Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 18D1098877	**(X3) Date Survey Completed** 08/22/2025
Name of Provider or Supplier Norton Children's Medical Group-Middletown	**Street Address, City, State** 12955 Shelbyville Road, Suite 1, Louisville, KY	
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	A recertification survey was conducted on 08/22/2025. The facility was found to not be in compliance with the laboratory requirements of 42 CFR Part 493 with standard deficiencies cited.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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: I. Based on direct observation, manufacturer's instructions, and laboratory environmental records, the laboratory failed to ensure refrigerator temperature ranges were within manufacturer's requirements for 2 of 5 days (random review of year 2024 and 2025). Findings Include: During the tour of the laboratory on 08/22/2025 at 9:50 AM, Eightcheck-3WB X-Tra tri-level controls were observed in the refrigerator of the testing area. Review of the Norton Medical Group Policy and Procedure Manual, (Approved 7/25/2023), Section: Complete Blood Count on Sysmex XP-300 Automated Analyzer manufacturer's instructions, Commercial control Storage, revealed "After opening, vials should be stored in the upright position at 2-8C." Review of the laboratory's environmental records revealed no refrigerator temperatures reported on January 31, 2024 and December 31, 2024 of patient testing. II. Based on direct observation, manufacturer's instructions, and laboratory environmental records, the laboratory failed to ensure the humidity range was within

	manufacturer's requirements for the Sysmex XP-300 Hematology Analyzer for 2 of 5 days (random review of year 2024 and 2025). Findings include: During the tour of the laboratory on 8/22/2025 at 9:50 AM, a Sysmex XP-300 Hematology Analyzer, Serial Number (SN) B0241 was observed in the testing area. Review of Sysmex XN-L Series Installation Site Requirements revealed: "Relative Humidity Requirements: The relative humidity in the laboratory should be 20% to 85%." Review of laboratory environmental records revealed no humidity readings were recorded for January 31, 2024 and December 31, 2024 of patient testing. III. Based on direct observation, manufacturer's instructions, and confirmed by interview, the laboratory failed to monitor and document the room temperature for 2 of 5 days of patient testing. Findings include: During the tour of the laboratory on 8/22/2025 at 9:50 AM, a Sysmex XP-300 Hematology Analyzer, Serial Number (SN) B0241 was observed in the testing area. Review of Sysmex XN-L Series Installation Site Requirements revealed: "The analyzer, pneumatic unit, IPU, and printer dissipate approximately 2,000 BTU per hour, while requiring an ambient room temperature of 60 to 95 F (15 to 35C)." Review of laboratory environmental records revealed no room temperature readings were recorded for January 31, 2024 and December 31, 2024 of patient testing. In an interview on 8/22/2025 at 11:15 AM in the office area, the Technical Consultant (TC) was asked if room temperatures were reported for the two days of patient testing. TC confirmed that temperatures were not monitored on the two days. This confirmed the 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 surveyor observation, review of policy and procedure manual, review of Sysmex XP-300 instructions for use, review of Sysmex XP-300 maintenance logs, and confirmed in interview, the laboratory failed to follow manufacturer's instructions for performing daily maintenance for 2 of 5 days of patient testing in 2024. Findings Included: During a tour of the facility on 08/22/2025 at 10:00 a.m., the surveyor observed a Siemens Sysmex XP-300 Hematology analyzer in the patient testing area (Serial Number: B0241). Review of the policy and procedure manual, "Complete Blood Count (CBC) on the Sysmex XP-300 Automated Hematology Analyzer" (Approved 7/25/2023), revealed the following: "Refer to the Sysmex XP-300 Instructions for Use for detailed, illustrated procedures." Review of the Sysmex XP-300 Instructions for Use stated: "To ensure proper functioning of the instrument, it is necessary to periodically clean and service the instrument. Perform maintenance according to the schedule below. And record the results in the Maintenance checklist." "12.1 Maintenance schedule Daily - Clean TD chambers and diluted sample lines (Shutdown) (see 12.3) Check trap chamber level and discard (see 12.4)" Review of laboratory XP-300 maintenance log records in 2024, revealed daily maintenance was not documented on January 31, 2024 and December 31, 2024. During an interview on 08/22/2025 with Technical Consultant (TC) at 11:00 AM in office area, TC stated the laboratory failed to follow manufacturer's instructions for documenting daily maintenance for 2 of 2 days of patient testing. This confirmed the findings.