Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0685723	03/20/2025
Name of Provider or Supplier	**Street Address, City, State**	
Children's Clinic Of Nashville Plc The	4322 Harding Road Suite #313, Nashville, TN	

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
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: Based on laboratory observation, a review of patient test records, and staff interviews, the laboratory failed to retain 2 of 5 complete blood counts (CBC) instrument test reports. The findings include: 1. Observation of the laboratory on 03/20/2025 at 10:45 a.m. revealed a Medonic hematology analyzer (ID: 49409) performing patient CBC testing. 2. A random review of five patient test records in 2024 and 2025 revealed that the laboratory did not retain the Medonic test reports for patients 20800 (04/05/2024) and 17341 (09/24/2024). 3. An interview with the practice manager, nurse manager, and laboratory director on 03/20/2025 at 12:30 p.m. confirmed the 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 review of the laboratory's procedure manual and staff interviews, the laboratory's procedure for complete blood count (CBC) testing failed to include reference intervals (normal values). The findings include: 1. A review of the laboratory's procedure manual revealed no reference ranges for patient CBC testing. 2. An interview with the practice manager, nurse manager, and laboratory director on 03/20/2025 at 12:30 p.m. confirmed that the laboratory's CBC testing procedure did not include the approved reference intervals.
D6011	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(2) (e)(2) provide a safe environment in which employees are protected from physical, chemical, and biological hazards; This STANDARD is not met as evidenced by: Based on laboratory observation and staff interviews, the laboratory failed to ensure appropriate safety measures were available to protect personnel from chemical and biological hazards involved in laboratory testing when no eyewash was present in the laboratory testing area. The findings include: 1. Observation of the laboratory on 03/20/2025 at 10:45 a.m. revealed that the saline eyewash bottles in the emergency eyewash station were empty. 2. An interview with the practice manager and nurse manager on 03/20/2025 at 11:00 a.m. confirmed that the laboratory did not have an eyewash available at the time of the survey.