

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  13D0056537	<b>(X3) Date Survey Completed</b>  03/13/2018
<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>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on an interview with the laboratory manager and a record review of personnel documents, the laboratory failed to establish and follow procedures to assess the technical consultant competency since the last survey on April 13, 2016. Findings: 1. A review of personnel documents and laboratory procedures and policies revealed the laboratory failed to establish in writing and assess the competency for the technical consultant listed on the CMS-209 Personnel Report form. 2. An interview on March 13, 2018 at 10:05 AM, with the laboratory manager, confirmed the laboratory failed to establish and assess the competency for the technical consultant.</p>
<b>D6032</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(14)</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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.</p>

This STANDARD is not met as evidenced by:  
Based on an interview with the laboratory manager and a record review, the laboratory director failed to specify in writing, the responsibilities and duties of the technical consultant engaged in the preanalytic, analytic, and postanalytic phases of testing since the last survey on April 13, 2016. Findings: 1. A review of the laboratory documents revealed the laboratory failed to specify in writing the responsibilities and duties of the technical consultant listed on the CMS-209 Personnel Report form. 2. An interview on March 13, 2018 at 10:10 AM, with the laboratory manager, confirmed the laboratory director failed to specify in writing the responsibilities for the technical consultant.

**D6033**

**TECHNICAL CONSULTANT-MODERATE COMPLEXITY**

CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:  
Based on an interview with the laboratory manager and record review, the technical consultant failed to meet the qualifications and provide technical oversight. Refer to D6035, D6046, and D6053.

**D6035**

**TECHNICAL CONSULTANT QUALIFICATIONS**

CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for

"laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:

Based on an interview with the laboratory manager and a record review of personnel documents, the laboratory failed to ensure the technical consultant was qualified prior to providing technical consultation for the laboratory in the specialty of hematology since the last survey on April 13, 2016. Findings: 1. A review of personnel education documents revealed that the laboratory failed to qualify the 1 technical consultant listed on the CMS-209 Personnel Report form prior to providing technical consultation to laboratory. 2. An interview on March 13, 2018 at 9:45 AM, with the laboratory manager, confirmed the laboratory failed to qualify the technical consultant who provides technical consultation for the laboratory.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on an interview with the laboratory supervisor and personnel records review, the laboratory failed to have a qualified individual perform competency assessments on the 10 testing personnel performing complete blood counts since the last survey on April 13, 2016. Findings: 1. A review of personnel records revealed the laboratory allowed testing personnel that do not qualify perform competency assessments on the 10 personnel listed on the CMS-209 Personnel Report form. 2. An interview on March 13, 2018 at 12:30 PM, with the laboratory supervisor, confirmed the laboratory failed to have a qualified individual perform competency assessments.

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on an interview with the laboratory manager and a record review of personnel documents, the laboratory failed to establish and follow a written procedure for assessing employee competency at least semiannually during the first year of patient testing on the Medonic analyzer used to test complete blood counts since the last survey on April 13, 2016. Findings: 1. A record review of personnel documents revealed 8 out of 14 testing personnel listed on the CMS-209 Personnel Report form,

failed to have competency assessments performed at least semiannually during the first year of patient testing. 2. An interview on March 13, 2018 at 9:30 AM, with the laboratory manager, confirmed the laboratory failed to perform competency at least semiannually on 8 testing personnel.

**D6065**

**TESTING PERSONNEL QUALIFICATIONS**

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on an interview with the laboratory manager and a record review of personnel documents, the laboratory failed to ensure all the testing personnel are qualified to perform testing on the Medonic complete blood count analyzer since the last survey on April 13, 2016. Findings: 1. A review of personnel education documents revealed that 1 out of 10 personnel listed on the CMS-209 Personnel Report form, from Peru, failed to have their foreign education equivalency evaluated before testing patient specimens. 2. An interview on March 13, 2018 at 9:45 AM, with the laboratory manager, confirmed the laboratory failed to have the foreign education equivalency evaluated prior to testing patient specimens.