Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2137771	12/14/2022
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 recertification survey was conducted at The Children's Clinic of Fredericksburg on December 14, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The inspector noted that the laboratory performs SARS-CoV-2 (COVID-19) testing and is in compliance with the applicable COVID-19 reporting requirements. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows and include the following Condition under 42 CFR part 493 CLIA Regulation: D5400 - 42 C.F.R. 493-1250 Condition: Analytic Systems, D6000 - 42 C.F.R. 493-1403 Condition: Moderate Complexity Laboratory Director.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a review of the laboratory's policies/procedures, instrument maintenance logs, instrument operation's manual, temperature logs, quality control documentation, patient reports, Centers for Medicare and Medicaid Services Statement of Deficiencies Plan of Correction (CMS-2567 POC), lack of documentation and interviews, the laboratory failed to: 1. monitor and document the laboratory's room temperature and relative humidity for fifty-three of six-hundred fifty-four days reviewed (see D5411); 2. follow their laboratory director approved POC (dated 02/19 /2021) to perform preventative maintenance per manufacturer's instructions (see 5429); 3. document performance of hematology analyzer's daily, weekly and monthly

	preventative maintenance according to manufacturer's instructions (see D5429); **REPEAT DEFICIENCY** 4. perform and document daily quality control materials on the hematology analyzer for five days from March 2021 until December 14, 2022 (see D5447); and 5. ensure the current quality assurance plan identified and addressed analytic issues in the subspecialty of hematology (see D5791).
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of the laboratory's temperature and humidity records, manufacturer requirements, lack of documentation, and interview, the lab failed to monitor and document the room temperatures and relative humidity for fifty-three (53) of six-hundred fifty-four (654) days reviewed from March 1, 2021 to December 14, 2022. Findings include: 1. Review of lab temperature "Environment Log" records revealed a lack of documentation of room temperature and relative humidity recordings for the following days from March 1, 2021 until December 14, 2022: 03/18/2021, 03/21 /2021, 03/22/2021, 04/1/2021, 04/03/2021, 04/07/2021, 04/08/2021, 04/14/2021, 05/09 /2021, 05/28/2021, 06/01/2021, 06/04/2021, 06/06/2021, 06/07/2021, 06/08/2021, 06 /10/2021, 07/01/2021, 07/30/2021, 08/02/2021, 08/11/2021, 08/15/2021, 08/23/2021, 09/02/2021, 09/09/2021, 09/10/2021, 10/08/2021, 10/21/2021, 10/25/2021, 10/26 /2021, 12/19/2021, 01/03/2022, 01/15/2022, 01/26/2022, 02/23/2022, 03/04/2022, 03 /23/2022, 03/30/2022, 04/29/2022, 05/13/2022, 05/14/2022, 06/09/2022, 06/15/2022, 06/16/2022, 06/23/2022, 07/15/2022, 08/14/2022, 08/15/2022, 09/09/2022, 09/11 /2022, 09/22/2022, 10/02/2022, 10/29/2022 and 10/30/2022. Total of 53 days of 654 days reviewed. The surveyor requested to review documentation of the room temperature and relative humidity for the above listed 53 days. The laboratory provided no documentation to review. 2. Review of the Sysmex XP-300 Hematology Instrument operator's guide revealed the required environment temperature range of 59-90 degrees Fahrenheit and humidity range of 10-90%. 3. An exit interview with the operations manager on December 14, 2022 at approximately 12:00 PM 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 the Sysmex XP-300 Hematology instrument maintenance records, 2021 Centers for Medicare and Medicaid Services Statement of Deficiencies Plan of Correction (CMS-2567 POC), lack of documentation, and an interview, the laboratory failed follow their established policy to document performance of the Sysmex XP-300's daily maintenance on 43 days, weekly maintenance for 39 weeks

	and monthly maintenance for 6 months from March 2021 until December 14, 2022. **Repeat Deficiency** Findings include: 1. Review of the laboratory's Sysmex XP-300 Hematology Instrument Instructions for Use and maintenance log revealed the following required maintenance procedures: Daily-Perform Shutdown; Verify Background; Verify Vacuum/Pressure; Check Trap Chamber; Perform Quality Control; Weekly-Clean SRV Tray; Monthly-Clean RBC and WBC Transducer, Clean Waste Chamber; Quarterly-Clean Sample Rotor Valve (SRV). 2. Review of the laboratory's CMS-2567 POC (Laboratory Director approved on 2/17/2021) outlined a corrective action plan that stated "The testing personnel were retrained on the importance weekly, monthly and keeping(sic) track of quarterly maintenance and record keeping, the importance of accurate documentation..." 3. Review of the XP-300 hematology maintenance logs from March 2021 until December 2022 revealed the following days lacked documentation of the daily maintenance: 03/21/2021, 03/22 /2021, 03/24/2021, 07/30/2021, 07/31/2021, 08/01/2021, 09/02/2021, 09/09/2021, 09 /10/2021, 09/12/2021,09/14/2021, 10/10/2021, 10/19/2021, 10/24/2021, 10/25/2021, 10/26/2021, 11/18/2021, 11/21/2021, 12/05/2021, 1/15/2022, 01/26/2022, 2/23/2022, 02/27/2022, 03/04/2022, 03/18/2022, 03/23/2022, 04/18/2022, 05/13/2022, 05/14 /2022, 06/04/2022, 06/15/2022, 06/16/2022, 06/29/2022, 08/14/2022, 08/15/2022, 09 /09/2022, 09/22/2022, 09/23/2022, 09/29/2022, 09/30/2022, 10/2/2022, 10/29/2022 and 10/30/2022. The surveyor requested documentation of the performance of the daily maintenance for the above listed dates. The laboratory provided no documentation of the daily maintenance to review. 4. Review of the XP-300 hematology maintenance logs from March 2021 until December 2022 revealed the following weeks lacked documentation of weekly maintenance: March 2021 - 4 of 4 weeks; July 2021 - 4 of 4 weeks; August 2021 - 4 of 4 weeks; September 2021 - 4 of 4 weeks; October 2021 - 4 of 4 weeks; November 2021 - 4 of 4 weeks; December 2021 - 1 of 4 weeks; January 2022 - 2 of 4 weeks; March 2022 - 1 of 4 weeks; May 2022 - 1 of 4 weeks; June 2022 - 2 of 4 weeks; July 2022 - 2 of 4 weeks; August 2022 - 2 of 4 weeks; September 2022 - 2 of 4 weeks; and October 2022 - 2 of 4 weeks. The surveyor requested documentation of the performance of the weekly maintenance for the weeks listed above. The laboratory provided no documentation of the weekly maintenance to review. 5. Review of the XP-300 maintenance logs from March 2021 until December 2021 revealed the following months lacked documentation of the monthly maintenance: 02/2021, 03/2021, 07/2021, 08/2021. 09/2021 and 04/2022.. The surveyor requested documentation of the performance of the monthly maintenance for the months listed above. The laboratory provided no documentation of the monthly maintenance to review. 6. In an exit interview with the operations manager on December 14, 2022 at approximately 12:00 PM the above findings were confirmed.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of quality control records (QC), laboratory policies and procedures, patient testing records, lack of documentation, and interview, the lab failed to follow

	their established policy and perform daily QC procedures for the Sysmex XP-300 hematology analyzer for five (5) days from 02/23/2021 until 12/14/2022 while reporting 5 patients. Findings include: 1. Review of the daily QC records and patient testing records from 02/23/2021 to 12/14/2022 for the Sysmex XP-300 hematology analyzer revealed a lack of documentation of QC procedures for the following dates and patients reported: 06/04/2021 - 1 patient reported; 07/19/2021 - 1 patient reported; 08/23/2021 - 1 patient reported; 08/27/2021 - 1 patient reported; and 02/23/2022 - 1 patient reported. Total 5 days and 5 patients. The surveyor requested to review the QC documentation for the above listed dates. The laboratory provided no documentation to review. 2. Review of the laboratory's policies and procedures revealed a policy, "Reagents, Controls, PT Testing Kit, etc", which stated "Quality Control low, normal and high are to be run daily." 3. In an exit interview with the operations manager on December 14, 2022 at approximately 12:00 PM, the above findings were confirmed.
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 the review of the laboratory's policies and procedures, quality control (QC) records, patient records, maintenance records, temperature and humidity records and interviews, the laboratory failed to follow their established Quality Assurance (QA) plan and identify and address analytic issues within the specialty of hematology (Cross Reference D5411, D5429 and D5447) from February 2021 until December 14, 2022. Findings include: 1. Review of the laboratory's "Quality Assessment (QA)", policies and procedures, quality control (QC) records, patient records, instrument maintenance records and temperature and humidity records revealed the following analytic issues: -lack of monitoring and documentation of the laboratory's room temperature and relative humidity (see D5411). -lack of documentation of the daily, weekly and monthly maintenance for the Sysmex XP-300 hematology analyzer (see D5429). -lack of documentation of quality control performed on the Sysmex XP-300 hematology analyzer for five days (see D5447). 2. Review of the QA plan revealed the following statements "Review all daily logs monthly which includes room temperature, refrigerator, room humidity and ensure temperatures were within the normal range according to the QC plan and appropriate corrective actions were taken for any temperatures that were out of range. Review and sign daily quality controls (low, normal high) to ensure flags were not shown and has passed accordingly... Ensure the laboratory director has signed all logs including but not limited to: Daily temperature logs, QC daily reports, Weekly and Monthly Maintenance, Bi-annually calibration reports, proficiency test, attestations and results, Corrective actions and testing personnel evaluations and training." 3. Review of available QA records revealed documentation of the monthly reviews by the laboratory director with no documentation of corrective actions taken for the lack of: temperatures and humidity documentation; daily, weekly and monthly hematology analyzer maintenance documentation; and QC documentation. 4. In an exit interview with the operations manager on December 14, 2022 at approximately 12:00 PM the above findings were confirmed.

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 a review of the laboratory's policies and procedures, temperature and humidity records, instrument maintenance documents, quality control (QC) documents, patient records, quality assessment (QA) documents, lack of documentation, and interviews, the laboratory director failed to: 1. ensure Quality Control (QC) policies and procedures were maintained for the non-waived Complete Blood Cell counts performed on the Sysmex XP-300 Hematology Analyzer for 5 days from March 2021 to December 14, 2022 (See D6020); and 2. ensure the established quality assessment plan identified and addressed analytic issues within the specialties of hematology from March 2021 until December 14, 2022 (See D6021).
D6020	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 the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of laboratory's policies and procedures, quality control (QC) documentation, patient records, lack of documentation, and interviews, the Laboratory Director failed to ensure Quality Control (QC) policies and procedures were maintained for the non-waived Complete Blood Cell counts performed on the Sysmex XP-300 Hematology Analyzer for 5 days from March 2021 to December 2022 (See D5447).
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 the review of the laboratory's quality assurance plan, policies and procedures, "Environment logs", Sysmex XP-300 maintenance records, quality control (QC) records, patient records, and interviews, the laboratory director failed to

	ensure the established quality assessment plan identified and addressed analytic issues within the specialties of hematology (See D5791).