

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0040859	(X3) Date Survey Completed 08/11/2025
Name of Provider or Supplier North Shore Health	Street Address, City, State 515 5th Avenue W, Grand Marais, MN	
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	<p>. The North Shore Health 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 6, 2025, and August 7, 2025. The following standard-level deficiency was cited: 493.1281 Comparison of test results .</p>
D5775	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with laboratory personnel, the laboratory failed to evaluate and document the relationship between two Chemistry testing methods at least twice annually in 2024. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the Administrative Laboratory Director (ALD) during a tour of the laboratory at 1:05 p.m. on 08/06/25. 2. The following Chemistry methods for Basic Metabolic Panel (BMP) testing were observed as present and available for use during the tour: Ortho Vitros 5600 - primary method implemented in October 2024 Abbott i-STAT Chem-8+ - back up method A Roche Integra was used for the primary BMP method prior to the implementation of the Ortho Vitros 5600. 3. Twice annual comparison of test results obtained from multiple non-waived methods was required as established in the laboratory's Quality Management System policy in Section B. Multiple Analysis Automated Instruments and Systems. 4. Comparison documentation of BMP test results obtained from the Roche Integra and Abbott i-STAT in 2024 was not found in laboratory records. The laboratory was unable to provide this documentation upon request. 5. In an interview</p>

at 1:10 p.m. on 08/07/25, the LAD confirmed the above finding. 6. In an email received at 9:43 a.m. on 08/11/25, the LAD indicated 38 patients received BMP testing performed on the Abbott i-STAT in 2024. .