Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	35D0409250	02/27/2024
Name of Provider or Supplier	**Street Address, City, State**	
Elbowoods Memorial Health Center	1058 College Drive, New Town, ND	

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) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (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 record review, staff interview, and policy review, the laboratory failed to verify calibration at least every six months for 1 of 1 year (2023) for analytes calibrated with less than three calibrators on the Beckman Coulter AU480 chemistry analyzer. The laboratory performed approximately 40,000 tests on the Beckman Coulter AU480 chemistry analyzer in 2023. Findings include: 1. Reviewed on 02/27 /24, the 2023 Beckman Coulter AU480 calibration verification records failed to

	include evidence of twice annual calibration verification for the following analytes: blood urea nitrogen, calcium, chloride, carbon dioxide, aspartate transaminase, direct bilirubin, alkaline phosphatase, lipase, magnesium, phosphorus, amylase, lactate dehydrogenase, iron, potassium, cholesterol, total bilirubin, triglycerides, glucose, creatinine, total protein, and sodium. The records failed to include evidence of calibration verification the second half of 2023 for the following analytes: albumin, alanine transaminase, transferrin, high-density lipoprotein cholesterol, and low-density lipoprotein cholesterol. 2. During interview at 3:45 p.m. on 02/27/24, a technical consultant (#1) confirmed the laboratory had failed to twice annually verify calibration for the above listed analytes on the Beckman Coulter AU480 in 2023. 3. Reviewed at 3:55 p.m. on 02/27/24, the policy "Quality Control," revised 06/19/13, stated, ". . . Quality control is performed as follows: A. . . . All AU480 chemistries must have calibration verified covering the reportable range . . . at 6 month intervals. . . ."
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on personnel record review and staff interview, the laboratory failed to document training for 2 of 5 personnel (Testing Personnel #2 and #3) performing moderate complexity testing on the MedTox Scan and Becton Dickinson (BD) Affirm analyzers in 2023 through 02/26/24. Findings include: 1. Reviewed on 02/27/24, the 2022-2023 personnel records failed to include evidence of training for moderate complexity testing on the MedTox Scan and BD Affirm analyzers for Testing Personnel #2 and #3. 2. During interview at 1:50 p.m. on 02/27/24, a technical consultant (#1) confirmed Testing Personnel #2 and #3 performed moderate complexity testing on the MedTox Scan and BD Affirm analyzers and the laboratory failed to document training before Testing Personnel #2 and #3 performed patient testing. 3. Upon request, the laboratory failed to provide a policy requiring documented training before testing personnel performed patient testing.