Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0221934	05/08/2024
Name of Provider or Supplier	**Street Address, City, State**	
Virginia Pediatric Group	8316 Arlington Blvd #300, 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 Group on May 8, 2024 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows and include the condition: D6063 -42 CFR. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing (PT) documentation, lack of documentation, and an interview, the laboratory failed to retain PT result evaluations and attestation statements signed by the laboratory director (LD) and testing personnel (TP) for nine (9) of ten (10) PT events from September 2022 until May 2024. The findings include: 1. Review of the laboratory's American Academy of Family Physicians (AAFP) and Wisconsin State Laboratory of Hygiene (WSLH) PT documentation, a total of 10 events (AAFP 2022 Event 3, WSLH 2023 HemeReg Events 1, 2, & 3, 2023 Bacti/Viral Event 1, 2023 ChemEndoTx Events 1, 2, & 3, 2024

	HemeReg Event 1 and 2024 ChemEndoTx Event 1) revealed the laboratory failed to retain signed PT result evaluations and attestation statements for the following PT events: AAFP 2022 Event 3 result evaluation lacked LD signature. WSLH 2023 Event 1 HemeReg attestations lacked TP signature. WSLH 2023 Event 1 Bacti/Viral attestations lacked TP signature. WSLH 2023 ChemEndoTx attestations lacked TP signature. WSLH 2023 Event 2 HemeReg attestation lacked LD and TP signatures. WSLH 2023 Event 3 HemeReg result evaluations and attestations lacked LD and TP signatures. WSLH 2023 Event 3 ChemEndoTx result evaluations and attestations lacked LD and TP signatures. WSLH 2024 Event 1 HemeReg result evaluation and attestation lacked LD and TP signatures. WSLH 2024 Event 1 ChemEndoTx result evaluation lacked LD signature. A total of 9 events. The surveyor requested to review the signed PT result evaluations and attestation documentation for the PT events listed above. The laboratory provided no documentation for review. 2. In an exit interview with the technical consultant and testing personnel at approximately 12:30 PM on May 8, 2024, the findings were confirmed.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS-209), available testing personnel records, lack of documentation, and an interview, the laboratory failed to retain documentation of personnel qualifications for one (1) of two (2) new testing personnel responsible for reporting Complete Blood Cell (CBC) counts and neonatal bilirubin (NBil) from March 2023 until December 2023 (See D6065).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), available testing personnel records, lack of documentation, and an interview, the laboratory failed to retain documentation of personnel qualifications for one (1) of two (2) new testing personnel responsible for

	reporting Complete Blood Cell (CBC) counts and Neonatal Bilirubins (NBil) from March 2023 until December 2023 (See Personnel Code Sheet). The findings include: 1. Review of the CMS 209 form revealed the laboratory director identified two new testing personnel (TP), that included TP A, as responsible for resulting CBCs and NBils from March 2023 until December 2023. 2. Review of the available personnel documents for TP A revealed no foreign education equivalency evaluation. Review of the laboratory personnel records revealed TP A was hired in March 2023 with initial training and sign off for patient testing verified/signed by the technical consultant on April 1, 2023. The surveyor requested to review a foreign education equivalency evaluation for TP A. The laboratory provided no documentation for review. 3. In an exit interview with the technical consultant and testing personnel at approximately 12: 30 PM on May 8, 2024, the findings were confirmed.