Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2120210	(X3) Date Survey Completed 03/04/2020
Name of Provider or Supplier Dominion Fertility And Endocrinology	**Street Address, City, State** 4040 North Fairfax Drive - Suite 600, Arlington, 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 Dominion Fertility and Endocrinology on March 4, 2020 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiencies are as follows:
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's protocols, quality control (QC) documentation, patient test logs, and interviews, the laboratory failed to follow the established policy for "Sperm Count QC Assessment" everyday of patient semen analysis testing on two hundred fifty-seven (257) days during the twenty-four (24) months reviewed. Findings include: 1. Review of the laboratory's protocols revealed "Protocol No. 0010.1 - Andrology Quality Management" which stated "1. Sperm Count QC Assessment-Test 1: Everyday that Semen analysis is performed, sperm count quality control (QC) assessment has to be performed." 2. Review of the laboratory's "Quality Assurance for Sperm Count" log sheet from January 2018 until December 2019 revealed a lack of QC documentation for 257 days of patient testing. The surveyor requested documentation of sperm count QC for the 257 days. The laboratory provided no documentation of QC for the 257 days. 3. In an interview with the Laboratory Director (LD) on March 4, 2020 at approximately 11:00 AM, the LD stated "During the CAP inspection in December 2017, the CAP inspector told the staff they did not have to run QC each day of testing. The staff began performing sperm count QC weekly instead of following the procedure to run QC each day of patient

	testing. They did not inform me that the stopped running QC each day of testing and I did not detect it during my reviews. The staff has been instructed to follow the policy to run QC each day of testing." 4. In an exit interview with the Laboratory Director on March 4, 2020 at approximately 12:00 PM, the above findings were confirmed.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) 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. This STANDARD is not met as evidenced by: Based on a tour of the laboratory, review of the laboratory's performance validation records, and interviews, the laboratory failed to evaluate and verify the accuracy, precision and reportable range for Human Chorionic Gonadotropin, (HCG), Estradiol, Progesterone, Lutenizing Hormone (LH), and Follicle Stimulating Hormone (FSH) after moving the Roche Cobas e-411 analyzer to a different location in January 2017. Findings include: 1. During a tour of the laboratory on March, 4, 2020 at approximately 9:30 AM, the surveyor noted a Roche Cobas e-411 used for performing Human Chorionic Gonadotropin, (HCG), Estradiol, Progesterone, Lutenizing Hormone (LH), and Follicle Stimulating Hormone (FSH) testing. The surveyor asked the Laboratory Director (LD) how long they had the instrument. The LD stated "We have had the instrument for awhile. It was moved from our other facility in January 2017." 2. Review of the Roche Cobas e-411 analyzer performance verification documentation revealed a lack of documentation of the verification of accuracy, precision and reportable range for HCG, Estradiol, Progesterone, LH and FSH after the analyzer was moved to a different location in January 2017. The surveyor requested the documentation of the validation records for the Roche Cobas e-411 performed when the instrument was moved in January 2017. The laboratory provided no documentation of validation of the Cobas after moving in January 2017. The laboratory provided documentation of a validation signed by the Laboratory Director on January 14, 2020. At approximately 10:20 AM on March 4, 2020, the Lab Director stated that they had not performed a validation of the Cobas after it was moved to a different location. 3. In an exit interview with the Laboratory Director on March 4, 2020 at approximately 12:00 PM, the above findings were confirmed.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on a review of the laboratory's calibration verification/linearity records, policy manual, College of American Pathologists (CAP) Troubleshooting Guide, and

	interviews, the laboratory failed to establish and follow a corrective action policy for calibration verification/linearity that was coded "different" for one (1) of five (5) analytes analyzed, Estradiol. Findings include: 1. The laboratory utilizes the CAP LN8-B Reproductive Endocrinology Calibration Verification/Linearity kit for annual Estradiol, Follicle Stimulating Hormone (FSH), Human Chorionic Gonadotropin (HCG), Lutenizing Hormone (LH), and Progesterone linearity verification. Review of the LN8-B Reproductive Endocrinology Calibration Verification/Linearity Executive Summary, dated November 5, 2019, revealed a code of "Different" for Estradiol and a "Note: For results Different, see the Calibration Verification Troubleshooting Guide and Investigation Checklist." 2. Review of the laboratory's policy manual revealed a lack of a policy for the corrective action to be taken when a code of "Different" is noted for analytes using the LN8-B Reproductive Endocrinology Calibration Verification/Linearity kit. 3. Review of the CAP "Calibration Verification Troubleshooting Guide" revealed a statement, "This troubleshooting guide provides suggested actions if you receive a calibration verification evaluation of Different, or if your evaluation result is verified over a range that does not include all of your reported results." 4. The surveyor requested documentation of the corrective actions taken for the analyte Estradiol with calibration verification/linearity evaluation of "Different". The laboratory provided no documentation of the corrective actions taken. On March 4, 2020 at approximately 11:30 AM, the Laboratory Director stated, "I reviewed the summary but we did not document any corrective actions." 5. In an exit interview with the Laboratory Director on March 4, 2020 at approximately 12:00 PM, the above findings were confirmed.