Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	35D0409250	02/19/2020
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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure the testing personnel and laboratory director signed the attestation statements for 2 of 9 (1-2019 core chemistry and 3-2019 microbiology) proficiency testing events reviewed from 2019. Findings include: 1. Reviewed at 9:05 a.m. on 02/19/20, the 2019 proficiency testing records lacked evidence the testing personnel and laboratory director signed the proficiency testing attestation statement for 1-2019 core chemistry and lacked evidence the laboratory director signed the proficiency testing attestation statement for 3-2019 microbiology. 2. During an interview at 10:30 a.m. on 02/19/20, the laboratory supervisor (#1) confirmed the testing personnel and laboratory director had not signed the 1-2019 core chemistry attestation statement and the laboratory director had not signed the 3-2019 microbiology attestation statement. 3. Upon request, the laboratory failed to provide a policy requiring the signing of proficiency testing attestation statements.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242.

	This STANDARD is not met as evidenced by: Based on record review, staff interview, and policy review, the laboratory failed to monitor the preanalytic system for 1 of 2 years reviewed (2019). Findings include: 1. Reviewed at 10:30 a.m. on 02/19/20, the 2018-2019 quality assessment records lacked evidence of preanalytic system monitoring in 2019. 2. During interview at 10:50 a.m. on 02/19/20, the laboratory supervisor (#1) confirmed the laboratory had not performed preanalytic monitoring in 2019. 3. Reviewed on 02/19/20, the policy "2019 Laboratory Quality Assurance Plan" stated, "I. Purpose A. EMHC [Elbowoods Memorial Health Center] is dedicated to providing patients and providers with the highest level of quality from specimen collection to result reporting. . . III. Quality Assurance Plan for 2019 A. Preanalytic Phase i. Test Request . . . ii. Rejected Specimens . . ."
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 transferrin calibration at least once every six months 1 of 2 times (second six months) in 2019. Findings include: 1. Reviewed at 12:10 p.m. on 02/19/20, the 2019 calibration verification records lacked evidence the laboratory verified transferrin calibration in the second six months of 2019. 2. Upon request on 02/19/20, the laboratory failed to provide additional evidence of calibration verification for transferrin in the second six months of 2019. 3. During interview at 1:00 p.m. on 02/19 /20, the laboratory supervisor (#1) confirmed the laboratory had not verified calibration for transferrin at least twice annually in 2019. 4. Reviewed on 02/19/20, the policy "Beckman Coulter AU480," dated 09/20/17, stated, ". . . Linearity is verified at installation and semi-annually thereafter. . . ."