

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2137771	(X3) Date Survey Completed 08/13/2026
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 CLIA recertification survey was conducted at The Children's Clinic of Fredericksburg on August 13, 2026 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The Children's Clinic of Fredericksburg was not in compliance with the applicable Conditions and Standards under 42 CFR part 493 CLIA Regulations. Specific deficiencies are as follows:
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: A. Based on review of laboratory policies and procedures, document review, lab tour and interview, the laboratory failed to retain documentation of laboratory refrigerator temperatures for fourteen (14) of 82 weeks reviewed. Review timeframe January 1, 2025 through July 31, 2026. 1. Review of the laboratory's Quality Control Plan revealed that every morning lab refrigerator temperatures are to be taken and recorded on the daily log. 2. Review of all available 2025 and 2026 Refrigerator Temperature logs revealed no refrigerator temperatures recorded for the four weeks of the following months: January 2025, March 2025, August 2025, and the two weeks of May 1 - 15, 2025. A total of 14 weeks. 3. A tour of the laboratory at 1pm on 8/13/26 confirmed that Hematology quality control vials are stored in the lab refrigerator. 4. In an interview on 8/13/26 at 1:15 pm, the Technical Consultant, Operations manager, and primary testing personnel confirmed the above findings. B. Based on a laboratory tour, policy and procedure and document reviews, and interviews, the laboratory failed to retain the March 2025 Maintenance Log and Temperature log, one (1) of 19

	months reviewed. Review timeframe January 1, 2025 through July 31, 2026. Findings include: 1. During an initial Lab tour and entrance interview with the technical consultant at 9:02 am on 8/13/26, it was revealed that the laboratory started utilizing the new Hematology Sysmex XN330 analyzer for patient Complete Blood Counts (CBCs) at the end of October 2024. 2. Review of the Laboratory Procedures and General policies revealed the statement, "All records are maintained a minimum of two years". 3. Review of the available 2025 and 2026 XN330 Maintenance Log and Temperature Log sheets (a total of 19 months) revealed no log sheet retained for March 2026. 4. In an interview on 8/13/26 at 1:15 pm, the Technical Consultant, Operations manager, and primary testing personnel confirmed the above findings.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on a laboratory tour, review of laboratory policy and procedures, lack of documentation and interviews, the laboratory failed to establish Hematology specimen rejection criteria at the time of the survey on August 13, 2026. Findings include: 1. During an initial Lab tour and entrance interview with the technical consultant (TC) at 9:02 am on 8/13/26, it was revealed that the laboratory started utilizing the new Hematology Sysmex XN330 analyzer for patient Complete Blood Counts (CBCs) at the end of October 2024. 2. Review of the laboratory's policy and procedures revealed a lack of rejection criteria for Hematology specimens to be run on the Sysmex XN330 analyzer. 3. When asked about Hematology specimen rejection criteria in an interview at 11:07 am on 8/13/26, the TC stated there were no criteria established. 4. In an interview on 8/13/26 at 1:15 pm, the Technical Consultant, Operations manager, and primary testing personnel confirmed the above findings.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references.

(b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on a laboratory tour, review of laboratory policy and procedures, lack of documentation and interviews, the laboratory failed to establish procedures defining Hematology Complete Blood Count critical (panic) or alert values at the time of the survey on August 13, 2026. Findings include: 1. During an initial Lab tour and entrance interview with the technical consultant (TC) at 9:02 am on 8/13/26, it was revealed that the laboratory started utilizing the new Hematology Sysmex XN330 analyzer for patient Complete Blood Counts (CBCs) at the end of October 2024. 2. Review of the laboratory's policy and procedures revealed patient specimens exceeding the panic values are retested and the physician notified. The procedure lacked critical (panic) values for patient CBC results. The inspector requested to review established alert or critical values. The document was not available for review. 3. When asked about Hematology critical values at 11 am on 8/13/26, testing personnel B stated that for patient results with flags, they give the analyzer printed CBC results to the provider. During the interview, there were no critical values observed as posted in the lab nor on the XN330 analyzer. 4. In an interview on 8/13/26 at 1:15 pm, the Technical Consultant, Operations manager, and primary testing personnel confirmed the above findings.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

(a)(1) 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 laboratory's Procedures and General Policies, maintenance records, lack of documentation, and interview, the laboratory failed to document performance of daily and weekly Sysmex XN3300 Hematology Analyzer preventative maintenance for thirty-two (32) days and 9 weeks during the 19 months reviewed. Review timeframe January 2025 - July 2026. The findings include: 1. Review of the Laboratory Procedures and General Policies revealed equipment maintenance is to be recorded on the log and retained for the life of the instrument. 2. Review of the laboratory's XN330 Maintenance Log and Temperature Log revealed the log is utilized to document daily Hematology XN330 analyzer background, shutdown, and performance of quality control as well as weekly analyzer cleaning. The available 2025 and 2026 maintenance logs lacked documentation of: daily activities performed each day in the month of March 2025, and on 5/19/25; and weekly cleaning documented in the 4 weeks of March 2025, the 4 weeks in May 2025, and the 1st week in July 2025. 3. In an interview on 8/13/26 at 1:15 pm, the Technical Consultant, Operations manager, and primary testing personnel confirmed the above findings.