Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 49D2137771	**(X3) Date Survey Completed** 01/08/2024
Name of Provider or Supplier Children's Clinic Of Fredericksburg, The	**Street Address, City, State** 4532 Plank Road, Fredericksburg, 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 test desk review was conducted for The Children's Clinic of Fredericksburg on January 8, 2024 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 and include the Condition under 42 CFR part 493 CLIA Regulation: D2016 -42 CFR. 493.803 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 American Proficiency Institute's (API) proficiency testing (PT) records (2023 First Event and 2023 Third Event) and

	interview, the laboratory failed to attain a score of at least eighty percent of acceptable responses for White Blood Cell count (WBC), Red Blood Cell count (RBC), Hemoglobin (HGB), Hematocrit (HCT), and WBC Differential (WBC diff) in two (2) out of three (3) Hematology testing events resulting in unsuccessful PT performance. See D2130.
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 interview, the laboratory failed to attain a score of at least eighty percent (80%) of acceptable responses for White Blood Cell count (WBC), Red Blood Cell count (RBC), Hemoglobin (HGB), Hematocrit (HCT), and WBC Differential (WBC Diff) for two (2) of three (3) hematology testing events resulting in unsuccessful PT performance. Findings include: 1. Desk review of the laboratory's American Proficiency Institute (API) PT records revealed WBC, RBC, HCT, HGB, PLT and WBC Diff scores of less than 80% for the following hematology events: 2023 Event 1 - WBC=0%; RBC=0%; HGB=0%; HCT=0%; and WBC diff=0%, Failure to participate; 2023 Event 3 - WBC=40%, RBC=40%, HGB=40%, HCT=40%, and WBC diff=67%, Unsuccessful; resulting in unsuccessful PT performance. 2. In a telephone interview with the Chief Operating Officer on January 8, 2023 at approximately 11:55 AM, the findings were confirmed.