

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  24D0040861	<b>(X3) Date Survey Completed</b>  08/21/2025
<b>Name of Provider or Supplier</b>  Lake View Silver Bay Medical Clinic	<b>Street Address, City, State</b>  50 Outer Drive, Silver Bay, MN	
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>D0000</b>	<p>. The Aspirus Lake View Silver Bay Clinic laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the recertification survey performed on August 21, 2025. The following standard-level deficiency was cited: 493.801 Testing of proficiency testing samples .</p>
<b>D2009</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by:                      . Based on document review and interview with laboratory personnel, the laboratory director failed to attest to the integration of proficiency testing samples into the routine patient workload for eight of ten proficiency testing (PT) events reviewed from 2024 and 2025. 1. The laboratory performed Chemistry and Hematology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 9:00 a.m. on 08/21/25. 2. The laboratory performed PT using the American Proficiency Institute (API) program in 2024 and 2025. 3. The laboratory director failed to sign two of eight 2024 attestation statements and two of two 2025 attestation statements found in the API 3 ring binders. The laboratory director attestation signature was missing for the following PT events: 2024 1st Chemistry Core event 2nd Chemistry Core event 3rd Chemistry Core event 2nd Chemistry Miscellaneous event 1st Hematology event 2nd Hematology event 2025 1st Hematology event 2nd Hematology event 4. In an interview at 10:50 a.m. on 08/21/25, the TC confirmed the above finding. .</p>