Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D0696101	11/09/2022
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 11/08-09/2022. 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.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) records for blood gases and interview with the respiratory care supervisor and the laboratory manager, the laboratory failed to test blood gas PT samples by personnel who routinely perform the testing in the laboratory. Findings include: 1. PT records reviewed for blood gases for American Proficiency Institute (API) PT program for 2021 and 2022, revealed that the PT testing was performed by the respiratory care supervisor for the testing events. 2. Interview with the respiratory care supervisor on 11/09/2022 at approximately 11:30 AM revealed that venous blood gas testing on the Opti CCA T52 was performed by the three clinical laboratory testing personnel when the respiratory care supervisor was not on duty. 3. The laboratory manager indicated on 11/09/2022 at approximately 11:45 AM, that the three clinical laboratory testing personnel did not participate with the blood gas PT testing events. The laboratory performs approximately 41,183 chemistry tests annually.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

	CFR(s): 493.1252(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 observation and interview with the laboratory manager, the laboratory failed to ensure that laboratory reagents were not used after their expiration date. Findings include: 1. A tour of the microbiology section revealed a bottle of Gram's iodine which expired on 9/22/2022 available for use. The bottle was opened on 9/26/2022 and used for quality control testing. A new shipment of unexpired Gram's iodine was received by the laboratory on 10/24/2022. 2. The media refrigerator contained an open box of thioglycollate tubes which expired on 10/17/2022 available for use. A box of unexpired thioglycollate tubes was found in the refrigerator. 3. The laboratory manager confirmed the findings during the survey on 11/08/2022 at approximately 1: 00 PM. The laboratory performs approximately 799 microbiology tests annually.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the Triage D-Dimer test procedure, review of the quality control records for the Triage D-Dimer and interview with the laboratory manager, the laboratory failed to perform two levels of external controls each day of testing patient samples. Findings include: 1. The laboratory failed to perform two levels of external controls each day of patient testing. The quality control records reviewed for January to October 2022 revealed that two levels of controls were performed every 30 days and with each new shipment of of the test cassettes. 2. The laboratory's procedure, "Triage D-Dimer" test procedure states, "The use of positive and/or negative controls is recommended to assess each shipment of product, and at least every 30 days, or whenever the laboratorian wishes to verify the performance of the controls or the test." 3. The laboratory manager confirmed the findings during the survey on 11/08 /2022 at approximately 3:00 PM and indicated that the Individualized Quality Control Plan was not developed for the Triage D-Dimer test. The laboratory performs approximately 27,543 hematology tests annually.
D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure, "Critical Laboratory Values," review of laboratory reports, and interview with the laboratory manager, the laboratory failed to follow the director approved procedure and document that critical values were called to the responsible party in the computer system. Findings include: 1. A review of two patient reports with critical values, on the laboratory computer system, patient with initials, JO from 5/09/2022 with a glucose value of 535 and patient with initials, JR from 6/29/2022 with a positive blood culture, revealed that the laboratory staff did not document the name of the person notified in the laboratory information system as required by the laboratory procedure, "Critical Laboratory Values." 2. "Critical Laboratory Values," states, "8. Document the receiver's name in the computer system. 9. If delivered face-to-face document the receiver's name in the computer system." 3. The laboratory manager confirmed the findings during the survey on 11/09/2022 at approximately 10:45 AM. The laboratory performs approximately 41,183 chemistry and 799 microbiology tests annually.
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on review of patient reports for November 2022, review of the laboratory procedure, "Corrected Reports," and interview with the laboratory manager, the laboratory failed to follow the director approved laboratory procedure and add required documentation to the corrected reports. Findings include: 1. Patient report reviewed for patient with initials, RL from 11/06/2022, revealed corrected results for calcium. On 11/06/2022 at 9:59 PM, the result was amended from 9.0 to 0.0. On 11/07 /202 at 8:55 AM, the calcium result was amended from 0.0 to 8.9. There was no documentation of who was notified, time of notification, and the date of notification in the LIS as required by the laboratory procedure. 2. Laboratory procedure,, "Corrected Reports," states, "4.a. Healthcare providers or healthcare personnel must be notified when changes in reported results may affect patient treatment. Any results that is corrected and has gone from normal value to an abnormal value or from an abnormal value to a normal value must be called to the caregiver or RN immediately. Documentation of notification must be put into the LIS. This documentation must include: who was notified, time of notification, and the date of notification." 3. The laboratory manager confirmed the findings during the survey on 11/09/2022 at approximately 10:45 AM. The laboratory performs approximately 41,183 chemistry tests annually.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

	This STANDARD is not met as evidenced by: Based on review of laboratory records, review of laboratory procedures and interview with the laboratory manger, the laboratory director failed to ensure that quality assessment (QA) programs were maintained to assure the quality of laboratory services provided. Findings include: 1. The QA program failed to identify and take corrective action that three of four testing personnel did not participate with the proficiency testing program for blood gases (Refer to D2007); that expired laboratory reagents were available for use (Refer to D5417); that two levels of quality controls were not performed each day of patient testing for the Triage D-Dimer test or that the Individualized Quality Control Plan had not been developed for an optional quality control plan (Refer to D5447); and that critical value reports and corrected reports were not consistently documented as required by laboratory procedures (Refer to D5813 and D5821). 2. The laboratory manager confirmed the findings during the survey on 11/09/2022 at approximately 11:00 AM. The laboratory performs approximately 41,183 chemistry, 27,543 hematology, and 799 microbiology tests annually.