

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0920824	(X3) Date Survey Completed 06/28/2018
Name of Provider or Supplier Maureen Moomjy Fertility Gynecology & Reproductive	Street Address, City, State 30 East 60th Street, Suite 1901, 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
D5543	<p>HEMATOLOGY CFR(s): 493.1269(a)(d)</p> <p>(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.</p> <p>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 June 28, 2018 at approximately 12:45 pm, that the laboratory performs two level of control material. Review of QC records from November 2017 through April 14, 2018 showed that the laboratory failed to test and document the two levels of Fertility Solution Brand AQC material in duplicate. Approximately 50 patient specimens were tested and results released during this time period.</p>
D6093	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based in a review of QC procedures, records and confirmed in an interview by the</p>

laboraory director on June 28, 2018 at approximately 12:45 pm the laboratory director failed to ensure that the QC program for hematology testing was maintained to assure quality laboratory services. Refer to: D5543