Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2137771	05/22/2025
Name of Provider or Supplier	**Street Address, City, State**	
Children's Clinic Of Fredericksburg, The	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 testing (PT) desk review was conducted for The Children's Clinic of Fredericksburg on May 22, 2025 by the Virginia Department of Health's Office of Licensure and Certification. The survey concluded with an interview with the laboratory's technical consultant on May 22, 2025. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The following deficiencies are a result of the PT desk review of scores obtained from the national database and verified with the proficiency testing company. The facility was found to be out of compliance with the following conditions of the CLIA program: D2016 - 42 CFR. 493.803 Condition: Successful Participation. D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing- Laboratory Director.
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 Center for Medicaid and Medicare Services (CMS) CASPER 0155 report, the laboratory's proficiency testing (PT) records and interview, the laboratory failed to attain a score of at least eighty percent of acceptable responses for Cell Identification (Cell ID)/White Blood Cell Differential (WBC Diff) on two consecutive hematology testing events, reviewed on May 22, 2025, resulting in an initial unsuccessful PT performance. Refer to D2130.
D2130	HEMATOLOGY CFR(s): 493.851(f) (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 Center for Medicaid and Medicare Services (CMS) CASPER 0155 report, 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 Cell Identification (Cell ID)/White Blood Cell differential (WBC diff) for two (2) consecutive Complete Blood Count (CBC) hematology testing events resulting in an unsuccessful PT performance as reviewed on the date of the inquiry May 22, 2025. The findings include: 1. Review of the CMS CASPER 0155 report revealed the following 2 PT events with unsatisfactory scores: Hematology 2024 3rd Event - 0%, Failure to Participate for analyte 0765 Cell ID; Hematology 2025 1st Event - 20% for analyte 0770 WBC Differential. As of 12/28/2024 analyte # 0765 Cell ID was replaced with analyte # 0770 WBC Differential. 2. Desk review of the laboratory's America Proficiency Institute (API) PT records on May 22, 2025 revealed Cell ID/WBC differential scores of less than 80% for the following 2 consecutive hematology CBC events: API 2024 Hematology/Coagulation Event 3: White Blood Cell Differential scored 0%, Failure to Participate; API 2025 Hematology /Coagulation Event 1: White Blood Cell Differential scored 20%; resulting in an unsuccessful PT performance. 3. A telephone interview with the technical consultant on May 22, 2025 at 12:00 PM confirmed the above findings.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on an off-site desk review of the Center for Medicaid and Medicare Services CASPER 0155 report, the laboratory's proficiency testing (PT) records and interview, the laboratory director (LD) failed to provide overall management, direction and quality of the laboratory services provided. Refer to D6016.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)

	(e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on an off-site desk review of the Center for Medicaid and Medicare Services (CMS) CASPER 0155 report, the laboratory's proficiency testing (PT) records, and interview, the laboratory director (LD) failed to ensure the overall quality of the laboratory services provided. The LD failed to ensure successful participation in a Health and Human Services (HHS) approved proficiency testing program. Refer to D2130.