

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0056537	(X3) Date Survey Completed 03/24/2022
Name of Provider or Supplier Byu - Idaho Student Health Center	Street Address, City, State 100 Shc, Rexburg, ID	
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 review of Proficiency Testing (PT) results from the American Association of Bioanalysts (AAB), the Centers for Medicare and Medicaid (CMS) PT data report (Report 155D) and an interview with the laboratory manger on 3/24/2022, the laboratory failed to successfully participate and achieve an overall satisfactory score for two (2) of three (3) testing events in 2021 for the subspecialty of hematology. See D2123 and D2131</p>
D2123	<p>HEMATOLOGY CFR(s): 493.851(c)</p>

Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:
Based on a review of Proficiency Testing (PT) results from the American Association of Bioanalysts (AAB), the Centers for Medicare and Medicaid (CMS) PT data report (Report 155D) and an interview with the laboratory manager on 3/24/2022, the laboratory failed to participate in two (2) of three (3) testing events in 2021 for the specialty of hematology. The findings include: 1. A review of Report 155D and graded PT results from AAB identified that the laboratory failed to participate in testing for events one (1) and three (3) in 2021 for the specialty of hematology for the analytes white blood cell differential, erythrocyte count, hematocrit, hemoglobin, leukocyte count and platelet count resulting in scores of zero (0). 2. An interview with the laboratory manager on 3/24/2022 at 1:32 pm confirmed the above findings. 3. The laboratory reports performing 5,500 hematology tests annually.

D2131

HEMATOLOGY
CFR(s): 493.851(g)

Failure to achieve an overall testing event score of satisfactory performance 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 a review of Proficiency Testing (PT) results from the American Association of Bioanalysts (AAB), the Centers for Medicare and Medicaid (CMS) PT data report (Report 155D) and an interview with the laboratory manager on 3/24/2022, the laboratory failed to successfully participate and achieve an overall satisfactory score for two (2) of three (3) testing events in 2021 for the specialty of hematology. The findings include: 1. A review of graded PT results from AAB and Report 155D identified that the laboratory failed to participate and achieve a satisfactory score for events one (1) and three (3) in 2021 for the specialty of hematology. Specialty Year Event Score hematology 2021 1 0% hematology 2021 3 0% 2. An interview with the laboratory manager on 3/24/2022 at 1:32 pm confirmed the above findings. 3. The laboratory reports performing 5,500 hematology tests annually.