Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D1081165	04/01/2022
Name of Provider or Supplier	**Street Address, City, State**	
Long Island Fertility Pllc	8 Corporate Center Drive, Suite 101, Melville, NY	

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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on the review of manufacturer requirement for chemistry analyzer Hitachi Roche Cobas 6000, the laboratory failed to monitor humidity, and establish humidity ranges for the analyzer. Finding: 1. As per user manual of chemistry analyzer Hitachi Roche Cobas 6000, the manufacturer requirement of humidity range is 45-85%. 2. No humidity records were available for review at survey from 12/18/2020 through survey date. 3. Confirmed on an interview with laboratory director on 4/1/2022 approximately 11:00am.
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 the review of thermometer calibration record from 4/17/2019, the thermometer SN#466818 used in heating block has been documented as "discarded out of range". It was confirmed on an interview with laboratory director on 4/1/2022 approximately 11:00am.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual the laboratory failed to establish a written maintenance policy for the microscope used for andrology. Confirmed on an interview with laboratory director on 4/1/2022 approximately 10: 30am.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on of review of the laboratory's QA procedures, lack of the corrective action documentation and an interview with the laboratory director, the laboratory director failed to maintain and perform a QA review every six months in year 2020 and 2021, as required by the QA policy, to identify and take remedial action when problems occur in all aspects of laboratory testing. Refer to: D5429, D5413 and D5415