Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D0696101	03/31/2021
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 3/31/2021. 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.
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 review of the laboratory's patient reports and interview with the laboratory supervisor, the laboratory failed to verify the blood gas reference intervals (normal values) for venous blood are appropriate for the laboratory's patient population. Findings include: 1. An interview with the respiratory services supervisor on 3/31/2021 at approximately 1:45 PM revealed that the laboratory added testing for blood gases using venous blood in November 2020. The supervisor confirmed that the laboratory did not verify the reference intervals for venous blood gases were appropriate for the laboratory's patient population and used the same reference intervals used for arterial blood gases. 2. Review of patient blood gas reports, Patient #56639 from 1/04/2021 reported at 8:48 PM from a venous sample, and Patient #50810 from 1/27/2021 reported at 5:35 PM from an arterial sample, used the same

	reference intervals for the different specimen types. 3. The laboratory performs approximately 30 blood gas analyses annually.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) 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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the blood bank's worksheets, the blood bank quality control records, and the laboratory's policy, and interview with the laboratory manager, the laboratory failed to follow their policy and perform tests using a negative and positive control material at least once a day patient specimens are examined. Findings include: 1. A review of the blood bank's worksheets and quality control records from 8/07 /2020 through 3/30/2021 revealed quality control testing was not performed and documented on 11/13/2020 and 2/18/2021. 2. ABO and Rh typing was performed on 11/13/2020 and ABO and Rh typing, antibody screen, and compatibility testing were performed on 2/18/2021. 3. Laboratory procedure, "Quality Assurance for Blood Bank," effective 10/18/2018, section VIII. When to Run the Quality Control states, "Quality control must be run at least to include: 2. Daily whenever patient testing takes place." 4. The laboratory manager confirmed the findings during the on-site survey on 3/31/2021 at approximately 3:00 PM. 5. The laboratory performs approximately 116 immunohematology tests annually.