Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0411115	11/20/2024
Name of Provider or Supplier	**Street Address, City, State**	
Mineral Community Hospital	1208 6th Avenue East, Superior, 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
D0000	An on-site validation survey was conducted on November 20, 2024 at 8:00 a.m. by the Montana CLIA Certification Program.
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: Based on record review, the laboratory's policies and procedures, and an interview with technical supervisor (TS) #1, the laboratory failed to provide a written policy for standing orders from November 20, 2022, through November 20, 2024. Findings: 1. A review of patients' results and test request for therapeutic phlebotomy revealed the patient test requests are part of a standing order. 2. A review of the laboratory's policies and procedures lacked a policy to define which tests may be covered by standing orders and at what interval standing orders should be renewed. 3. An interview with the TS #1 on November 20, 2024, at 12:30 PM confirmed the laboratory did not have a policy for standing orders in place to define which tests are covered and the frequency they are renewed from November 20, 2022, through November 20, 2024.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii)

	Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of patient results' reports, verification studies, and an interview with the technical supervisor (TS) #1, the laboratory failed to verify the manufacturer's or previously established normal reference ranges (normal values) were appropriate for the laboratory's patient population for C-reactive protein (CRP) and complete blood count (CBC) with differential prior to the laboratory director's approval from August 8, 2023, to November 20, 2024. Findings: 1. No patient population verification studies for CBC with differential performed on the Sysmex XP-300 hematology analyzer were available for review to support the reference ranges (normal ranges) listed in the laboratory's patient results reports (#60019241 and 60022703). 2. No patient population verification studies for analyte CRP performed on the Siemens Dimension EXL chemistry analyzer were available for review. 3. An interview with the TS #1 on November 20, 2024, at 3:00 PM, stated the reference ranges (normal values) for CBC with differential were established by the previous hematology instrument and confirmed CRP had not been verified prior to the laboratory director's approval from August 8, 2023, to November 20, 2024.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview with the Technical Supervisor (TS) #1, the laboratory failed to document the quality check of each new lot number and shipment for positive and negative reactivity for one out of five biochemical tests and two out of seven culture media types from November 20, 2022, to November 20, 2024. Findings: 1. A review of Microbiology Log for quality control lacked documentation for quality check for positive and negative reactivity for new lot numbers and shipments for one biochemical test: Nitrocefin, and for two blood culture media: BACT/ALERT FN Plus and BACT/ALERT FA Plus. 2. A review of the "Lab - Order Volume - Summary" form revealed 49 blood cultures, and 47 wound cultures were performed from October 28, 2023, to October 28, 2024. 3. An interview on November 20, 2024, at 3:00 PM with TS #1 confirmed the laboratory failed to document the quality check for positive and negative reactivity for new lot numbers and shipments of Nitrocefin, BACT/ALERT FN Plus, and BACT/ALERT FA Plus from November 20, 2022, to November 20, 2024.
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. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on record review, procedures, and an interview with technical supervisor (TS) #1, the laboratory failed to perform comparison studies twice a year and define the relationship between the test results for manual and automated differential blood count from November 20, 2022, to November 20, 2024. Findings: 1. No comparison studies between manual differential blood count and automated differential blood count performed on the Sysmex XP 300 were available for review. 2. No procedures for comparison studies to include a written criteria for acceptable differences in test values for differential blood count were available for review. 3. An interview with TS #1 on November 20, 2024, at 1:20 PM confirmed the laboratory failed to perform comparison studies twice a year and define the relationship between the test results between manual and automated differential blood count from November 20, 2022, to November 20, 2024.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on a record review, and an interview with the technical supervisor (TS) # 1, the laboratory failed to monitor the manual entry of results for manual differentials cell counts for correctness for four out of four patient results reports from February 16, 2024, to November 20, 2024. Findings: 1. A review of patient results' reports against the Manual Differential Log revealed the following discrepancies: Patient results' report (60022703) listed "Normal" for red blood cell morphology, but the Manual Differential Log failed to have documentation for red blood cell morphology. Patient results' report (60021069) listed "Monocyte Man" 4 and "Eos Man" 3, but the Manual Differential Log documented 5 Monocytes and 2 Eosinophils. Patient results' report (60021045) failed to list Eosinophils, but the Manual Differential Log documented 3 Eosinophils. Patient results' report (60019241) lists results for "Hypochromia, Poik, Polychrome, Schistocytes and Anisocyte" but the Manual Differential Log failed to have documentation for these types of cells. 2. No corrective action forms for incorrect patient results' reports or incomplete logs were available for review. 3. Review of the "Lab - Order Volume - Summary" form revealed 222 manual differentials were performed from October 28, 2023, to October 28, 2024. 4. An interview with TS # 1 on November 20, 2024, at 5:00 PM, confirmed these findings.