Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0678565	12/02/2025
Name of Provider or Supplier	**Street Address, City, State**	
Mountainview Medical Center	16 West Main St, White Sulphur Springs, 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	The Montana CLIA Program conducted an announced CLIA recertification survey on December 2, 2025. The laboratory was surveyed under 42 CFR part 493 CLIA regulations and was found to be in compliance with condition-level CLIA requirements. However, the following standard-level deficiencies were identified during the survey.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on record review, manufacturer product inserts, and interviews with Technical Supervisors (TS) #1 and #2, the laboratory failed to follow manufacturer instructions by using five expired immunohematology reagents for testing on 17 of 17 patients and 12 of 12 Red Blood Cell (RBC) units between 4/23/24 to 11/6/24. Findings: 1. A review of the Blood Bank Quality Control Record revealed the following expired immunohematology reagents were used for patient and Red Blood Cell (RBC) unit testing: ORTHO Antibody Enhancement Solution: Lot #AEP031A (Exp. 4/7/24), used on 4/23/24. Lot #AEP035A (Exp. 10/17/24), used on 10/29/24, 10/30/24, and 11/5/24. ORTHO Confidence System Kit: Lot #CNF357 (Exp. 9/17/24), used on 9/21/24 and 9/24/24. ORTHO Coombs Control (OCC): Lot #K955 (Exp. 6/18/24), used on 6/21/24, 6/25/24, and 6/30/24. Lot #K972 (Exp. 9/10/24), used on 9/21/24 and 9/24/24. Lot #K982 (Exp. 10/22/24), used on 10/24/24, 10/29/24, and 10/30/24. ORTHO Reagent Red Blood Cells SELECTOGEN I and II (SC1/SC2): Lot #VS502 (Exp. 8/13/24), used on 8/19/24 and 8/27/24. Lot #VS617 (Exp. 10/1/24), used on 10/2/24 and 10/8/24. Lot #VS623 (Exp. 10/29/24), used on 10/30/24, 11/5/24, and 11/6/24. ORTHO Reagent Red Blood Cells AFFIRMAGEN (A1 and B): Lot #A822 (Exp. 8/20/24),

	used on 9/2/24, 9/21/24, and 9/24/24. 2. A review of the ORTHO product inserts for Antibody Enhancement Solution, Coombs Control, SELECTOGEN, AFFIRMAGEN, and Confidence System revealed staff failed to follow the manufacturer's instructions to not use the products beyond their labeled expiration dates. 3. A review of the "Transfusion Service Record" revealed the dates of patients and RBC units testing that utilized the expired reagents listed in Finding 1: Patient Testing Dates: 04/23/2024, 06 /21/2024, 06/30/2024, 08/19/2024, 09/02/2024, 09/21/2024, 09/24/2024, 10/02/2024, 10/24/2024, 10/29/2024, 10/30/2024, 11/05/2024, and 11/06/2024. RBC Unit Testing Dates: 06/25/2024, 08/27/2024, and 10/08/2024. 4. An interview with Technical Supervisors (TS) #1 and #2, conducted on December 2, 2025, at 12:45 PM, confirmed that the laboratory failed to follow the manufacturer's instructions and used expired immunohematology reagents for testing 17 patients and 12 RBC units between 4/23 /24 to 11/6/24.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (1) 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. This STANDARD is not met as evidenced by: Based on record review, manufacturer's instructions for use, and interview with Technical Supervisor (TS) #1 and #2, the laboratory failed to perform a negative quality control (QC) organism for twelve of twelve days quality control was performed for the Bacitracin Differentiation Disk from 8/23/24, to 9/19/2025. Findings: 1. A Review of the "Media/Microbiology QC Log" revealed a negative control organism was not performed on the following QC test dates: 8/23/24 9/21/24 11/6/24 12/18/24 12/24/24 1/29/25 3/12/25 4/18/25 6/4/25 6/12/25 8/21/25 9/19/25 2. A review of the Bacitracin Differentiation Disks manufacturer 's instructions for use states: "Known positive (group A streptococci) and negative (non-group A streptococci) controls should be used to monitor the accuracy of the disks and inoculum." Staff failed to perform the required negative quality control organism as instructed. 3. An interview with TS #1 and TS #2 on December 2, 2025, at 2:15 PM confirmed the laboratory failed to perform a negative QC organism for Bacitracin Differentiation Disks on the dates listed above.
D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) (e)(4) Ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed and that-- This STANDARD is not met as evidenced by: Based on record review and interview with Technical Supervisor (TS) #1, the laboratory director failed to ensure the laboratory was enrolled in a proficiency testing program for the microbiology subspecialty of bacteriology for one of one analyte (Group A Streptococcus) performed during calendar year 2025. Findings: 1. A review

	of microbiology records revealed the laboratory performed testing using HardyDisk Bacitracin Differentiation Disks on throat cultures for the presumptive identification of Group A Streptococcus. 2. A review of 2025 records from the American Proficiency Institute (API) revealed the laboratory lacked documentation of proficiency testing participation for Group A Streptococcus using throat cultures. 3. An interview conducted on December 2, 2025, at 10:20 AM with Technical Supervisor (TS) #1 confirmed the laboratory director did not enroll the laboratory in a PT program for Group A Streptococcus during calendar year 2025. 4. An email communication from TS #1 dated December 3, 2025, at 2:02 PM confirmed the laboratory performed Bacitracin Differentiation Disk testing on three patient throat cultures during calendar year 2025.