Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2137771	03/19/2019
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 announced CLIA initial survey was conducted at The Children's Clinic of Fredericksburg on March 19, 2019 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiencies are as follows:
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 validation records, manufacturer's validation protocol, patient test logs, and an interview with the Office Manager (OM), the laboratory failed to verify the normal values (reference ranges) for Complete Blood Count (CBC) testing prior to reporting eight hundred twenty-six (826) patient CBC panels from October 16, 2017 to the date of the survey, March 19, 2019. Findings include: 1. Review of hematology analyzer records revealed a new instrument installation, by a Sysmex service technical specialist, occurred on 9/26/17. The inspector noted that the validation documentation contained no verification of the CBC patient normal values by the laboratory for the new Sysmex XP300 (Serial Number B2259). The surveyor requested documentation of the normal range (reference range) verification. No normal value verification documentation was available for review. 2. Review of the Sysmex Automated Analyzer XP-300 Validation Protocol revealed the instruction: "It is the customers responsibility to perform additional studies, following the

	requirements of their accrediting agency. The following protocols are provided: Correlation Studies and Reference Range Verification." 3. Review of the patient test log from the laboratory's electronic medical record revealed that the laboratory had reported 826 CBC reports from 10/16/17 to the date of the survey on 3/19/19. 4. In an exit interview at approximately 1:00 PM, the OM confirmed the findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of manufacturer's operations guide, maintenance logs, and interview with the Office Manager (OM), the laboratory failed to follow manufacturer's instructions for performing and documenting the performance of the Siemens XP-300 Hematology Analyzer's weekly, and monthly maintenance procedures from November 2017 to March 2019. Findings include: 1. Review of the laboratory's Sysmex XP-300 Instructions for Use and maintenance log revealed the following required maintenance procedures: Weekly-Clean SRV Tray; Monthly-Clean RBC and WBC Transducer, Clean Waste Chamber; Quarterly-Clean Sample Rotor Valve (SRV). 2. Review of the XP-300 maintenance logs from November 2017 to the date of the survey March 19, 2019 revealed the following weeks lacked documentation of weekly maintenance: 12/10/17, 3/8/18, 5/13/18, 6/17/18, 7/1/18, 7 /15/18, 8/3/18, 8/10/18, 8/17/18, 8/24/18, 8/31/18, 9/7/18, 9/14/18, 9/21/18, 9/28/18, 10/5/18, 10/19/18, 10/26/18, 11/2/18, 11/9/18, 11/16/18, 11/30/18, 12/7/18, 12/14/18, 12/21/18, 12/28/18, 1/4/19, 1/11/19, 1/18/19, 1/25/19, 2/1/19, 2/8/19, and 2/15/19. The surveyor requested documentation of the performance of the weekly maintenance for the weeks listed above. No documentation was available for review. 3. Review of the XP-300 maintenance logs from November 2017 to the date of the survey March 19, 2019 revealed the following months lacked documentation of monthly maintenance: January 2018 and January 2019. The surveyor requested documentation of the performance of the monthly maintenance. No documentation was available for review. 4. In an exit interview at approximately 1:00 PM, the OM confirmed the findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual, Hematology Quality Control (QC) records and an interview with the Office Manager (OM), the laboratory failed to establish and follow a written policy for an ongoing mechanism to monitor, assess and correct "Accuracy bias codes" identified in the monthly Sysmex Insight QC reports for the XP 300 Hematology analyzer for twelve (12) of seventeen

	(17) monthly reports from October 2017 to March 2019. Findings include: 1. Review of the laboratory's policy and procedure manual revealed a lack of a mechanism to monitor, assess and correct "Accuracy bias codes" identified in the monthly Sysmex Insight QC reports for XP 300 Hematology analyzer from October 2017 to March 2019. 2. Review of the Sysmex Insight Report revealed a section, "Interpreting the Period Report Flags", which stated "SDI values for the following parameter will flag if outside of the established SDI range. You will see the flag in the notes column of the report. This indicates that the analyzer should be monitored. Flagging at +/- 2 SDI range*: RBC, HGB, HCT, MCV, PLT, WBC, and RET. Flagging at +/- 2.5 SDI range*: MCH, MCHC, RDW, NEUT, LYMPH, MONO, EO, BASO, NRBC, IRF, MPV, IG, RET-He, and IPF. If a Accuracy bias flag persists for more than two reporting periods, the bias should be investigated." 3. Review of the monthly Sysmex Insight QC reports revealed the Laboratory Director (LD) reviewed seventeen (17) of seventeen monthly reports. The surveyor noted Accuracy bias codes for the following months and analytes: 10/16/17 to 11/17/17-Accuracy bias code PLT; 11/18/17 to 12/20 /17-Accuracy bias code PLT; 12/06/18 to 01/07/18-Accuracy bias code PLT; 01/08/18 to 02/09/18-Accuracy bias code PLT, WBC, MCV; 02/10/18 to 03/14/18-Accuracy bias code PLT, W-SMV, HCT, WBC, RDW-SD; 05/23/18 to 06/24/18-Accuracy bias codes PLT, MCV, RDW-CV; 06/25/18 to 07/27/18-Accuracy bias codes PLT, MPV, RDW-CV; 07/28/18 to 08/29/18-Accuracy bias codes PLT, MPV; 09/17/18 to 10/19 /18-Accuracy bias code HGB; 11/07/18 to 12/09/18-Accuracy bias codes PLT, MPV; 12/10/18 to 01/11/19-Accuracy bias code MPV; 01/12/19 to 02/13/19-Accuracy bias codes MCV, MCH. A total of 12 of 17 reports with Accuracy bias codes. The surveyor requested documentation of corrective actions taken for the months with "Accuracy bias codes" that persisted for more than 2 reporting periods. No documentation was provided by the laboratory. 4. In an exit interview at approximately 1:00 PM, the OM confirmed the findings.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual and an interview with the Office Manager (OM), the laboratory director failed to establish a written Quality Assessment policy. Findings include: 1. Review of the laboratory's policy and procedure manual revealed no policy for the quality assessment of the analytic system. The surveyor requested to review the laboratory's Quality Assessment policy. No policy was provided by the laboratory. 2. In an exit interview at approximately 1: 00 PM, the OM confirmed the findings
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on the review of the Laboratory Personnel Report (CLIA) (Form CMS-209), personnel records, and interview with the Office Manager (OM), the Laboratory Director (LD) failed to document the review and approval of the initial training and competency assessments for five (5) of the five (5) new testing personnel (TP) from October 2017 until March 2019. Findings include: 1. Review of the CMS 209 Form and personnel records revealed that there were 5 new TP that had training and initial competency assessment documentation from October 2017 until March 2019. 2. Review of the TP initial competency assessment records revealed no evidence of the Laboratory Director's review and approval of the training and competency assessments. (See attached Personnel Code list.) The surveyor requested documentation of the Laboratory Director's review and approval of the Testing Personnel's initial training and competency. No documentation was provided. 3. In an exit interview at approximately 1:00 PM, the OM confirmed the findings.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on the review of the Laboratory Personnel Report (CLIA) (Form CMS-209), personnel records, and interview with the Office Manager (OM), the Technical Consultant (TC) failed to perform annual Hematology competency evaluations for one (1) of two (2) Testing Personnel (TP) in calendar year 2018. Findings include: 1. Review of the laboratory's CMS 209 and personnel records revealed the LD performed the duties of TC and two (2) TP performed Complete Blood Count (CBC) patient testing during calendar year 2018. 2. Review of the testing personnel files revealed TP A's training was completed on 9/26/17 and a semi-annual competency was completed on 4/3/18. No 2018 annual competency for TP A was found. In an interview at approximately 10:30 AM, the OM stated the facility began seeing patients at the end of October 2017 and TP A began testing patients when the facility opened. (See Personnel Code Sheet.) The surveyor requested documentation of TP A's 2018 competency. No documentation was provided. 3. In an exit interview at approximately 1:00 PM, the OM confirmed the findings.