Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0681031	03/19/2025
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
D2123	HEMATOLOGY CFR(s): 493.851(c) (c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Office Manager (OM), the laboratory failed to participate in the Medical Laboratory Evaluation (MLE) PT for the 1st event of 2024 for Andrology tests. The findings include: 1. The laboratory failed to participate in MLE Embryology, Andrology & Fetal S1 2024. 2. The OM confirmed on 3/19/25 at 11:00 am that the laboratory did not participate in the above mention PT event..
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

	This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), Final Reports (FR) and interview with the Office Manager (OM), the laboratory failed to follow the PM for "Semen Analysis" "Instructions" from 4/15/24 to 3/19/25. The findings include: 1. The PM stated "2. Analysis should start within 60 minutes of ejaculation" 2. Five out of five FR's had sample analysis times over one hour after the specimen was colleted. a) Sample 34389 had a collection date and time of 3/5/25 8:00am. Analysis time of 9: 15am. b) Sample 33464 had a collection date and time of 5/24/24 7:55am. Analysis time of 9:49am. c) Sample 32642 had a collection date and time of 5//6/24 9:34am. Analysis time of 11:10am. d) Sample 33256 had a collection date and time of 4/15/24 6:15am. Analysis time of 7:45am. e) Sample 33249 had a collection date and time of 4 /17/24 8:00am. Analysis time of 10:00am 3. The OM confirmed on 3/19/25 at 11:30 am that the laboratory did not follow the PM.
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on surveyor review of the Test Reports (TR) for Semen Analysis and interview with the Office Manager (OM) the laboratory failed to ensure the TR included all the required information from 11/15/23 to 3/19/25. The findings include: 1. TR did not include the name address of the laboratory where Routine Semen analysis was performed. 2. Routine Semen analysis and Krueger Strict Morphology testing are performed at two different laboratories. 3. The FR did not delineate where Routine Semen analysis and Krueger Strict Morphology testing are performed 4. The OM confirmed on 3/19/25 at 12:00 pm, the laboratory failed to ensure the TR included all the required information.