

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D0909225	<b>(X3) Date Survey Completed</b>  01/31/2022
<b>Name of Provider or Supplier</b>  Main Line Fertility Fort Washington	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5421</b>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Beckman Unicel Dxl 600 validation records and interview with the Laboratory Director (LD), the laboratory failed to establish criteria for acceptable performance specifications of precision and accuracy for 9 of 9 endocrinology analytes performed on the Beckman Unicel Dxl 600 from 02/14/2020 to 01/31/2022. Findings Include: 1. On the day of survey, 01/31/2022 at 11:15 a.m, review of the of the Beckman Unicel Dxl 600 validation records revealed, the validation performed on 02/14/2020 did not include performance specifications for precision and accuracy for free thyroxine (free T4), free triiodothyronine (free T3), human chorionic gonadotropin (hCG), Follicle-stimulating hormone (FSH), luteinizing hormone (LH), Prolactin (PRL), Progesteron, Estradiol, thyroid stimulating hormone (TSH). 2. From 12/2020 to 01/2022, 74,571 patients were analyzed on the Beckman Unicel Dxl 600. 3. The LD confirmed the findings above on 01/31/2022 at 12:30 p.m..</p>