Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0681031	11/15/2023
Name of Provider or Supplier	**Street Address, City, State**	
Shore Institute For Reproductive Medicine, Pc	106 Grand Avenue, Englewood, 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
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to verify the accuracy of Endocrinology test results obtained from the College of American Pathologists (CAP) in the Calendar years 2022 and 2023. The findings include: 1. The PT program assigned an artificial score of 100%, results were reported with the comments "See Note 20", "Response was not formally graded due to insufficient peer group data. Please see the participant summary for additional information" 2. There was no documented evidence the laboratory verified human chorionic gonadotropin (hCG), Estradiol (E2), Follicle-stimulating hormone(FSH), Luteinizing Hormone (LH), and Progesterone (PRG) in the calendar years 2022, and 2023. 3. The TP confirmed on 11 /15/23 at 1:20 pm that the accuracy of the PT results were not verified and the PT program assigned an artificial score of 100%,
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 review of the Manufacturers Package Insert (MPI), the Quality Control Records (QC) and interview with theTesting Personnel (TP), the laboratory failed to follow the MPI for ACCU-Beads "Manual Counting Procedures" for Semen Analysis from 4/26/21 to the date of the survey. The finding includes: 1. The MPI states: "5. Count another aliquot of the same sample. The results should be within 10% of each other to be considered valid" The TP stated the laboratory does not count another aliquot of the same sample. 2. The TP confirmed on 11/15/23 at 2:30 pm that the laboratory did not follow the MPI.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the lack of Quality Control Verification (QCV) records and interview with the Testing Personnel (TP), the laboratory failed to verify Accu-beads Lot # 232908351 before use for Semen Analyses (SA) tests on the date of survey. The TP confirmed 11/15//23 at 1:15 pm that QC material was not verified before putting in use.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on the lack of a Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to establish a procedure for verifying manually entered results from 4/26/21 to the date of survey. The TP confirmed on 11/15/23 at 1:00 pm that the laboratory did not have the procedure mentioned above.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)

	The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on the lack of a Procedure Manual (PM) and interview with the testing Personnel (TP), the Laboratory Director (LD) failed to establish a Competency Assessment (CA) procedure with all the required elements for Testing Personnel at the time of survey. The TP confirmed on 11/15/23 at 3:00 pm that a CA procedure was not established.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on lack of a Procedure Manual (PM) and interview with the Testing Personnel (TP), Laboratory Director (LD) failed to have an approved PM for Endocrinology and Semen Analysis testing from 4/26/21 to the date of the survey. The TP confirmed on 11/15/23 at 1:10 pm that the LD did not ensure an approved PM was available.