

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0061030	(X3) Date Survey Completed 05/10/2023
Name of Provider or Supplier Bear Valley Community Health Care District	Street Address, City, State 41870 Garstin Dr, Big Bear Lake, CA	
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
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 a recertification survey conducted 5/10/2023, review of CLIA database, CASPER Report 0155D and the laboratory's American Proficiency Institute (API) proficiency testing (PT) result reports, and interview with the laboratory manager; it was determined that the laboratory failed to achieve an overall testing event score of acceptable responses for Compatibility Testing in two consecutive testing events or two out of three consecutive testing events resulting in unsuccessful performance. The findings included: a. The laboratory failed to achieve scores of 100 % of acceptable responses for Compatibility Testing in Q2 2021, and Q3 2021 API PT events which was two out of two consecutive testing events resulting in unsuccessful performance.</p>

See D-2181 (b). b. The laboratory failed to achieve scores of 100 % of acceptable responses for Compatibility Testing in Q3 2021 and Q2 2022 API PT events which was two out of three consecutive testing events resulting in unsuccessful performance. See D-2181 (c).

D2122

HEMATOLOGY
CFR(s): 493.851(b)

Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

This STANDARD is not met as evidenced by:
Based on an on-site visit 5/10/2023, review of CLIA database Casper Report 0155D and the laboratory's American Proficiency Institute (API) proficiency testing (PT) result reports, and interview with the laboratory manager; it was determined that the laboratory failed to attain an overall testing event score of at least 80 percent for White Blood Counts (WBC) resulting in unsatisfactory performance. The findings included:
a. The laboratory failed to attain an overall testing event score of at least 80 percent for WBC Differentials in Q1 2023 API PT event resulting in unsatisfactory performance. b. WBC Differentials are a part of Complete Blood Cell (CBC) count testing including, Basophils, Eosinophils, Lymphocytes, Monocytes, and Neutrophils. c. The laboratory attained an overall testing event score of 72% for WBC Differentials in Q1 2023 API PT event which was unsatisfactory performance, as follows: . Q1 2023 API PT event Basophils 60% Eosinophils 60% Lymphocytes 100% Monocytes 80% Neutrophils 60 % d. The laboratory performed approximately 1192 patient Complete Blood Counts monthly. e. The laboratory manager affirmed (5/10/2023 @ 12: 15 PM) that the laboratory attained a score of 72% for WBC Blood Cell Differentials in Q1 2023 API PT event which was unsatisfactory performance.

D2181

COMPATIBILITY TESTING
CFR(s): 493.863(e)

Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:
Based on on-site visit, 5/10/2023, review of CLIA database Casper Report 0155D and the laboratory's American Proficiency Institute (API) proficiency testing (PT) result reports, and interview with the laboratory manager; it was determined that the laboratory failed to achieve an overall testing event score of acceptable responses for two consecutive testing events or two out of three consecutive testing events was unsuccessful performance for Compatibility Testing. The findings included: a. The laboratory manager verified and confirmed by phone conversation (5/23/2023 @ 2:55 PM) that the laboratory failed to attain scores of 100% satisfactory responses for Compatibility Testing in Q2 2021, Q3 2021 and Q2 2022 for API PT events. b. The laboratory failed to achieve an overall testing event score of 100 % acceptable responses for Compatibility Testing in Q2 2021 and Q3 2021, two out of two consecutive testing events was unsuccessful performance, as follows: Year Event Score (%) 2021 Q2 80 2021 Q3 80 c. .The laboratory failed to achieve an overall testing event score of 100 % acceptable responses for Compatibility Testing in Q3

	<p>2021 and Q2 2022, two out of three consecutive testing events was unsuccessful performance, as follows: Year Event Score (%) 2021 Q3 80 2022 Q1 100 2022 Q2 60 d. The laboratory performed compatibility testing on approximately 23 patient samples monthly.</p>
<p>D6016</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</p> <p>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;</p> <p>This STANDARD is not met as evidenced by: Based on on-site visit 5/10/2023, review of CLIA database Casper Report 0155D and the laboratory's American Proficiency Institute(API) proficiency testing (PT) result reports, and interview with the laboratory manager; it was determined that the laboratory director failed to ensure satisfactory performance for proficiency testing samples. The laboratory director failed to ensure the laboratory attained an overall testing event score of at least 80 percent for WBC Blood Cell Differentials in Q1 2023 API PT event resulting in unsatisfactory performance, see D-2122.</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on the servery of the deficiencies cited herin, the Condition: Laboratories performing High Complexity was not met. The laboratory director , high complexity testing fail to ensure Proficiency Testing (PT) samples were tested as required under Subpart H of this part. See D-2181 and D-6089. .</p>
<p>D6089</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i)</p> <p>The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on on-site visit 5/10/2023, review of CLIA database Casper Report 0155D and the laboratory's American Proficiency Institute(API) proficiency testing (PT) result reports, and interview with the laboratory manager; it was determined that the laboratory director failed to ensure acceptable performance for proficiency testing samples. The findings included: a. The laboratory director failed to ensure the laboratory to achieve scores of 100% acceptable responses for Compatibility Testing</p>

in Q2 2021, Q3 2021 and Q2 2022 API PT events resulting in unsuccessful performance. b. The laboratory failed to achieve scores of 100 % of satisfactory responses for Compatibility Testing in Q2 2021, and Q3 2021 API PT events which was two out of two consecutive testing events constituting unsuccessful performances in the test events. See D-2181 (b). c. The laboratory failed to achieve scores of 100 % of satisfactory responses for Compatibility Testing in Q3 2021 and Q2 2022 API PT events which was two out of three consecutive testing events constituting unsuccessful performances in the test event. See D-2181 (c).