Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0666786	03/13/2025
Name of Provider or Supplier	**Street Address, City, State**	
Regional Medical Center	709 West Main Street, Manchester, IA	

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
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 review of calibration and calibration verification records and confirmed by interview with General Supervisor (GS) #1 at 12:50 pm on 03/13/2025, the laboratory failed to perform calibration verification procedures for procalcitonin testing every six months for five out of five time periods from 01/01/2023 - 03/13/2025. The findings include: 1. The laboratory used the Ortho Vitros XT 7600 test system to perform procalcitonin testing. 2. At the time of the survey, GS #1 confirmed the laboratory did not perform calibration verification procedures which included a minimal (zero) value, a mid-point value, and maximum value for procalcitonin from 01/01/2023- 03 /13/2025.