Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0874288	01/24/2018
Name of Provider or Supplier	**Street Address, City, State**	
New York Fertility Institute	1016 Fifth Avenue, New York, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on a lack of quality control (QC) records, assay range sheets and patient test reports and an interview with the laboratory director, the laboratory failed to retain copies of QC records, manufacturers assay sheets and patient test reports from August 2016 through the date of this survey. FINDINGS: The laboratory director confirmed on January 24, 2018 at approximately 1:45 pm that the laboratory failed to retain the manufacturer's assay sheets, QC and patient test records for the Tosoh AIA 360 endocrinology analyzer for a period of at least two years.
D5543	HEMATOLOGY CFR(s): 493.1269(a)(d) (a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a review of quality control (QC) records, patient worksheets and an interview with the laboratory director, the laboratory failed to test and document the Accubeads QC material. Findings Include: 1. It was confirmed with the laboratory director on January 24, 2018 at approximately 1:00 pm, that the laboratory failed to

	test the QC material each day of patient testing as required by the manufacturer. The laboratory director stated, "Accubeads are performed once a month." 2. Approximately 100 patient specimens were tested and results released during this time period.
D6020	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 the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's QC procedures and records and confirmed in an interview with the laboratory director at the time of the survey, the laboratory director failed to ensure that the QC program was maintained for hematology testing. Refer to: D5543