Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 39D0909225	**(X3) Date Survey Completed** 08/20/2024
Name of Provider or Supplier Main Line Fertility Fort Washington	**Street Address, City, State** 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**
D2005	ENROLLMENT CFR(s): 493.801(a)(4) Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act. This STANDARD is not met as evidenced by: Based on review of the laboratory's College of American Pathologists (CAP) proficiency testing (PT) evaluation reports, the laboratory director failed to ensure PT data was released by the PT program (CAP) to the state agency, Pennsylvania Deparment of Health (PA SA) in 2024. Findings include: 1. On the day of the PT desk review survey, 08/20/2024, review of the laboratory's CAP PT evaluation reports revealed the laboratory director failed to ensure PT data was released by CAP to the appropriate state agency (PA SA) in 2024. 2. Further review of the CAP PT evaluation reports revealed the PT results were only copied to CMS in 2024.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-

	approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of the CASPER 155 report and graded results from the proficiency testing (PT) organizations, American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) and College of American Pathologists (CAP) , the laboratory failed to successfully participate in PT for the endocrinololgy analyte: Human chorionic gonadotropin (HCG). Refer to D2107.
D2107	ENDOCRINOLOGY CFR(s): 493.843(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of the CASPER 155 report and graded results from the proficiency testing (PT) organizations, American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) and College of American Pathologists (CAP), the laboratory failed to successfully participate in PT for the endocrinology analyte: Human chorionic gonadotropin (HCG). The laboratory had unsatisfactory scores for the 1st and 2nd Events in 2024. Findings include: Analyte Year Event Score HCG 2024 1 60%. (CAP) HCG 2024 2 60% (AAB-MLE)