Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	35D0409250	03/11/2026
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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to review and evaluate proficiency testing results for 1 of 3 Hematology/Coagulation events (1st Event) in 2025. Findings include: 1. Reviewed at 10:48 a.m. on 03/11/26, the 1st Event 2025 Hematology/Coagulation proficiency testing records lacked evidence of results review and evaluation for unacceptable Monocytes % results for sample ID DXH-04. 2. During an interview the morning of 03/11/26, the general supervisor (#1) confirmed the laboratory failed to document review and evaluation of the unacceptable Monocytes % results for 1st Event 2025. 3. Upon request, the laboratory failed to provide procedures related to review and evaluation of proficiency testing results.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on record review, policy review, and staff interview, the laboratory failed to perform required DxH 520 (hematology analyzer) monthly maintenance for 5 of 14 months (January 2025, April 2025, and August 2025 through October 2025) reviewed. The laboratory performed 23,926 Complete Blood Count (CBC) patient tests the past

	year. Findings include: 1. Reviewed at 1:05 p.m. on 03/11/26, the DxH 520 maintenance log showed the monthly maintenance, "Clean the WBC (white blood cell) Bath Filter". 2. Reviewed the afternoon of 03/11/26, the January 2025, April 2025, and August 2025 through October 2025 maintenance logs for the DxH 520 lacked evidence of the "Clean the WBC Bath Filter" monthly performance. 3. Reviewed the afternoon of 03/11/26, the policy, "Complete Blood Count", dated 12 /2025, stated, "Procedure . . . Cleaning the WBC Bath Filter . . . Purpose . . . To remove buildup and deposits trapped by the filter . . . Frequency . . . Monthly . . ." 4. During an interview the afternoon of 03/11/26, the general supervisor (#1) confirmed the laboratory had not completed the monthly "Clean the WBC Bath Filter" maintenance in January 2025, April 2025, and August 2025 through October 2025.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have control procedures that monitor accuracy and precision for 2 of 9 test systems (Medtox UDS [urine drug screen] and BD [Becton Dickinson] Affirm) reviewed. The laboratory performed 459 urine drug screen patients and 562 BD Affirm microbial identification patients the past year. Findings include: 1. Reviewed at 1:57 p.m. on 03/11/26, the QC (quality control) records for the Medtox UDS showed QC was performed weekly in September 2025 and the BD Affirm showed QC was performed monthly from October 2025 through February 2026. 2. During an interview the afternoon of 03/11 /26, the general supervisor (#1) confirmed she was unable to locate the initial Individualized Quality Control Plans (IQCP) for the Medtox UDS and BD Affirm which would indicate the frequency testing personnel perform QC.