Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 27D2147879	**(X3) Date Survey Completed** 12/09/2025
Name of Provider or Supplier Bozeman Health Urology	**Street Address, City, State** 931 Highland Blvd, Ste 3360, Bozeman, 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 9, 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.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of American Proficiency Institute (API) proficiency testing records and an interview with the technical consultant (TC) #1, the laboratory failed to have an attestation form signed by testing personnel and the laboratory director for six of seven proficiency testing events from December 9, 2023, to December 9, 2025. Findings: 1. A review of API proficiency testing records revealed the absence of signed Attestation Statements for the following events: API 2023 Hematology /Coagulation - 3rd Event API 2024 Hematology/Coagulation - 1st Event API 2024 Hematology/Coagulation - 2nd Event API 2024 Hematology/Coagulation - 3rd Event API 2025 Hematology/Coagulation - 1st Event API 2025 Hematology/Coagulation - 2nd Event 2. An interview with TC #1 on December 9, 2025, at 9:30 AM confirmed the laboratory did not obtain signed attestation forms from testing personnel and the laboratory director for the six events listed above from December 9, 2023, to December 9, 2025.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232

	The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on observation, review of procedures, and an interview with Technical Consultant (TC) #1, the laboratory failed to establish a procedure for specimen labeling to ensure that two of two patient specimens' urine aliquots and urine microscopy slides were labeled with two unique identifiers throughout the testing process on December 9, 2025. Findings: 1. On December 9, 2025, at 11:00 AM, two fifteen milliliter (15 mL) conical tubes containing aliquoted patient urine specimens and urine microscopy slides were observed in the laboratory. Both the tubes and slides were labeled with only one patient identifier (the patient's last name). 2.A review of the laboratory's "Clean-catch (midstream) urine specimen collection" procedure revealed that staff are instructed to "confirm patient's identity using at least two unique identifiers" at the time of collection but failed to maintain those identifiers throughout the testing process. 3. A review of Urine Sediment Microscopy Procedures revealed the procedure did not include specific instructions for labeling urine aliquots or urine microscopic slides with two unique patient identifiers. 4. A review of the laboratory's test volume report revealed that 1,211 urine microscopic patient samples were processed between December 5, 2024, and December 5, 2025 (a 12-month period). 5. An interview with Technical Consultant (TC) #1 on December 9, 2025, at 11:10 AM confirmed that two patient specimens' urine aliquots and urine microscopy slides, processed on December 9, 2025, failed to include two unique identifiers and the laboratory did not have a procedure for specimen labeling.