Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0406304	03/20/2025
Name of Provider or Supplier	**Street Address, City, State**	
Lake Region Healthcare - Elbow Lake	1411 Hwy 79 E, Elbow Lake, 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	. The Lake Region Healthcare Elbow Lake 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 completed on March 20, 2025. The following standard-level deficiencies were cited: 493.1445 Procedure manual 493.1251 Laboratory director responsibilities
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel,

	the laboratory failed to include accurate Hematology and Chemistry reference intervals in the procedure manuals for one of three coagulation analytes reviewed and one of eight reported venous blood gas (VBG) analytes in 2023 and 2024. Findings are as follows: The laboratory performed Hematology and Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 12:02 p. m. on 3/19/2025. A. Hematology 1. An ACL Elite coagulation instrument was observed as present and available for use during the tour. 2. The Prothrombin Time (PT/INR) reference interval on a patient test report from 4/7/23 was discrepant with the Prothrombin Time (PT) and INR Laboratory procedure found in the Hematology, Phlebotomy, & Coagulation Manual. See below. PT/INR Procedure: 0.9 - 3.5 seconds Patient test report: 6.5 - 10 seconds 3. In an interview at 10:15 a.m. on 3/20/2025, the GS confirmed the above findings. 4. The laboratory performed 585 PT/INR tests in 2023 and 455 PT/INR tests in 2024 as indicated by the GS in an email received at 2: 17 p.m on 3/20/2025. B. Chemistry 1. A Siemens EPOC blood gas instrument was observed as present and available for use during the tour. 2. The P02 reference interval on a patient test report from 4/10/24 was discrepant with the EPOC Blood Gas procedure found in the Chemistry and Immunology Manual. See below. P02 Procedure: 80 - 150 mmHg Patient test report: 30 - 50 mmHg 3. In an interview at 10: 15 a.m. on 3/20/2025, the GS confirmed the above findings. 4. The laboratory performed 15 VBG tests in 2023 and 24 VBG tests in 2024 as indicated by the GS in an email received at 2:17 p.m on 3/20/2025. .