Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D0696101	01/14/2025
Name of Provider or Supplier	**Street Address, City, State**	
Battle Mountain General Hospital Lab	535 S Humboldt St, Battle Mountain, NV	

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	This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on January 13-14, 2025. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.
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 the laboratory 2023 and 2024 American Proficiency Institute (API) Proficiency Testing (PT) records, and an interview with the laboratory manager, the laboratory director failed to attest to the routine integration of the PT samples and to ensure the analysts performing the testing signed the attestations. Findings include: 1. A review of the 2023 and 2024 API PT records found that the second testing event for Chemistry Miscellaneous in 2023 was missing the attestation. 2. A review of the 2023 and 2024 API PT records found that the first event of Microbiology in 2024 did not have the laboratory director's signature. 3. An interview with the laboratory manager on January 13, 2025, at approximately 3:00 PM confirmed these findings. The laboratory performs approximately 50,355 chemistry and 1350 Microbiology tests annually.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)

	(d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493. 1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, blood banking control logs, a review of the transfusion logs, and an interview with the laboratory manager, the laboratory failed to perform and document blood banking quality controls (QC). Findings include: 1. The laboratory director approved policy titled "Quality Assurance For Blood Bank" stated that quality controls must be performed "Daily whenever patient testing takes place". 2. A review of the 2023 and 2024 transfusion records found that patients were tested on the following dates: 6/11/2023, 8/25/2023, 1/10 /2024, 3/11/2024, 6/28/2024, and 6/30/2024. 3. A review of the 2023 and 2024 blood banking QCs revealed that the laboratory failed to document the daily QC required when patient testing is performed according to the patient testing dates listed in finding number 2 above. 4. An interview with the laboratory manager on January 13, 2025, at approximately 3:00 PM confirmed these findings. The laboratory performs approximately 120 immunohematology tests annually.
D5551	IMMUNOHEMATOLOGY CFR(s): 493.1271(a)(f) (a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, blood banking controls logs and an interview with the laboratory manager, the laboratory failed to establish written policies and procedures for the temporary use of expired reagents when non-expired reagents are not available. Findings include: 1. The laboratory director approved policy titled "Quality Assurance For Blood Bank" states "Do not use the reagents after the expiration date shown on the vials, when circumstance prevents the shipment of new reagents in a timely manner refer to the "Delay in Shipment" bulletin". The delay in shipment bulletin was not available for review. 2. The screen cell reagent (lot 3SS554) expired 11/26/2024 and was used on 11/27/2024, 12/3/2024, 12/12/2024 and 12/13/2024. 3. The A1/B cells (lot A860) expired 12/10/2024 and was used on 12/12/2024 and 12/13/2024. 4. The Coombs cells (lot K989) expired 12/3 /2024 and was used on 12/12/2024 and 12/13/2024. 5. A comment on the blood bank control logs indicated that each expired reagents were tested twice on the days of use

	after the expiration date. 6. There was no laboratory director policy available to indicate that this is the correct process for using expired blood bank control reagents. 7. An interview with the laboratory manager on January 13, 2025, at approximately 3: 00 PM confirmed these findings. The laboratory performs approximately 120 immunohematology tests annually.