Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2257480	09/06/2024
Name of Provider or Supplier	**Street Address, City, State**	
Spero Health Virginia Core Lab	5631 S Laburnam Ave, Richmond, 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 Spero Health Virginia Core Lab on September 5 & 6, 2024 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on the review of the policy and procedure (P&P), lab test menu, proficiency testing records (PT), lack of documentation, and interviews, the laboratory failed to review and sign the PT results for 47 of 47 urine toxicology analytes for seven of ten events in 2023 and 2024. Findings include: 1. Review of the policy "Proficiency Testing and Employee Competency" revealed the following statement, "The results will be reviewed by the lab director and/or designee, and any failed results will be investigated, and corrective action taken if necessary to correct the problems." 2. Review of the lab test menu revealed the lab performs toxicology screening via AB Sciex 4500 Triple Quad Liquid Chromatography (LC) - mass spectrometer (MS) analyzer for the following analytes: 6-MAM, alpha-Hydroxyalprazolam, Amphetamine, Alprozolam, Benzoyleconine, Buprenorphine, Carisoprodol, Clonazepam, Codeine, Diazepam, dihydrocodeine, EDDP, Fentanyl, flunitrazepam, Gabapentin, Hydrocodone, Hydromorphone, JWH-018-spice, Lorazapam, MDA, MDEA, MDMA, MDPV, Meperidine, Meprobamate, Methadone, methapmhewtamine, methylphenidate, Morphine, Nordiazepam, Norfentanyl, Norhydrocodone, normeperidine, Noroxycodone, Oxaepam, Oxycodone, Oxymorphone, phentermine, Pregabalin, Tapentadol, Temazepam, Tramadol, Zolpidem, THC-COOH, naloxone, PCP and mytriganine. 3. Review of the College of

	American Pathology (CAP) DMPM, DAI and UDS6 PT records for 2023 and 2024 revealed lack of documentation of review of results by testing personnel, laboratory director or designee for the following events: CAP 2023 DMPM- B and 2024 DMPM-A - no review, CAP 2023 DAI-B and 2024 DAI- A & B- no review, CAP 2023 UDS6- B and 2024 UDS6- A- no review. 4. An exit interview with the general supervisor on 09/06/24 at 11:00 AM confirmed the findings.
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: Based on review of chemistry analyzer calibration records, manufacturer's package insert, lack of documentation and interview, the lab failed to perform calibration verification studies at least every six months for the creatinine analyte for 21 months from 12/01/22 up to the date of survey on 09/05/24. Findings include: 1. Review of the Beckman Coulter AU640 calibration records for the creatinine analyte revealed the laboratory assays two levels of quality control each day of patient testing and the creatinine analyte has a two-point calibration. 2. Review of the manufacturer's package insert (used as a procedure by the laboratory) for the creatinine analytes revealed instructions for the laboratory to develop their own quality control and calibration standards. 3. The inspector requested to review calibration verification documents for the creatinine analyte from 12/01/22 up to the date of survey on 09/06 /24. No documentation was available for review. 4. An exit interview with the general supervisor on 09/06/24 at 11:00 AM confirmed the findings.