Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0886776	02/01/2018
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
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the General Supervisor (GS), the laboratory failed to take corrective action when two out of three levels of controls were out of range for Human Chorionic Gonadotropin (HCG) test performed on the Immulite analyzer QC records reviewed from July 2017 through November 2017. The findings include: 1. Bio-Rad Lyphocheck Immunoassay Plus Control level 1, and 2 lot number 40320 for HCG test ran on Immulite analyzer were out of range on 11/22/17. 2. A total of 14 patient samples ran and reported. 3. The GS confirmed on 2/1/18 at 1:00 pm that QC the laboratory did not take corrective action on 11/22/17.