

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D0696101	(X3) Date Survey Completed 04/27/2020
Name of Provider or Supplier Battle Mountain General Hospital Lab	Street Address, City, State 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 generated as a result of the CLIA proficiency testing desk review, conducted off-site for your laboratory on 4/27/2020. 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.
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on self-reporting by the laboratory director and laboratory manager on 4/22 /2020 and desk review of the American Proficiency Institute (API) proficiency testing</p>

(PT) evaluation forms, the laboratory did not successfully participate in a proficiency testing program. The laboratory's failure to achieve an overall satisfactory proficiency testing event performance for two out of three testing events for basophils, red cell count, hematocrit, hemoglobin, white cell count, and platelet count, with a score of 0% for each listed analyte for the second testing event of 2019 and with a score of 60% for each listed analyte for the first testing event of 2020, resulted in unsuccessful proficiency testing performance. Findings include: The laboratory failed to maintain successful participation with the API PT program shown by the unsuccessful performance for basophils, red cell count, hematocrit, hemoglobin, white cell count, and platelet count in the second testing event of 2019 and the first testing event of 2020 with scores of 0% and 60%, respectively. The laboratory director and laboratory manager contacted the CLIA surveyor on 4/22/2020 at approximately 9:30 AM to report the PT failure. Refer to D2130.

D2130

HEMATOLOGY
CFR(s): 493.851(f)

Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:
Based on self-reporting by the laboratory director and laboratory manager on 4/22 /2020 and desk review of the American Proficiency Institute (API) proficiency testing (PT) evaluation forms, the laboratory did not successfully participate in a proficiency testing program. The laboratory's failure to achieve an overall satisfactory proficiency testing event performance for two out of three testing events for basophils, red cell count, hematocrit, hemoglobin, white cell count, and platelet count, with a score of 0% for each listed analyte for the second testing events of 2019 and with a score of 60% for each listed analyte for the first testing event of 2020, resulted in unsuccessful proficiency testing performance. Findings include: The laboratory failed to maintain successful participation with the API PT program shown by the unsuccessful performance for basophils, red cell count, hematocrit, hemoglobin, white cell count, and platelet count with a score of 0% for each listed analyte for the second testing event of 2019 and a score of 60% for each listed analyte for the first testing event of 2020. The laboratory director and laboratory manager contacted the CLIA surveyor on 4/22/2020 at approximately 9:30 AM to report the PT failure.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:
Based on self-reporting by the laboratory director and laboratory manager on 4/22 /2020 and desk review of the API PT evaluation report, the Condition: Laboratories Performing Moderate Complexity Testing: Laboratory Director was not met. The laboratory director failed to provide overall management and direction in accordance with CFR 493.1407. Findings include: The laboratory director failed to ensure that the laboratory successfully participated in a PT program approved by CMS; as described

in subpart 1 of this part of each specialty, subspecialty and analyte or test in which the laboratory is certified under CLIA. Refer to D6016.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(i)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on self-reporting by the laboratory director and laboratory manager on 4/22/2020 and desk review of the API PT evaluations, the laboratory director failed to ensure that PT samples were tested as required under Subpart H of this part. Findings include: The laboratory failed to maintain successful participation with the API PT program shown by the unsuccessful performance for basophils, red cell count, hematocrit, hemoglobin, white cell count, and platelet count with a score of 0% for each listed analyte for the second testing event of 2019 and a score of 60% for each listed analyte for the first testing event of 2020. The laboratory director and laboratory manager contacted the CLIA surveyor on 4/22/2020 at approximately 9:30 AM to report the PT failure.