Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0909225	09/04/2019
Name of Provider or Supplier	**Street Address, City, State**	
Main Line Fertility Fort Washington	467 Pennsylvania Ave, Suite 202b, Fort Washington, PA	

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
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the Siemens Immulite 2000 system analyzer records and interview with the laboratory director (LD), the laboratory failed to perform calibration verification at least once every 6 months on 1 of 1 Siemens Immulite 2000 system analyzer in 2017 and 2018. Findings Include: 1. On the day of survey, 09/04/2019, the laboratory could not provide documentation of calibration verification performed at

	least once every 6 months on 1 of 1 Siemens Immulite 2000 system analyzer used to analyze endocrinology tests in 2017 and 2018. 2. In 2017, (10/12/2017 to 12/31/2017) 5,065 endocrinology patient tests were performed. 3. In 2018, 23,014 endocrinology patient tests were performed. 4. The LD confirmed the findings above on 09/04/2019 around 10:00 am.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records, and interview with laboratory director, the laboratory failed to document QC procedures performed on 122 of 122 post vasectomy semen analysis examinations from 2017 to the date of survey. Findings Include: 1. On the day of survey, 09/04/2019, the laboratory could not provide documentation of QC performed on 122 of 122 post vasectomy semen examinations were performed from 10/12/2017 to 09/04/2019. 2. In 2017, (10/12 /2017 to 12/31/2017) 22 post vasectomy semen examinations were performed. 3. In 2018, 63 post vasectomy semen examinations were performed. 4. In 2019, (01/01 /2019 to 05/29/2019) 37 post vasectomy semen examinations were performed. 5. The LD confirmed the findings above on 09/04/2019 around 10:24 am.