Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0521010	06/04/2019
Name of Provider or Supplier	**Street Address, City, State**	
Rexburg Medical Center	393 E 2nd North, 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
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 on a review of Individualized Quality Control Plans (IQCPs), a review of the procedure manual, and an interview with the laboratory manager, the laboratory failed to have control procedures to monitor the performance of serum human chorionic gonadotropin (hCG) test kit from OneStep since the last survey on July 1, 2017. Based on a review of Individualized Quality Control Plans (IQCPs) and an interview with the laboratory manager, the laboratory failed to specify the manufacturer's requirement for the number, type, and frequency of external quality control testing for the Rapid Test Heliocobacter pylori (H. pylori), human chorionic gonadotropin (hCG), and Cardinal Health Mononucleosis (Mono) Rapid test kits since the last survey on July 1, 2017. Findings: 1. A review of the laboratory IQCPs revealed the quality control plans for serum hCG, mononucleosis, and H. pylori failed to specify the manufacturer's requirement for the number, type, and frequency of external quality control testing since the last survey. 2. A review of the laboratory's procedure manual revealed there was no written procedure for serum hCG quality control performance. 3. The laboratory performed approximately 48 H. pylori, 50 Rapid Mono, and 10

	serum hCG tests in 2018. 4. An interview with the laboratory manager on June 4, 2019 at 9:55 AM, confirmed the laboratory failed to establish quality control procedures for serum hCG tests performed on patient specimens.
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 patient report records and an interview with the laboratory manager, the laboratory failed to indicate the units of measurement for wet preps and urine microscopic tests from dates reviewed between June 2018 through June 2019. Findings: 1. A review of 3 patient test reports for wet preps and 2 patient test reports for urine microscopic revealed the units of measurement failed to be indicated on the reports. 2. The laboratory performed approximately 40 wet preps and 590 urine microscopic tests in 2018. 3. An interview with the laboratory manager on June 4, 2019 at 11:10 AM, confirmed the units of measurement was not included on the patient wet prep and urine microscopic test reports.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on patient report records and an interview with the laboratory manager, the laboratory failed to indicate the reference ranges for wet preps and urine microscopic tests from the dates reviewed between June 2018 through June 2019. Findings: 1. A review of 3 patient test reports for wet preps and 2 patient test reports for urine microscopic revealed the reference ranges failed to be indicated on the patient test reports. 2. The laboratory performed approximately 40 wet preps and 590 urine microscopic tests in 2018. 3. An interview with the laboratory manager on June 4, 2019 at 11:10 AM, confirmed the reference ranges were not included on the wet prep and urine microscopic tests.
D6101	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(11) The laboratory director must 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 a record review and an interview with the laboratory manager, the laboratory director failed to ensure that an on-site general supervisor was available to provide supervision during the weekend hours of laboratory operations and failed to ensure testing personnel had the appropriate education or training since the last survey on July 19, 2017. Findings: 1. A review of laboratory records revealed high-complexity serology test kits for Heliocobacter pylori (H. pylori) and mononucleosis were being performed by 2 out of 2 testing personnel who failed to meet the personnel qualification requirements. 2. An interview with the laboratory manager on June 4, 2019 at 12:15 PM, confirmed the laboratory director failed to ensure testing personnel were qualified for high-complexity tests and an on-site general supervisor was provided for supervision.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (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 review of personnel documents and an interview with the laboratory manager, the technical supervisor failed to evaluate the competency of 6 out of 6 testing personnel performing hematology, chemistry, and microbiology tests since the last survey on July 1, 2017. Findings: 1. A review of competency assessment records revealed the laboratory technical supervisor failed to perform and document competency assessments for 6 out of 6 testing personnel who performed tests for the specialties of hematology, chemistry, and microbiology since the last survey. 2. An interview with the laboratory manager on June 4, 2019 at 8:45 AM, confirmed testing personnel competency assessments were not performed since the last survey.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on a review of personnel records and an interview with the laboratory manager, the laboratory failed to ensure that prior to testing patient specimens 2 out of 2 personnel met the qualification requirements for high-complexity testing since the last survey on July 19, 2017. Findings: 1. A review of personnel records revealed 2 out of 2 testing personnel performing high-complexity serology tests for Heliocobacter pylori (H. pylori) and mononucleosis failed to meet the qualification requirements. 2.

	An interview with the laboratory manager on June 4, 2019 at 11:00 AM, confirmed the laboratory failed to ensure the 2 testing personnel performing high-complexity tests met the qualifications.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) 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 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; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)

	(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on personnel records and an interview with the laboratory manager, 2 out of 2 testing personnel failed to meet the qualification requirements for high-complexity testing personnel under 493.1489 since the last survey on July 19, 2017. Findings: 1. A record review of personnel education documents revealed the laboratory employed 2 unqualified testing personnel for weekend shifts who performed high-complexity Heliocobacter pylori (H. pylori) and mononucleosis tests. 2. An interview with the laboratory manager on June 4, 2019 at 9:30 AM, confirmed the laboratory failed to verify education and test complexity for weekend shift work.