Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0670586	(X3) Date Survey Completed 03/20/2024
Name of Provider or Supplier Fairfax County Health Dept Laboratory	**Street Address, City, State** 10310 Layton Hall Drive, Fairfax, 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 recertification survey was conducted at the Fairfax County Health Department Laboratory on March 19-20, 2024 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 deficiency cited is as follows:
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: A. Based on a review of the laboratory's policies and procedures, chemistry Analytical

	Measuring Range (AMR)/linearity validation studies, lack of documentation, and interviews, the laboratory failed to follow their established policy to perform AMR /linearity validation studies, every six months, for one (1) of six (6) AMR/linearity studies for the twenty-two (22) analytes analyzed on the Siemens Atellica chemistry analyzer from 12/28/2022 until the date of the survey on 3/20/2024 (15 months). The findings include: 1. Review of the laboratory's procedures revealed a policy, "Quality Control Policy", with the statements, "The AMR (Analytical Measuring Range) is verified as part of the initial instrument evaluation to ensure the measuring range is as stated by the manufacturer. The AMR must be reverified every six months...." 2. Review of the laboratory's AMR/linearity studies for the Atellica chemistry analyzer from June 2022 until the date of the survey on March 20, 2024 revealed AMR verification studies were performed for 22 analytes on 12/28/2022, 5/15/2023, and 8 /23/2023. The surveyor requested to review the every 6 month AMR/linearity studies for the 22 analytes performed on the Atellica for February 2024. The laboratory provided no documentation to review. The director stated on March 20, 2024 at 10:30 AM, "We have ordered the linearity kit and will perform the studies when the kit arrives. 3. Review of the Atellica test menu revealed the following 22 analytes were analyzed and reported for patients from 8/23/23 until the date of the survey on March 20, 2024: Albumin Alkaline Phosphatase Alanine Aminotranserase Aspartate Aminotransferase Blood Urea Nitrogen Calcium Cholesterol Cholesterol, High Density Lipoprotein Cholesterol, Low Density Lipoprotein Chloride Carbon Dioxide Creatinine Gamma Glutamyl Transferase Glucose Iron Lactate Dehydrogenase Phosphorus Potassium Sodium Total Bilirubin Total Protein Triglyceride Uric Acid 4. In an exit interview with the laboratory director, medical director and quality manager on March 20, 2024 at approximately 2:00 PM, the findings were confirmed. B. Based on a review of the laboratory's policies and procedures, chemistry Analytical Measuring Range (AMR)/linearity validation studies, lack of documentation, and interviews, the laboratory failed to follow their established policy to perform AMR /linearity validation studies, every six months, for six (6) of 6 drugs of abuse analyzed on the Siemens Atellica chemistry analyzer from 12/28/2022 until the date of the survey on 3/20/2024 (15 months). The findings include: 1. Review of the laboratory's procedures revealed a policy, "Quality Control Policy", with the statements, "The AMR (Analytical Measuring Range) is verified as part of the initial instrument evaluation to ensure the measuring range is as stated by the manufacturer. The AMR must be reverified every six months...." 2. Review of the laboratory's AMR/linearity studies for the Atellica chemistry analyzer from June 2022 until the date of the survey on March 20, 2024 revealed the following AMR verification documentation: 6-AM (Herione Marker) performed on 11/23/2022, 4/25/2023, and 8/18/2023 (due 2/2024). Buprenorphine performed 11/29/2022, 4/19/2023, and 9/19/2023 (due 3/2024).. Ethanol performed on 10/27/2022 and 4/6/2023 (due 10/2023). Methadone performed on 12/1/2022, 4/14/2023, and 9/1/2023 (due 3/2024). Phencyclidine performed on 12 /22/2022, 4/14/2023, and 8/15/2023 (due 2/2024). MDMA (Ecstasy) performed on 12 /16/2022, 5/2/2023, and 7/3/2023 (due 1/2024). The surveyor requested to review additional documentation of the every 6 month AMR studies for the analytes listed above. The laboratory provided no documentation for review. 3. In an exit interview with the laboratory director, medical director and quality manager on March 20, 2024 at approximately 2:00 PM, the findings were confirmed.