Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0681031	06/14/2018
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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(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 and interview with the Testing Personnel (TP), the laboratory did not complete the "Out of Control form" (OCF) from 6/28/16 to the date of survey. The findings include: 1.The OCF had a five-step procedure for any control outside 2 Standard Deviations (SD). 2. The laboraotry had two controls over 2 SD in March of 2018. 3. The laboratory did not complete the OCF for any controls over 2 SD from 6/28/16 to the date of survey. 4. The TP # 1 listed on CMS form 209 confirmed on 6/14/18 at 11:00 am that the laboratory did not complete the OCF.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor observation of the Quality Control (QC) material and interview

	with the Testing Personnel (TP), the laboratory failed to put open and new expiration dates on Endocrinology controls from 6/28/16 to the date of survey. The findings include. 1. The MPI stated that QC material for Estradiol expired 5 days after opening if stored at 2 to 8 Celsius. a) The TP was not aware that QC material expired 5 days after opening. b) The laboratory did not put open and new expiration dates on Lyphocheck Immunoassay Plus Controls Lot# 40930. 2. The TP #1 listed on CMS form 209 confirmed on 6/14/18 at 11:30 am the laboratory failed to put new and open expiration dates on the control material.