Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0056537	11/04/2020
Name of Provider or Supplier	**Street Address, City, State**	
Byu - Idaho Student Health Center	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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on an American Association of Bioanalysts (AAB) proficiency test (PT) record review from 2018 to 2020 and an interview with the laboratory supervisor on November 4, 2020, the laboratory director failed to attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. Findings: 1. A PT record review revealed that the AAB Hematology 2019 event 3 attestation was not signed by the laboratory director. 2. A PT record review revealed that the AAB Hematology 2020 event 1 and event 2 attestation were signed by the technical consultant not the laboratory director. There was no delegation of authority for the technical consultant to act as a designee for the laboratory director for the attestation of PT . 3. An interview with the laboratory supervisor on November 4, 2020 at 3:30 pm, confirmed that the 2019 event 3 attestation had not been signed and the 2020 events 1 and 2 had been signed by the technical consultant. It was also confirmed that there was no delegation of authority for the technical consultant to act as a designee for the laboratory director for the attestation of PT.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) 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.

	This STANDARD is not met as evidenced by: Based on policy and procedure review and an interview with the laboratory supervisor on November 4, 2020, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the laboratory. Findings: 1. Based on policy and procedure review the laboratory did not have a quality assurance procedure to monitor, assess and correct problems identified in the laboratory. The laboratory has an instrument error/action log used for the Medonic hematology analyzer but no procedure for when to fill it out and what to do when a problem can not be resolved. 2. The instrument Error/Action log for February 20, 2020 had documented that the high quality control (QC) had been performed four times and the low QC was repeated for complete blood count (CBC) testing. The instrument Error/Action log for February 24, 2020 had documented that the high QC had been performed six times for CBC testing. The instrument Error/Action log for February 25, 2020 had documented that the high QC had been performed four times for CBC testing 3. An interview with the laboratory supervisor on November 4, 2020 at 4:07, confirmed that the laboratory did not have a policy or procedure to monitor, assess, and, correct problems identified in the laboratory. It was confirmed that they have an instrument Error/Action log for the Medonic hematology analyzer but not everyone documents analyzer errors and or issues and that they do not monitor the log. 4. The laboratory reports performing 1200 patient CBC specimens annually.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on the Medonic hematology maintenance log review and an interview with the laboratory supervisor on November 4, 2020, the laboratory failed to perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. Findings: 1. The laboratory performs complete blood counts (CBC) on the Medonic hematology analyzer. A random review the Medonic hematology maintenance log from April 2018 to November 2020, revealed that the monthly maintenance of monthly cleaning and clot prevention maintenance were not documented in May, August, September of 2020 and these logs were all reviewed and signed by the technical consultant on October 29, 2020. 2. A random review the Medonic hematology maintenance log from April 2018 to November 2020, revealed that monthly clot prevention maintenance was not documented in June, and July of 2020 and these logs were reviewed and signed by the technical consultant on October 29, 2020. 3. A random review the Medonic hematology maintenance log from April 2018 to November 2020, revealed that the daily maintenance was not documented on 7 /30/20, 8/18/20, 9/17/20, 9/18/20, 9/21/20-9/25/20, 10/26/20-1030/20 and 11/2/20. 3. An interview with the laboratory supervisor confirmed that the Medonic monthly maintenance had not been completed in May, June, July, August and September of 2020 and the logs were reviewed and signed by the technical consultant on October 29, 2020. 4. The laboratory reports performing 1200 patient CBC specimens annually.

D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based record review of the laboratory's Medonic quality control (QC) logs and interview with the laboratory supervisor on November 4, 2020, the laboratory failed to monitor over time the accuracy and precision of test performance for hematology testing that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. Findings: 1. A Medonic QC log record review revealed that the laboratory failed to monitor shifts and trends of their hematology complete blood count (CBC) testing over time to ensure proper testing performance. 2. An interview with the laboratory supervisor on November 4, 2020 at 3:40 pm, confirmed that the laboratory failed to monitor shifts and trends of their hematology CBC QC using a Levy- Jennings chart or by any other method. 3. The laboratory reports performing 1200 patient CBC specimens annually.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review of the laboratory's quality control (QC) logs for the Medonic hematology analyzer and an interview on November 4, 2020, with the laboratory supervisor, the laboratory failed to perform 2 levels of controls for each day of patient testing. Findings: 1. A record review of the laboratory's quality control (QC) logs for the Medonic hematology analyzer for October of 2020 and the first four days in November of 2020, the laboratory failed to document QC on six of the patient testing days. 11/ 2/ 2020 no QC documented 3 patients analyzed 10/30/2020 no QC documented no patients analyzed 10/29/2020 no QC documented no patients analyzed 10/28/2020 no QC documented 2 patients analyzed 10/27/2020 no QC documented 6 patients analyzed. 10/26/2020 no QC documented no patients analyzed 2. Based on the record review of the laboratory's quality control (QC) logs for the Medonic hematology analyzer for October it was determined that the technical consultant had reviewed and signed the documents on October 29, 2020 despite having no QC documented for the dates listed above and no documentation that the analyzer was out

	of service. 3. An interview with the laboratory supervisor on November 4, 2020 at 2: 50 pm, confirmed that QC had not been perform, and patients samples had been analyzed on the above mentioned dates and the technical consultant had signed off on the Medonic analyzer QC log for October .
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a random review of patient test reports and an interview with the laboratory supervisor on November 4, 2020, the laboratory failed to indicate the name and address of the laboratory where the test was performed on the test report for those patient specimens that are performed at a different laboratory or location for testing. Findings: 1. A review of a patient test report from 6/29/2020 in which the specimen was sent to Express Laboratory for testing indicated that the testing was performed at BYU. 2. A review of a patient test report from 10/30/2020 in which the specimen was sent to LabCorp for testing indicated that the testing was performed at BYU. 3. An interview with the laboratory supervisor on November 4, 2020 at 4:36 pm confirmed that the testing on reports were performed at Express Laboratory and LabCorp and that the reports in the patient charts did not identify the referring laboratory's name and location for those patient tests that had been performed by the referred laboratory.
D6028	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10) 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)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart; This STANDARD is not met as evidenced by: Based on record review of personnel education documents and an interview with the laboratory supervisor on November 4, 2020, the laboratory director failed to employ laboratory personnel with the appropriate education and either experience or training to accurately perform tests and report test results in accordance with the personnel responsibilities described in the state operations manual subpart M. Findings: 1. A review of personnel education documents revealed that 2 out of 13 testing personnel listed on the CMS-209 Personnel Report Form did not have educational

	documentation. 2. An interview with the laboratory supervisor on November 4, 2020 at 1:30 pm, confirmed that the laboratory failed to have the educational documentation for 2 of 13 testing personnel. 3. The laboratory reports performing 13,200 moderate and waived patient tests annually.
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 a document review of the laboratories personnel competency assessments and an interview with the laboratory supervisor on November 4, 2020, the technical consultant failed to establish and follow a written procedure for evaluating the competency of all testing personnel and assure that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. Findings: 1. The laboratory testing personnel report (CMS-209) identifies 13 testing personnel performing moderate and waived testing. 2. A document review of personnel competency assessments revealed that 4 of 13 testing personnel had missing or incomplete initial training and were performing patient testing. 3. A document review of personnel competency assessments revealed that 2 of 13 testing personnel did not have a semi-annual competency. 4. A document review of personnel competency assessments revealed that 6 of 13 testing personnel did not have an annual competency for 2019. 5. A document review of personnel competency assessments revealed that 2 of 13 testing personnel did not have an annual competency for 2020. 6. The laboratory records revealed gaps in compliance with daily and monthly maintenance and quality control for the Medonic hematology analyzer. See D5429, D5447 7. An interview with the laboratory supervisor on November 4, 2020 at 1:50 pm, confirmed that the testing personnel did not have all required competency assessments performed. 8. The laboratory reports performing 13,200 moderate and waived patient tests annually. 9. The laboratory was cited on previous survey, 3/13/2018, for the deficient practice of not evaluating the competency of all testing personnel and at the time of the current survey the laboratory did not have evidence of correction as stated in the previous surveys plan of correction.
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 record review of personnel documents and an interview with the laboratory supervisor on November 4, 2020, the laboratory failed to ensure that 2 of 13 testing personnel listed on the the CMS-209 Personnel Report Form meet the requirements to qualify as testing personnel. Findings: 1. A review of personnel education documents revealed that 2 out of 13 testing personnel listed on the CMS-209 Personnel Report Form did not have educational documentation. 2. An interview with the laboratory supervisor on November 4, 2020 at 1:30 pm, confirmed that the laboratory failed to have the educational documentation for 2 of 13 testing personnel. 3. The laboratory was cited on the previous survey, 3/13/2018, for failing to ensure that the testing personnel listed on the CMS-209 qualified as testing personnel and at the time of the current survey the laboratory did not have evidence of correction as stated in the previous surveys plan of correction.