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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>13D0056537 | <b>(X3) Date Survey Completed</b><br><br>10/26/2023 |
| <b>Name of Provider or Supplier</b><br><br>Byu - Idaho Student Health Center   | <b>Street Address, City, State</b><br><br>100 Shc, Rexburg, ID             |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |  |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>   |
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| <b>D5291</b>              | <p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT<br/>CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on a review of the laboratory quality assessment (QA) plan, QA documents and an interview with the laboratory manager on 10/26/2023, the laboratory failed to follow the established QA plan. The findings include: 1. A review of "Quality Assessment Plan- Student Health Center Lab" identified 15 quality indicators to be review and the timeline for reviews. 2. A review of Quality Assessment Review Forms, competency assessments and proficiency testing documents identified that the laboratory failed to review 11 of 15 quality indicators in 2022. 3. An interview with the laboratory manager on 10/26/2023 at 2:52 pm confirmed that the laboratory failed to follow their QA plan in 2022. 4. The laboratory reports performing 7,460 tests annually.</p> |
| <b>D5401</b>              | <p>PROCEDURE MANUAL<br/>CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by:</p>  |

Based on a review of the procedure manual and an interview with the laboratory manager on 10/26/23, the laboratory failed to establish a policy for performance of proficiency testing (PT). The findings include: 1. A review of the laboratory procedure manual identified that the laboratory failed to have a policy for PT performance that included enrollment, testing, attestation, results review and corrective actions. 2. An interview with the laboratory manager on 10/26/2023 at 4:42 pm confirmed that the laboratory failed to have a PT procedure. 3. The laboratory reports performing 7,460 tests annually.

**D6030**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(12)

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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:  
Based on a review of laboratory policies and procedures and an interview with the laboratory manager on 10/26/2023, the laboratory director failed to establish a written policy for training and competency assessment of laboratory personnel. The findings include: 1. A review of laboratory policies and procedures identified that the laboratory director failed to establish a policy for training new testing personnel. 2. A review of laboratory policies and procedures identified that the laboratory director failed to establish a policy for assessing testing personnel competency using the six required elements. 3. A review of laboratory policies and procedures identified that the laboratory director failed to establish a policy for assessing the competency of the technical consultant based on position responsibilities which includes assessment frequency. 4. An interview with the laboratory manager on 10/26/2023 at 4:42 pm confirmed that the laboratory director failed to establish a training and competency policy. 5. The laboratory reports performing 7460 tests annually.