

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0040861	(X3) Date Survey Completed 02/02/2022
Name of Provider or Supplier Lake View Silver Bay Medical Clinic	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by:</p> <p>. Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure 2 of 6 reportable ranges obtained during performance verification activities were adopted by the laboratory. Findings are as follows: The laboratory performed Chemistry and Hematology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 9:05 a.m. on 02/02/22. A. Chemistry 1. An Alere Afinion 2 chemistry analyzer was observed as present and available for use during the tour of the laboratory. 2. Performance verification (PV) activities on the Afinion for Hemoglobin A1c (HbA1c) were completed in November 2021. The laboratory began testing patient specimens using this analyzer on 11/29/21 as indicated by laboratory records. 3. The upper and lower limit of the reportable range for HbA1c in the Afinion 2 Analyzer Validation Summary and the Reference Range Job Aide - Clinics table did not reflect the actual reportable range value obtained by the laboratory during the PV. See below. Analyte HbA1c PV 5.3-12.5 Summary 4.0-14.6 Table 2.5-15.0 4. The laboratory performed approximately 300 Chemistry tests annually as indicated on the Clinic Laboratory Improvement Amendments (CLIA) Application Form provided by the laboratory on date of survey. 5. In an interview at 10:40 a.m. on 02/02/22, the TC confirmed the above finding. B. Hematology 1. A Sysmex XN-330 hematology analyzer was observed as present and</p>

available for use during the tour of the laboratory. 2. Performance verification (PV) activities on the XN-330 for Red Blood Cells, White Blood Cells, Hemoglobin, Hematocrit and Platelets were completed in November 2019. 3. The upper limit of the reportable range for Hematocrit (HCT) in the Sysmex XN-L 330 Validation Protocol Final Summary and the Reference Range Job Aide - Clinics table did not reflect the actual reportable range value obtained by the laboratory during the PV. See below. Analyte HCT PV 0.0-73.3 Summary 0.2-75.0 Table 0-75.0 4. The laboratory performed approximately 5145 Hematology tests annually as indicated on the Clinic Laboratory Improvement Amendments (CLIA) Application Form provided by the laboratory on date of survey. 5. In an interview at 10:42 a.m. on 02/02/22, the TC confirmed the above finding. .