Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0942551	03/18/2025
Name of Provider or Supplier	**Street Address, City, State**	
Virginia Pediatric & Adolescent Center Pc	4001 Fair Ridge Dr #301, 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 Virginia Pediatric & Adolescent Medicine on March 18, 2025 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) (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 a laboratory tour, review of the laboratory's policies and procedures, Reichert UNISTAT Bilirubinometer calibration verification records, lack of documentation and interviews, the laboratory failed to establish and follow a policy to perform calibration verification for the Reichert Unistat Bilirubinometer every 6

	months during the twenty-four (24) months reviewed from January 2023 until January 2025. The findings include: 1. During a tour of the laboratory on March 18, 2025, at 9: 00 AM, the surveyor noted a Reichert Unistat Bilirubinometer analyzer in use for Neonatal Bilirubin patient testing. 2. Review of the laboratory's policies and procedures revealed a lack of a policy for the every 6 month performance of calibration verification of the Reichert Unistat Bilirubinometer. 3. Review of the laboratory's Reichert Unistat Bilirubinometer calibration verification records from January 2023 until January 2025 revealed calibration verification was performed on 01 /06/2023, 08/10/2023, 12/22/2023, 06/25/2024 and 12/18/2024. The surveyor requested to review Neonatal Bilirubin calibration verification documentation performed in the timeframe of July 2023. The laboratory provided no further documentation for review. 4. In an exit interview with the technical consultant at 12: 00 PM on March 18, 2025, the findings were confirmed.