Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0406287	12/11/2025
Name of Provider or Supplier	**Street Address, City, State**	
Lake Region Healthcare Barnesville	209 2nd Street Se, Barnesville, 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 Barnesville 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 December 12, 2025. The following standard-level deficiencies were cited: 493.1255 Calibration and calibration verification procedures. 493.1413 Technical consultant responsibilities .
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to perform and document calibration verification at least once

	every six months for one of two Chemistry test systems in 2025. Findings are as follows: 1. The laboratory performed moderate complexity Chemistry testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 11:20 a. m. on 12/11/25. 2. An Abaxis Piccolo Xpress was observed as present and available for use during the tour. The laboratory performed moderate complexity Chemistry testing using the Piccolo in 2025 as indicated on the Form CMS-2567 provided by the laboratory on the date of survey. 3. Piccolo system calibration verification was required every six months as established in the Instrument Performance, Maintenance, and Test Calibrations procedure found in MediaLab. 4. Calibration verification was performed in September 2024 and September 2025. Documentation for calibration verification performed in March 2025 was not found in the CAL VER binder provided by the laboratory on the date of survey. 5. In an interview at 1:35 p.m. the TC indicated the March 2025 calibration verification had been missed. 6. In an email received at 12:39 p.m. on 12/12/25, the TC indicated the laboratory performed 78 Chemistry tests on patient samples between March 2025 and the next calibration verification performed in September 2025. .
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the Technical Consultant (TC) failed to assess competency for all moderate complexity test systems at least annually for two of four testing personnel (TP) in 2024. Findings are as follows: 1. The laboratory performed moderate complexity testing under the Microbiology, Chemistry, and Hematology specialties as indicated on the Form CMS-2567 provided by the laboratory on the date of survey. 2. The following moderate complexity test systems were observed as present and available for use during a tour of the laboratory at 11:20 a.m. on 12/11/25. See below. An Abaxis Piccolo Xpress Chemistry analyzer An Alere Triage Meter device used for Chemistry testing A Sysmex XN-430 Hematology analyzer An Alcor miniiSED Hematology analyzer A Zeiss Axiostar microscope used for Microscopic Urinalysis and KOH (potassium hydroxide) testing 3. 2024 annual competency documentation for TP 3 and TP4 was not found during review of laboratory records. The laboratory was unable to provide the missing documentation upon request. 4. In an interview at 9: 50 a.m., the TC indicated the 2024 competency assessment documents for TP3 and TP4 were not included in the competency assessment records. .