Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D0696101	08/30/2018
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 August 29-30, 2018. 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.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing (PT) evaluations, review of the laboratory's performance review and corrective action, and interview with the acting laboratory manager, the laboratory failed to evaluate and verify the accuracy of the ungraded bacteriology culture, thyroid stimulating hormone, and LDL and triglycerides results. Findings include: 1. Review of the API PT bacteriology results from the second event of 2017 showed an ungraded organism identification. The laboratory reported Klebsiella pneumoniae and the expected result was Klebsiella variicola. There was no documentation that the laboratory evaluated the PT report to assess their performance and investigate how to correctly identify the organism in the future. 2. Review of the API PT LDL and triglycerides results for sample CH-01 from the first event of 2017 showed an ungraded response with a note to "See Data Summary." There was no documentation that the laboratory evaluated the PT report and the Data Summary to assess their performance and verify the accuracy of the analytes. 3. Review of the API PT thyroid stimulating hormone result for sample CH-11 from the third event of 2016 showed an ungraded response with a

	note to "See Data Summary." There was no documentation that the laboratory evaluated the PT report and the Data Summary to assess their performance and verify the accuracy of the analyte. 4. The acting laboratory manager confirmed the findings during the on-site survey on 8/29/18 at approximately 12:30 PM. The laboratory performs approximately 30,500 chemistry and 1,180 microbiology tests 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 quality control logs and interview with laboratory personnel, the laboratory failed to perform quality control testing using a positive and negative control material each day patient specimens were tested with the MedTox urine drug screens. Findings include: 1. Review of the MedTox urine drug screen control log for July to August 2018 showed that quality control testing was performed for each new lot number of tests used and monthly thereafter. Positive and negative controls were not tested each day patient specimens were tested. 2. Laboratory personnel #2, #3, and #4 interviewed during the on-site survey on 8/30/18 confirmed the findings. The laboratory performs approximately 30,500 chemistry tests annually.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the laboratory blood bank refrigerator temperature logs and the chart recorders and interview with the acting laboratory manager, the laboratory failed to take corrective action for a defective chart recorder which did not record temperatures from 1/10/18 to 1/15/18. Findings include: 1. Review of the blood bank refrigerator temperature chart recorder where blood and blood products are stored revealed that the recorder stopped recording temperatures from 1/10/18 to 1/18/18, The January 2018 temperature log had temperatures recorded by the staff read from the refrigerator chart recorder from 1/10/18 to 1/15/18 as 3.0 degrees Centigrade (C) but there was no documentation that the chart recorder was not recording and no corrective action was taken. The laboratory staff could not verify that the storage temperatures were within the acceptable range of 1 to 6 degrees C during that period except that the audible alarm did not sound to indicate out of range temperatures during that period. 2. The message on the temperature chart noted by the previous laboratory manager said, "Ink was not moving." There was no corrective action

	documented to indicate what was done to repair the malfunctioning recorder and what steps were taken to prevent future recurrence of this malfunction. 3. The acting laboratory manager and laboratory personnel #3 confirmed the findings during the on-site survey on 8/30/18 at approximately 10:00 AM. The laboratory performs approximately 160 immunohematology tests annually.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of laboratory procedures and interview with laboratory personnel, the laboratory did not have a system in place to ensure test results entered manually are accurate and reliably sent from the point of entry to the final report designation. Findings include: 1. The laboratory did not have a system in place to verify the accuracy of test results entered manually for instruments not interfaced with the laboratory information system or tests performed by manual methods such as the Med Tox urine drug screens and mononucleosis tests. 2. The acting laboratory manager, laboratory personnel #2, #3, and #4, interviewed during the on-site survey on 8/30/18 confirmed the finding. The laboratory performs approximately 30,500 chemistry tests annually.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of proficiency testing reports, review of laboratory PT performance reviews and corrective actions, review of laboratory quality assessment procedures, review of testing personnel records, and interview with the acting laboratory manager, and testing personnel, the laboratory director failed to provide overall management and direction in accordance with CFR 493.1445 of this subpart. The laboratory director failed to ensure that proficiency testing reports were evaluated and corrective actions taken to prevent future recurrence of failures (D6092), failed to ensure that testing personnel were trained and their competencies assessed prior to testing patient samples (D6102), and failed to establish and maintain a quality assessment program that would assure the quality of laboratory services provided and identify any failures (D6094).
D6092	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing (PT) program evaluations, review of the laboratory's performance review and corrective actions and interview with the acting laboratory manager, the laboratory director failed to ensure that an approved corrective action plan is followed when any PT result is found to be unacceptable or unsatisfactory. Findings include: 1. The laboratory did not complete the corrective action form, Checklist for Corrective Action, provided by API, to investigate unacceptable PT results which covered possible sources of errors such as specimen handling, clerical errors, quality control, calibration, instrument, and reagents. 2. Review of the API PT evaluation for the third event of 2016 for LDL revealed a score of 40% with three unacceptable results out of five samples tested. The performance review and corrective action stated that the three PT samples with the unacceptable results were repeated. Two of the three repeated sample results were still unacceptable. The corrective action stated, "The lab will make sure by the next survey the result will be in range. Proper mixing and proper lab temperature and time plays a great part in obtaining good results." No other corrective actions or investigations for the unacceptable results to prevent future failures were documented. 3. The API PT evaluation of the next PT event for LDL, the first event of 2017, revealed a score of 60%, indicating two consecutive failures. The performance review and corrective action stated that the two PT samples with the unacceptable results were repeated and were still unacceptable. It also noted, "The lab will make sure to mix the sample properly so as not to get unacceptable result." No other corrective actions or investigations for the unacceptable results to prevent future failures were documented. 4. The API PT evaluation for bacteriology for ear/eye culture for the second event of 2017 had a score of 0%. The laboratory reported Staph. coagulase negative when the expected result was Moraxella catarrhalis. The performance review and corrective action stated, "The lab will see to it that proper staining will be done, although it was stained multiple times before releasing the result." There was no further investigation into the misidentification of the organism and no corrective action to correctly identify the organism in the future. 5. The acting laboratory manager confirmed the findings during the on-site survey on 8/29/18 at 4: 30 PM.
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 the quality assessment program, review of the proficiency testing evaluations, review of the PT performance review and corrective actions, review of the quality control logs, review of the personnel training and competency assessments, and review of the testing personnel job descriptions and duties and responsibilities, the laboratory director failed to ensure that the quality assessment program was

	maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. Findings include: 1. The quality assessment program failed to identify that the corrective actions taken for the failed proficiency test for LDL from the third event of 2016 did not prevent the failure of LDL for the first event of 2017, resulting in two consecutive failures. There was no documentation whether patient results may have been affected by the test system which resulted in the two failures (see D6092). 2. The quality assessment program failed to identify that ungraded PT results for bacteriology and chemistry tests were not evaluated for accuracy (see D5213). 3. The quality assessment program was not established to ensure that manually entered test results were verified for accuracy (see 5801). 4. The quality assessment program failed to identify that quality control tests were not performed each day of patient testing for the MedTox urine drug screens (see D5449). 4. The quality assessment program was not established to ensure that testing personnel possessed a current Nevada State personnel certification (see D6170), to ensure that training and competency evaluations were completed before testing personnel began testing patient samples (see D6102), and to ensure that testing personnel complied with the duties and responsibilities in their job descriptions (see D6174).
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of laboratory personnel records and interview with the acting laboratory manager, the laboratory director failed to ensure that prior to testing patients' specimens, all personnel receive the appropriate training for the services offered and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. Findings include: 1. Review of laboratory personnel training and competency records revealed two of four testing personnel did not have training and competency assessments documented before testing patients' specimens. One testing personnel began employment on 6/01/18 and the other testing personnel began employment on 7/12/18. 2. The acting laboratory manager and laboratory personnel #2 confirmed the findings during the on-site survey on 8/29/18 at approximately 2:00 PM.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manuals and interview with the acting laboratory manager, the laboratory director failed to approve the procedure manuals. Findings include: Review of the procedure manuals showed that the laboratory director was in the process of reviewing and signing the procedures in the blood bank

	manual. Procedures for other laboratory departments still required review and approval by the director. The acting laboratory manager confirmed the finding during the on-site survey on 8/30/18 at approximately 10:00 AM.
D6170	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(a) Each individual performing high complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required. This STANDARD is not met as evidenced by: Based on review of laboratory personnel records, review of the State of Nevada DPBH laboratory personnel certification database and interview with laboratory personnel (LP) #2, LP #2 did not possess a current state license. Findings include: 1. Review of the personnel record for LP #2 revealed a national certification from ASCP for Medical Laboratory Technician for LP #2. In an interview with LP #2 on 8/29/18 at approximately 2:30 PM, he stated that he had a BS degree in Microbiology. 2. Review of the DPBH laboratory personnel certification database revealed that LP #2 had submitted his application for general supervisor for a specialty in hematology on 5 /23/18. A general supervisor's license in hematology would not have allowed for high complexity testing in microbiology and blood bank or any testing in chemistry. No documentation of his education, national certification, and full time work experience as a clinical laboratory technologist required for qualification for a general supervisor license was submitted and thus no license was issued.
D6174	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(a) Each individual performs only those high complexity tests that are authorized by the laboratory director and require a degree of skill commensurate with the individual's education, training or experience, and technical abilities. This STANDARD is not met as evidenced by: Based on review of the job description for laboratory technician and interview with the acting laboratory manager and laboratory personnel (LP) #2, a laboratory technician who began employment on 6/01/18 performed high complexity testing in blood bank and microbiology although the job description excluded those departments from the duties and responsibilities of a laboratory technician. Findings include: 1. The job description for laboratory technician stated, "Competently perform all laboratory tests, including phlebotomy with the exception of Microbiology and Blood Bank department." 2. In an interview with laboratory personnel #2 on 8/29/18 at approximately 2:00 PM, LP #2 stated that he routinely performed high complexity tests in microbiology and blood bank since his employment on 6/01/18. He stated that the previous laboratory manager had trained him in the two departments so he was not aware of any restrictions on his duties and responsibilities. 3. The acting laboratory manager stated during the on-site survey on 8/29/18 at approximately 2:00 PM that she had not reviewed the job description and was not aware of any restrictions on the duties and responsibilities for LP #2.