Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0227482	(X3) Date Survey Completed 04/25/2022
Name of Provider or Supplier Pediatric Center One Colonial Place	**Street Address, City, State** 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 unannounced, off-site CLIA proficiency testing desk review was conducted for Pediatric Center One Colonial Place on April 25, 2022 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 (note: the laboratory was not in compliance with the following Condition under 42 CFR part 493 CLIA Regulations: D2016 - 42 CFR. 493.803 Condition: Successful Participation):
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on an off-site desk review of the laboratory's proficiency testing (PT) records

	and interviews, the laboratory failed to attain a score of at least eighty percent of acceptable responses for the Complete Blood Count with Auto Differential module (Cell Identification, Red Blood Cell Count, Hematocrit, Hemoglobin, White Blood Cell Count, Platelet) on two (2) consecutive hematology testing events, reviewed on April 25, 2022, resulting in unsuccessful PT performance. See 2130.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on an off-site desk review of the laboratory's proficiency testing (PT) records and interviews, the laboratory failed to attain a score of at least eighty percent (80%) of acceptable responses for Cell Differential Identification (Cell ID), Red Blood Cell (RBC), Hematocrit (HCT), Hemoglobin (HGB), White Blood Cell (WBC), and Platelet (PLT) counts for two (2) consecutive Complete Blood Count (CBC) hematology testing events resulting in unsuccessful PT performance as reviewed on the date of the inquiry April 25, 2022. Findings include: 1. Desk review of the laboratory's College of American Pathologists (CAP) PT records revealed Cell ID, RBC, HCT, HGB, WBC, and PLT scores of less than 80% for the following 2 consecutive CAP FH-1 Hematology Auto Differentials hematology events: 2021 Event 3 - Hematology Module scored at 0% Unsatisfactory Performance (CBC challenge samples FH1-11, FH1-12, FH1-13, FH1-14, FH1-15 all scored as 0% for Cell ID, RBC, HCT, HGB, WBC, and PLT) 2022 Event 1 - Hematology Module scored at 0% Unsatisfactory Performance (CBC challenge samples FH1-01, FH1-02, FH1-03, FH1-04, FH1-05 all scored as 0% for Cell ID, RBC, HCT, HGB, WBC, and PLT) resulting in unsuccessful PT performance. 2. Interviews on 4/25/22 with the primary testing personnel at approximately 2:00 PM, and lab lead at approximately 4: 30 PM confirmed the above findings.