Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0227482	01/12/2021
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Center One Colonial Place	10571 Telegraph Road - Suite 110, Glen Allen, 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-One Colonial Place 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 1/11/2021. 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:
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report Form (CMS 209), proficiency testing (PT) records, policies, Centers for Medicare and Medicaid Services 2019 Statement of Deficiencies and Plan of Correction Form (CMS 2567), and an interview, the laboratory failed to rotate PT among personnel performing patient complete blood count (CBC) testing in 2019. *REPEAT DEFICIENCY Findings include: 1. Review of the CMS 209 revealed a total of seven (7) laboratory testing personnel (TP) identified as performing non waived hematology testing. 2. Review of the laboratory's College of American Pathologists (CAP) 2019 hematology PT documentation revealed TP A signed attestations and performed the following: 2019 Event B and 2019 Event C. TP A signed and performed two (2) of three (3) events in 2019. (See Personnel Code Sheet) 3. Review of the laboratory's policies revealed a proficiency testing policy that stated "PT samples will be rotated and tested using staff members who routinely performs patient testing". 4. Review of the laboratory director's approved CMS 2567 Plan of

	Correction (dated 10/1/18) revealed a plan: "The lab manager will introduce a schedule that assigns each TP to a testing event so that testing events are not ran repetitiously by the same TP at the same location." 5. In an interview with the lead laboratory TP on 1/12/21 at approximately 10:45 AM, the above findings were confirmed.
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 2020 proficiency testing (PT) documentation, and an interview, the laboratory failed to retain attestation statements signed by the laboratory director (LD) and testing personnel (TP) for one (1) of three (3) events reviewed. Findings include: 1. Review of the laboratory's 2020 College of American Pathologists (CAP) hematology PT documentation, a total of 3 events, revealed no LD or TP signed attestation statements for the following event: 2020 Event A. The inspector requested to review the attestation documentation. No documentation was available for review. 2. In an interview with the lead laboratory TP on 1/12/21 at approximately 10:45 AM, 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 May 5, 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 007318) installation by Peak Technical Application Specialist occurred on 5/7/19. During the tour of the laboratory on 1/12/21 at

	approximately 10:00 AM, 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 10:30 AM: "When we replaced our CD 1800 with the Emerald, Peak Services completed the instrument set up for us. I see a tab for method comparison but will have to check with Peak about the data. I do not have any record that our lab director signed or reviewed that part." 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 10:45 AM, the above findings were confirmed.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of policies and procedures, hematology calibration records, and interviews, the laboratory failed to document Abbott Emerald calibration procedures every six (6) months for Complete Blood Count (CBC) in calendar year 2020. Findings include: 1. Review of the laboratory's Quality Assurance (QA) procedures revealed a policy that stated "calibration frequency for CBC is at least once every six (6) months". 2. Review of the available Abbott calibration documentation from January 2019 to the date of the inspection on 1/12/21, a total of twenty-four (24) months, revealed the following calibration records: 2/11/19, 10/11/19, 4/10/20. The inspector requested to review additional calibration records for the Abbott analyzer in calendar year 2020. No additional calibration documentation was available for review. The lead testing personnel stated, during the virtual record review on 1/11/21 at approximately 11:00 AM, "I will reach out to our service representative at Peak Service to see if they they have additional records of a calibration. I do not have records for other calibrations in 2020." 3. In an exit interview with the lead laboratory TP on 1/12/21 at approximately 10:45 AM, the above findings were confirmed.