Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0227781	01/12/2021
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Center-West End	2304 John Rolfe Parkway, 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 for Pediatric Center West End on January 12, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The survey included an entrance interview on 1/6/2021 and virtual record review conducted on 1/8/2021. The inspector noted that the laboratory performs COVID-19 testing and was in compliance with the applicable COVID-19 reporting requirements. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows:
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 2019 and 2020 proficiency testing (PT) documentation, and an interview, the laboratory failed to retain attestation statements signed by the laboratory director (LD) for two (2) of six (6) events and attestations signed by testing personnel (TP) for one (1) of 6 events reviewed. Findings include: 1. Review of the laboratory's 2019 and 2020 College of American Pathologists (CAP) hematology PT documentation, a total of 6 events, revealed: 2020 Event B- no LD signed attestation; 2020 Event C- no LD or TP signed attestations. The inspector requested to review the

	attestation documentation outlined above. No documentation was available for review. 2. In an interview with the lead laboratory TP on 1/12/21, at approximately 3: 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 review of analyzer performance verification documentation, manufacturer's user guide instructions, and an interview, the laboratory director (LD) failed to evaluate and verify the normal values (reference ranges) for Complete Blood Count (CBC) testing of a newly installed hematology analyzer from the installation date of April 3, 2019 to the date of the survey, January 12, 2021. Findings include: 1. Review of the laboratory's instrument validation records revealed a new Abbott Emerald analyzer (Serial Number 007317) installation by Peak Technical Application Specialist occurred on 4/3/19. During the tour of the laboratory on 1/12/21 at approximately 2:30 PM, the inspector requested to review documentation that the laboratory director validated the new instrument's patient normal value ranges prior to patient testing. No documentation was available for review. The primary testing personnel stated at approximately 2:30 PM: "When we replaced our CD 1800 with the Emerald, Peak Services completed the instrument set up for us. I will email our rep and have to follow up with you." 2. Review of the Abbott Emerald user guide for new instrument installation revealed instructions "The patient Reference Range must be validated by the Lab Director". 3. In an interview with the lead laboratory TP on 1/12 /21, at approximately 3:00 PM, the above findings were confirmed.