

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 20D0089573	(X3) Date Survey Completed 01/31/2024
Name of Provider or Supplier Northern Light Mayo Hospital	Street Address, City, State 897 West Main Street, Dover Foxcroft, ME	
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
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 lack of documentation and interview with the Technical Consultant (TC), the laboratory failed to document routine maintenance and function checks on the CS-2500 hematology analyzer. Findings include: 1. Record review of the CS-2500 hematology analyzer instructions on 1/30/2024 revealed daily maintenance to include: "Discarding used cuvettes... discarding waste fluids... checking and discarding trap chamber fluid". 2. Record review of the CS-2500 analyzer "Maintenance History" documentation on 1/30/2024 revealed daily maintenance for the above to be undocumented for 12 working days between December 2022 and December 2023. 3. Interview with the TC on 1/30/2024 at 11:15am confirmed the above findings. 4. The laboratory performs 120,030 hematology tests per year.</p>
D6042	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4)</p> <p>(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;</p> <p>This STANDARD is not met as evidenced by:</p>

Based on lack of documentation and interview with the Technical Consultant (TC), the TC failed to ensure quality assurance levels for daily maintenance of the CS-2500 hematology analyzer. Findings include: 1. Record review of the CS-2500 hematology analyzer instructions on 1/30/2024 revealed daily maintenance to include: "Discarding used cuvettes... discarding waste fluids... checking and discarding trap chamber fluid". 2. Record review of the CS-2500 analyzer "Maintenance History" documentation on 1/30/2024 revealed daily maintenance for the above to be undocumented for 12 working days between December 2022 and December 2023. 3. Record review of the laboratory's Technical Consultant delegated duties policy on 1/30/24 revealed the following: "Resolve technical problems and inures remedial action is taken whenever there is a system failure.... Identify training needs... and education appropriate for testing...". 4. Interview with the TC on 1/30/2024 at 11:15am confirmed the above findings. 5. The laboratory performs 120,030 hematology tests per year.