

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D1063391	(X3) Date Survey Completed 12/21/2022
Name of Provider or Supplier Virginia Fertility & Ivf	Street Address, City, State 4100 Olympia Cir Suite 201, Charlottesville, VA	
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
D0000	An announced CLIA validation survey was conducted at Virginia Fertility and IVF on December 21, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiency cited is as follows:
D5421	<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 a pre-survey review of the Centers for Medicare and Medicaid Services CLIA database (CMS Aspen) and CMS Survey form (CMS 116), a tour, policies, chemistry analyzer performance verification records, lack of documentation, and interviews, the laboratory failed to record an evaluation/verification of precision and reportable range for seven (7) of 7 Roche e411 endocrine analytes after a physical move/installation prior to reporting seven hundred eighty-four (784) patient test results from June 2021 to August 30, 2021. Findings include: 1. During a pre-survey review the inspector noted: CMS Aspen database: Virginia Fertility and IVF reported a physical address change recorded in June 2021 from 595 Martha Jefferson Drive, Suite 390 in Charlottesville, Virginia to the current address of 4100 Olympia Circle, Suite 201 in Charlottesville, Virginia. CMS 116 form: the laboratory director (LD) identified patient endocrine testing for Estradiol, Follicle Stimulating Hormone (FSH), Human Chorionic Gonadotropin (hCG), Luteinizing Hormone (LH),</p>

Progesterone, Prolactin, and Thyroid Stimulating Hormone (TSH). 2. During a tour of the laboratory on 12/21/22 at approximately 10:30 AM, the inspector noted one Roche e411 chemistry analyzer (Serial Number 1591-24) with a patient test menu that matched the CMS 116 information outlined above. The inspector inquired if the analyzer was newly installed and the laboratory director (LD) stated: "This is the same analyzer we had in our previous location. We moved our facility and instrument to this new location in June 2021." 3. Review of the Roche analyzer's performance verification documentation revealed no precision or reportable range evaluation /verification approved by the LD for the timeframe of the installation in the new laboratory location in June 2021. The inspector requested the performance records. The LD provided documentation of running five to ten patient sample correlations on 6/23/21 for the 7 endocrine analytes outlined above with correlations varying from 5 % to 32%. No documentation of a precision or reportable range study was available for review. 4. The inspector inquired of the laboratory protocol for verification/validation. The LD stated on 12/21/22 at approximately 12 noon, "Calibration verification and linearity validation are performed when instructed by the manufacturer, when a major instrument part is changed or after major preventative maintenance, when QC necessitates, or if instrument is moved. We also run linearity every six months. I had the Roche field service in to reinstall the machine after we moved. They did mechanical checks and precision for TSH. They had us do a standard 2 level calibrator assay and QC. We also ran some patient correlation samples but no full, 3 or more levels reportable range check or a precision on all. We did a full linearity for all the tests later in August as part of our routine twice annual linearity check." 5. Review of the patient test logs revealed that the laboratory resulted the following patient endocrine results during the timeframe of the instrument relocation (June 2021) up to the date of a linearity verification on August 30, 2021: hCG - 125; Estradiol - 277; FSH - 30; LH - 53; Progesterone - 147; Prolactin - 17; TSH - 135. 784 patient test values were reported prior to a LD approved evaluation/verification of precision and reportable ranges. 6. An exit interview with the LD on 12/21/22 at approximately 1 PM confirmed the above findings