

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 13D0056537	<b>(X3) Date Survey Completed</b> 10/30/2025
<b>Name of Provider or Supplier</b> Byu - Idaho Student Health Center	<b>Street Address, City, State</b> 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>
<b>D0000</b>	During an offsite paper revisit the laboratory was found to be in compliance with CLIA regulations (42 CFR Part 493 effective April 24, 2003.), all previous deficiencies found were corrected.
<b>D2007</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) documents, facility PT policy, the Centers for Medicare and Medicaid Services (CMS) 209 personnel form and an interview with the laboratory manager on 10/30/2025, the laboratory failed to have PT samples tested by the testing personnel (TP) that routinely test patient samples since the last inspection on 10/26/2023. The findings include: 1. A review of hematology PT attestation records for 2023 event three, 2024 events one, two and three and 2025 events one and two identified that the laboratory manager and the technical consultant, who is not a TP, performed all the of the PT sample testing. 2. A review of the laboratories policy "BUYI Policy for Proficiency Testing" established as evidence of correction from the 10/26/2023 inspection identified that the facility failed to follow their policy and treat samples the same as patient samples. 3. A review of the CMS 209 listed ten TP performing patient testing identifying that the laboratory failed to have nine of ten TP perform PT testing in 2023, 2024 and 2025. 4. An interview with the laboratory manager on 10/30/2025 at 10:33 am confirmed that the regular TP that performed patient testing did not perform PT. 4. The laboratory reports performing 10,032 hematology tests annually.</p>
<b>D5209</b>	<b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b>

CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:

Based on a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, laboratory policies, competency assessment records and an interview with the laboratory manager on 10/30/2025, the laboratory failed to follow written policies and procedures to assess testing personnel and technical consultant in 2024 and 2025. The findings include: 1. A review of the CMS 209 form identified ten testing personnel (TP) and one technical consultant. 2. The laboratory policy "BYUI Policy on Competency and Training" which was implemented as evidence of correction from the 10/26/2023 inspection, states that there will be an initial training, six month competency, one year after the start date then annual competency each year after. 3. A review of competency assessment and training records identified the laboratory failed to have initial training for eight of eight TP hired after the last inspection on 10/26/2023. 4. A review of competency assessment records identified the laboratory failed to have six month competency assessments for eight of eight TP. 5. A review of competency assessment records identified the laboratory failed to have annual competency assessments for two of two TP in 2024 and six of six TP in 2025. 6. A review of competency assessment records identified that the laboratory director failed to perform competencies for the technical consultant (TC) for their TC responsibilities in 2024 and 2025. 7. An interview with the laboratory manager on 10/30/2025 at 10:00 am confirmed that the laboratory failed to follow their policy and perform initial training and competencies in 2024 and 2025. 8. The laboratory reports performing 10,032 tests annually.