Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0863212	02/07/2023
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
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: All proficiency testing evaluation and verification activities must be documented. Based on surveyor review of Proficiency Testing (PT) results and interview with the General Supervisor (GS), the laboratory failed to review coded results for Sperm Morphology & Motility and Semen Analysis Testing performed with the College of American Pathologists (CAP) in the calendar years 2021 an 2022. The findings include: 1. The laboratory received a coded result (Code 26 -Educational Challenge) for Forward Progression No in event SPCD-A 2022 specimens SPCD-01 and SPCD-02. 2. The laboratory received a coded result (Code 20 -No appropriate target /response cannot be graded) for Anti-Sperm Ab in event SEM-A 2022 specimens SEM-07 and SEM-09 and event SEM-A 2021 specimen SEM-08. 3. The laboratory received a coded result (Code 27 - Lack of participation or referee consensus) for Anti-Sperm Ab in event SEM-A 2021 specimens SEM-07. 4. There was no documented evidence that coded PT results were reviewed. 5. The GS confirmed on 2/7/23 at 11: 15 am that the laboratory did not review coded PT results. .
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

	This STANDARD is not met as evidenced by: Based on surveyor observation of the Bio-Rad Lyphochek Immunoassay Plus Controls Manufacturers Package Insert (MPI), Control Values (CV) in the COBAS Analyzer and interview with the General Supervisor (GS), the laboratory failed to follow MPI for control values on the date of survey. The findings include: 1) MPI for Bio-Rad Lyphochek Immunoassay Plus Controls Lot 40420 had CV as follows: a. Level 1 Estrodil (E2) 67.7-113 pg/dL b. Level 2 E2 142-206 pg/dL c. Level 3 E2 312-418 pg/dL d. Level 1 Human chorionic gonadotropin (HCG) 3.54-5.73 mIU/mL e. Level 2 HCG 20.1-29.0 mIU/mL f. Level 3 HCG 198-268 mIU/mL g. Level 1 Luteinizing Hormone (LH) 1.23-1.97 mIU/mL h. Level 2 LH 17.8-24.2 mIU/mL i. Level 3 LH 61.4-82.7 mIU/mL j Level 1 Progesterone (PROG) .330-.915 ng/mL k. Level 2 PROG 10.0-11.8 ng/mL 2) CV in the COBAS Analyzer was as follows: a. Level 1 E2 71.59-115.79 pg/dL b. Level 2 E2 150.95-220.95 pg/dL c. Level 3 E2 331.9-441.9 pg/dL d. Level 1 HCG 3.6-5.8 mIU/mL e. Level 2 HCG 20.7-29.07 mIU /mL f. Level 3 HCG 181.3-271.3 mIU/mL g. Level 1 LH 1.29-2.097 mIU/mL h. Level 2 LH 18.75-25.75 mIU/mL i. Level 3 LH 65.49-87.49 mIU/mL j Level 1 PROG .476-1.076 ng/mL k. Level 2 PROG 8.84-12.44 ng/mL 3) The TP confirmed on 2/7/23 at 11:30 am the MPI was not followed.