Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0042084	07/27/2023
Name of Provider or Supplier	**Street Address, City, State**	
Northern Montana Hospital	30 13th Street, Havre, MT	

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
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on a review of chemistry calibration verification records, procedures, and an interview with the technical supervisor (TS #1), the laboratory failed to establish a procedure for the performance and evaluation of calibration verification data for five out of five analytes performed on the VITROS XT 7600 from July 26, 2021, to July 27, 2023. Findings: 1. The laboratory lacked a procedure for calibration verification for analytes Estradiol, Vitamin B-12, 25-OH Vitamin D, Total Iron Binding Capacity (TIBC), and Carcione Embryonic Antigen (CEA) to include the number, type, and concentration of calibration materials, frequency of studies, acceptable limits, and what to do when the calibration verification fails. 2. Calibration verification documents lacked evaluation of data for acceptability prior to patient testing for Estradiol, Vitamin B-12, 25-OH Vitamin D, TIBC, and CEA. 3. An interview with TS #1 on July 26, 2023, at 1:30 PM confirmed the laboratory failed to have a procedure and evaluate calibration verification data for five out of five analytes (Estradiol, Vitamin B-12, 25-OH Vitamin D, TIBC, and CEA) performed on the VITROS XT 7600 from July 26, 2021, to July 27, 2023.

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 review of calibration verification records, procedure, and interview with the Technical Supervisor (TS) #1, the laboratory failed to follow their procedures to perform at least three-point (minimal, mid-point, and maximum) calibration verification every six months for Triage Meter for analyte D-Dimer and for two of two Beckman Coulter DxH 600 hematology analyzers for complete blood counts (CBC) and from July 26, 2021, to July 27, 2023. Findings: 1. No records of calibration verification for the two Beckman Coulter DxH 600 hematology analyzers for complete blood count (red blood cells (RBC), white blood cells (WBC), platelets, hemoglobin, hematocrit and mean corpuscular volume (MCV)) and the Triage Meter for D-Dimer were available for review at the time of the survey. 2. The laboratory failed to follow their Individualized Quality Control Plan (IQCP) procedure for the Triage Meter to perform calibration verification every 6 months. 3. An interview with the TS #1 on July 27, 2023, at 11:30 AM, confirmed the laboratory failed to perform and retain documentation of calibration verification for the two Beckman Coulter DxH 600 analyzers for complete blood counts and the Triage Meter for D-dimer every six months from July 26, 2021, to July 27, 2023.
D5535	ROUTINE CHEMISTRY CFR(s): 493.1267(a)(d) For blood gas analyses, the laboratory must perform the following: (a) Calibrate or verify calibration according to the manufacturer's specifications and with at least the frequency recommended by the manufacturer. (d) Document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a review of blood gas calibration records, procedure manual, and an

	interview with Technical Supervisor (TS) #1, the laboratory failed to establish a procedure and perform at least three-point (a minimal, mid-point, and maximum) calibration verification every six months for the i-STAT CG 4+ cartridge and the Radiometer ABL80 Flex CO-OX blood gas analyzers from July 26, 2021, to July 27, 2023. Findings: 1. A review of calibration verification records for the Radiometer ABL80 Flex CO-OX lacked records of passing calibration verifications studies prior to patient testing for the year 2022 and for the i-STAT CG 4+ cartridge lacked documentation of calibration verification for the year 2021 and one of two studies for the year 2022. 2. A review of the test volume sheet revealed 471 patient tests performed for analytes pH, carbon dioxide partial pressure (pCO2), oxygen partial pressure (pO2), hydrogen carbonate ion (HCO3), Base Excess, and hemoglobin oxygen saturation (O2 SAT) from July 26, 2022, to July 26, 2023 (12-month time frame). 3. A review of the procedure manual lacked instruction for acceptable limits, frequency of calibration and what to do when the calibration verification fails for the Radiometer ABL80 Flex CO-OX and i-STAT CG 4+ cartridge. 4. Interview with TS #1 on July 27, 2023, at 9:00 AM, confirmed the laboratory failed to perform at least three-point calibration verification every six months for two of two blood gas analyzers from July 26, 2021, to July 27, 2023, and failed to define the frequency of calibration verification, acceptable limits, and corrective action for failures.