PS for the Cobas Pro-e88 analyzer before it was used for patient testing. 2. The GS1 as stated on the CMS 209 form confirmed on 9/11/24 at 11:15 am, the LD failed to approve the PS before the instrument was put into use.
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 surveyor review of the Proficiency Testing (PT) records and interview with the General Supervisor 1 (GS1), the Laboratory Director (LD) failed to ensure that all Hematology results performed with the College of American Pathologists (CAP) were reviewed and evaluated by the appropriate staff in calendar years 2023 and 2024 The findings include: 1. There was no documented evidence the laboratory reviewed and evaluated coded results for the following events: a) SEMI-A-2024 b) SPCD- A-2023 c) SPCD-B-2023 2. The laboratory was previously cited for this deficiency on 2/7/23. Their plan of correction for this deficiency stated: "The lab director will then compare the test results obtained within the lab to the educational challenge results provided by the CAP, if available. The Director in consultation with senior testing personnel will review the results and determine if any action is appropriate." 2. The GS1 as stated on the CMS 209 form confirmed on 9/11/24 at 11:30 am, the LD did not ensure all PT reports were reviewed.