

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D2075399	(X3) Date Survey Completed 02/15/2024
Name of Provider or Supplier Norton Children's Medical Group-Brownsboro	Street Address, City, State 9880 Angies Way, Suite 400, 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 02/15/2024. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation, maintenance log review, and interview, the laboratory failed to perform and maintain the maintenance logs for the Sysmex Hematology Analyzer for twelve (12) of twelve (12) months in 2022. Findings include: 1. On 2/15/2024 at 11:35 AM, a Sysmex Hematology Analyzer XN-330 was observed in the testing area. 2. Review of the Maintenance log for the Sysmex Hematology Analyzer 2022 and 2023, the maintenance results for twelve (12) of twelve (12) months for the year 2022 were not present in the manual. 3. In an interview on 02/15/2024 at 11:38 AM in the office, Testing Personnel (TP1) and Technical Consultant (TC) were asked for the maintenance for 2022. No documentation could be provided. This confirmed the findings.</p>