Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2082475	(X3) Date Survey Completed 02/22/2018
Name of Provider or Supplier Reproductive Medicine Associates Of New York Llp	**Street Address, City, State** 200 West 57th Street 9th Floor, 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
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 a review of procedures and an interview with the laboratory director, the laboratory failed to follow manufacturer's procedures, laboratory procedures and CLIA regulations for performing semen analysis quality control (QC) and patient testing. Finding Include: On February 22, 2018 at approximately 12:45 PM it was confirmed by the laboratory director, that the laboratory failed to follow the Accubeads package insert and CLIA regulations for performing and documenting in duplicate QC testing. The laboratory's QC log sheets were reviewed from August 2016 through the date of this survey and failed to show that Accubead QC were performed in duplicate. This is a repeat citation from the survey of July 18, 2016.
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 QC material each day of patient testing in duplicate. Findings Include: It was confirmed by the laboratory director on Feburary 22, 2018 at approximately 12:45, that the laboratory performs two level of control material. Review of QC records from August 2016 through the date of this survey showed that the laboratory failed to test and document the two levels of Accubeads QC material in duplicate. Approximately 1100 patient specimens were tested and results released during this time period. This is a repeat citation from the survey of July 18, 2016.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based in a review of QC procedures, records and confirmed in an interview by the laboraory dirctor on February 22, 2018 at approximately 1:45 PM that the laboratory director failed to ensure that the QC program for hematology testing was maintained to assure quality laboratory services. Refer to: D5401 and D5443 This is a repeat citation from the survey of July 18, 2016.