

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 20D0928589	(X3) Date Survey Completed 05/16/2023
Name of Provider or Supplier Northern Light	Street Address, City, State 364 Pritham Ave, Greenville, 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 Technical Supervisor (TS), the laboratory failed to document routine maintenance and function checks on the Vitros Chemistry analyzer and annual maintenance on the Unico G380 microscope. Findings include: 1. Record review of the Vitros maintenance logs on 5/16/2023 for the time period of 2022-2023 revealed no recorded weekly maintenance for 7 of 16 months and no recorded monthly maintenance for 9 of 16 months. 2. Record review of the Unico G380 microscope maintenance logs on 5/16/2023 revealed the last maintenance performed in December 2021. 3. Record review of the Unico G380 Microscope manual on 5/16/2023 revealed the following statement: "To keep your microscope in top condition for years, have it professionally serviced once a year." 4. Interview with (TS) on 5/16/2023 at 10:15 AM, confirmed the above findings. 5. The laboratory performs 89,180 tests under the specialty of Chemistry and 26,194 test under Hematology per year.</p>
D6123	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(iii)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.</p>

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to review the preventive maintenance records for the Vitros Chemistry analyzer. Findings include:

1. Record review on 5/16/2023 of the Vitros maintenance logs revealed no review signatures or dates for monthly maintenance records from 2022-2023.
2. Staff interview with the Technical Supervisor on 5/16/2023 at 10:30AM confirmed the above findings.
3. . The laboratory performs 89,180 tests under the specialty of Chemistry.