Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0227482	08/29/2018
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 at Pediatric Center-One Colonial Place on August 29, 2018 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:
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, and an interview, the laboratory failed to rotate PT among personnel performing patient complete blood count (CBC) testing for the six (6) PT events reviewed. Findings include: 1. Review of the CMS 209 revealed a total of seven (7) laboratory testing personnel (TP). (See attached Personnel Code Sheet.) 2. Review of the laboratory's College of American Pathologists (CAP) hematology PT documentation, a total of six (6) events, revealed that TP A signed and performed the following five (5) events: 2016 Event 3, 2017 Event 1, 2017 Event 2, 2017 Event 3, 2018 Event 1. 3. Review of the laboratory's policies revealed a proficiency testing policy that stated: "PT samples will be tested using staff members who routinely performs patient testing". 4. In an interview with the primary testing personnel at approximately 3:30 PM, it was confirmed that the laboratory failed to rotate the proficiency testing among the personnel performing CBC testing for the six (6) events reviewed as outlined above.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)

	The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on a review of polices and procedures, proficiency testing (PT) records and an interview, the laboratory director failed to document evaluation of and corrective action for two (2) of six (6) PT events reviewed. Findings include: 1. Review of the laboratory policy and procedure manual revealed a quality assurance policy that stated: "the lab director will review and evaluate all unsatisfactory or unacceptable proficiency testing scores". 2. Review of the laboratory's College of American Pathologists (CAP) hematology PT documentation, a total of six (6) events, revealed no evidence of evaluation for the following unacceptable analyte scores: 2016 CAP Event 3: Hematocrit (HCT) FH1-13, MCH FH1-13, MCHC FH1-13; 2017 CAP Event 1: Red Blood Cell (RBC) FH1-03, and FH1-05 (resulting in unsatisfactory 60% score), Hematocrit (HCT) FH1-03, and FH1-05 (resulting in unsatisfactory 60% score), Hemoglobin (HGB) FH1-03, MCH FH1-05. The inspector requested to review documentation that the laboratory evaluated the HCT, MCH, MCHC, RBC, and HGB challenge failures outlined above. Documentation was not available for review. 3. In an interview with the primary testing personnel at approximately 3:45 PM, it was confirmed that the laboratory director failed to document evaluation for the PT performance scores in the two (2) proficiency testing events listed above in 2016 and 2017.