

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  20D2163591	<b>(X3) Date Survey Completed</b>  04/29/2025
<b>Name of Provider or Supplier</b>  Mainehealth DbA Maine Medical Center	<b>Street Address, City, State</b>  84 Campus Dr, Scarborough, ME	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D6018</b>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</p> <p>(e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; and</p> <p>This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) reports in the specialty of Chemistry, no review by the Lab Director (LD) or designee was documented. Findings include: 1. Record review on 4/29/2025 or the American Proficiency Institute (API) PT reports for Chemistry events: 2-2023 3-2023, and 3-2024 revealed no documented review. 2. Interview with the Technical Consultant on 4/29/2025 at 10:30 AM confirmed the LD had not documented a review. 3. The laboratory performs 20 tests annually in the specialty of Chemistry.</p>
<b>D6031</b>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13)</p> <p>(e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with laboratory Technical Consultant (TC), the laboratory director (LD) failed to ensure that an approved procedure manual was available to testing personnel. Findings include: 1. Record review of the laboratory testing manual on 4/29/2025 revealed no signature of approval by the LD.</p>

2. Interview with the TC on 4/29/2025 at 10:00am confirmed the above findings. 3. The laboratory performs 20 tests annually in the specialty of Chemistry and 6 tests annually in the specialty of Hematology.