Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0042084	03/19/2025
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
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation, the manufacturer's product insert, and an interview with the general supervisor (GS #3), the laboratory failed to label 11 out of 11 sets of chemistry and immunoassay quality control (QC) material once opened with the open-vial stability expiration date from March 18, 2023, to March 19, 2025. Findings: 1. Observed on March 19, 2025, at 12:35 PM, one tray with 11 sets of quality control for the Vitros 7600 chemistry and immunoassay analyzer in use in the refrigerator. The quality control labels lacked the open-vial stability expiration date. 2. A review of Bio-Rad's product inserts revealed the laboratory failed to label their quality control vials with the manufacturer's stability expiration date for the following sets of QC: Liquichek Pediatric, Liquichek Ethanol/Ammonia, Liquichek Diabetes, Liquichek Elevated CRP, Liquichek Urine Chemistry, Liquichek Specialty Immunoassay, Liquichek Immunoassay Plus, Lyphochek Specialty Immunoassay, Liquichek Spinal Fluid, VIROTROL I, II, III, Clear and Liquid Assayed Multiqual. 3. Interview with GS #3 on March 19, 2025, at 12:40 PM, confirmed the QC vials lacked the stability expiration date after the vail was opened to prevent QC being used past the manufacturer's recommend stability of their product from March 18, 2023, to March 19, 2025.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)

	(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Based on record review of instrument comparison documentation, procedure, and interview with Technical Supervisor (TS) #1, the laboratory failed to perform comparison studies twice a year and define the relationship between the test results of two different test methods or instruments for ABO Rhesus (RH) factor typing, blood gas, troponin, comprehensive metabolic panel (CMP), prothrombin, D-Dimer, differential counts, and hematology's two analytical modules, every six months from March 18, 2023 to March 19, 2025. Findings: 1. A review of instrument comparison documentation revealed the laboratory failed to perform comparison studies for years 2023 and 2024 for the following systems: Conventional tube and gel-based ABO Rh factor typing, ABL 90 and iSTAT blood gas, pH, Partial Pressure of Oxygen (PO2), Partial Pressure of Carbon Dioxide (PCO2) and Lactate, Triage and Vitros 7600 troponin, Piccolo and Vitros 7600 CMP: (alanine aminotransferase (ALT), albumin, alkaline phosphatase (ALP), aspartate aminotransferase (AST), calcium, chloride, creatinine, glucose, potassium, sodium, total bilirubin, total carbon dioxide, total protein, and blood urea nitrogen (BUN)), Sysmex CA-600 and iSTAT prothrombin, Sysemx CA-600 and Triage D-Dimer, Beckman Coulter DXH 600 two analytical modules, Automated and manual differential counts. 2. An interview with TS #1 on March 19, 2025, at 11:00 AM confirmed the laboratory failed to perform comparison studies twice a year and define the relationship between the test results between the systems listed above from March 18, 2023, to March 19, 2025.