Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0886776	06/07/2023
Name of Provider or Supplier	**Street Address, City, State**	
Shore Institute For Reproductive Medicine	475 Route 70, Lakewood, 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
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to retain graded results for Endocrinology performed with the American Association of Bioanalysts (AAB). The findings include: 1) There were no Graded results for PT events Q2-2022 and Q3-2021. 2) The TP confirmed on 6/7/23 at 10:15 am that all PT graded results were not retained.
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: Based on surveyor review of Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to evaluate coded results obtained from the American Association of Bioanalysts (AAB) for Andrology & Embryology events S1 and S2 2022. The findings include: 1. The laboratory did not evaluate Code ? (This score may not truly evaluate performance for this specimen which was not graded because of a lack of participant consensus) response from AAB for the following: b) Sperm Cell ID sample 3 event S1-2022. c) Sperm Cell ID sample 7 event S2-2022. 2. The TP confirmed on 6/7/23 at 10:30 am that the laboratory failed to evaluate the above mentioned coded results.

D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor observation of Endocrinology reagents and interview with the Testing Personnel (TP), the laboratory failed to discard expired Access Substrate reagent from 5/31/23 to the date of survey. The finding include: 1. Access Substrate reagent Lot 40431 expired 5/31/23. 2. The TP confirmed on 6/7/23 at 11:30 am that the laboratory failed to discard expired reagent.
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 QC material before use for Semen Analyses and endocrinology on the date of survey. The findings includes, 1) There was no documented evidence that QCV was performed on Bio Rad lyphochek immunoassay plus controls lot # 4030. 2) There was no documented evidence that QCV was performed on Accubeads Lot # 211410351 3) The TP confirmed 6/7/23 at 11:15 am that QC material was not verified before putting in use.
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 testing Personnel (TP), the LD failed to ensure that PS were adequate to perform Endocrinology tests performed on the Beckman coulter access 2

	analyzer on the date of survey. The findings include: 1. The laboratory did not verify Patient Normal Range. 2. The laboratory did not verify the Laboratory Information system (LIS). 3. The TP confirmed on 6/7/23 at 11:15 am that not all PS were adequate.