

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2137771	(X3) Date Survey Completed 02/10/2021
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 announced off-site CLIA recertification survey was conducted for The Children's Clinic of Fredericksburg on February 10, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The survey included an entrance interview on January 15, 2021 and virtual record review conducted on February 5, 2021. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The Children's Clinic of Fredericksburg is performing SARS-CoV-2 (COVID-19) testing and is in compliance with the applicable COVID-19 reporting requirements. The specific deficiencies are as follows:
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), the laboratory's proficiency testing (PT) records and an interview, the laboratory failed to rotate PT among testing personnel performing Complete Blood Cell counts (CBCs) for three (3) of six (6) PT events from March 2019 until December 2020. Findings include: 1. Review of the CMS Form 209 revealed four (4) testing personnel (TP) performing patient CBC testing in 2019 and 2020. 2. Review of the laboratory's American Proficiency Institute (API) PT documentation from March 2019 to December 2020 (a total of 6 events) revealed TP A performed the following PT Events: 2020 API Hematology/Coagulation Event 1; 2020 API Hematology/Coagulation Event 2; 2020 API Hematology/Coagulation Event 3. 3 of 6 PT events were performed by TP A. (See Personnel Code Sheet.) 3. In an interview with the Operations Manager on February 10, 2021 at approximately 10:45 AM, the above findings were confirmed.</p>

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on the review of Quality Control (QC) package insert, temperature logs and interview, the laboratory failed to follow the manufacturer's storage requirements for Hematology quality control (QC) materials for nine days (9) from March 2019 until December 2020. Findings include: 1. Review of the Sysmex EightChek 3WP Extra Control package insert for storage requirements revealed the quality control materials are to be stored at 2-8 degrees Celsius. 2. Review of the refrigerator temperature logs revealed the following 9 days when the temperatures were outside the acceptable range for the storage of the QC materials: 07/11/2019 = 9 degrees Celsius (C) 08/26/2019 = 9 C 09/02/2019 = 9 C 09/28/2019 = 9 C 09/29/2019 = 9 C 10/01/2019 = 9 C 10/02/2019 = 9 C 10/14/2019 = 9 C 10/17/2019 = 0 C 3. In an interview with the Operations Manager on February 10, 2021 at approximately 11:15 AM, the above findings were confirmed.

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 instrument maintenance records, maintenance log, lack of documentation, and an interview, the laboratory failed to document performance of the Sysmex XP-300's weekly, monthly and quarterly maintenance as required during from March 2019 until December 2020. ****Repeat Deficiency**** 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 hematology maintenance logs from March 2019 until December 2020 revealed the following weeks lacked documentation of weekly maintenance: 3/10/2019, 3/17/2019, 3/24/2019, 3/31/2019, 5/5/2019, 5/12/2019, 6/2/2019, 7/7/2019, 9/15/2019, 9/22/2019, 10/20/2019, 10/27/2019, 11/3/2019, 11/10/2019, 1/6/2020, 2/2/2020, 2/23/2020, 3/2/2020, 3/9/2020, 5/10/2020 and 5/25/2020. The surveyor requested documentation of the performance of the weekly maintenance for the 21 weeks listed above. The laboratory provided no documentation of the weekly maintenance to review. 3. Review of the XP-300 maintenance logs from March 2019 until December 2020 revealed the following months lacked documentation of the monthly maintenance: 3/2019, 4/2019, 11/2019, 12/2019 and 10/2020. The surveyor

requested documentation of the performance of the monthly maintenance for the 5 months listed above. The laboratory provided no documentation of the monthly maintenance to review. 4. Review of the XP-300 maintenance logs from March 2019 until December 2020 revealed the following: 2/2019 quarterly maintenance documented; 5/2019 no quarterly maintenance documented; 8/2019 quarterly maintenance documented by service; 11/2019 quarterly maintenance documented; 2/2020 no quarterly maintenance documented; 5/2020 no quarterly maintenance documented; 8/2020 no quarterly maintenance documented; 11/2020 no quarterly maintenance documented. The surveyor requested documentation of the performance of the quarterly maintenance for the 5 quarters with no maintenance listed above. The laboratory provided no documentation of the quarterly maintenance to review. 5. In an interview with the Operations Manager on February 10, 2021 at approximately 11:00 AM, the above findings were confirmed.