

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0962844	(X3) Date Survey Completed 07/16/2019
Name of Provider or Supplier Rexburg Community Care	Street Address, City, State 404 N 2nd St E, 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a record review and an interview with the technical supervisor, the laboratory failed to verify the accuracy of Helicobacter pylori (H. pylori) at least twice annually since the last survey on October 10, 2017. Findings: 1. A record review of laboratory documents revealed the laboratory failed to document the accuracy of H. pylori at least twice a year since the last survey. 2. The laboratory performed approximately 85 H. pylori tests in 2018. 3. An interview with the technical supervisor on July 16, 2019, at 8:50 AM, confirmed the laboratory failed to document the accuracy of H. pylori at least twice a year.</p>
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p>

This STANDARD is not met as evidenced by:
 Based on a record review and an interview with the technical supervisor, the laboratory failed to identify and document corrective actions for the refrigerator temperatures that were lower than the stated reference range of 2C to 8C where quality control material for the Sysmex XP-300 complete blood count analyzer was stored from December 2018 through February 2019. Findings: 1. A record review of the laboratory refrigerator temperature chart revealed the acceptable reference range was 2 to 8C. 2. A review of the refrigerator temperature chart revealed the laboratory staff failed to identify and document corrective actions for the refrigerator temperatures that were below the reference range for 12 out of 29 days in December 2018, 12 out of 31 days in January 2019, and 16 out of 28 days in February 2019. 3. An interview with the technical supervisor on July 16, 2019, at 9:15 AM, confirmed the laboratory staff failed to document and correct temperatures for the refrigerator that were below the reference range.

D6102

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
 Based on a record review and an interview with the technical supervisor, the laboratory director failed to ensure that 7 out of 9 testing personnel were qualified by education, experience, and training prior to performing high-complexity tests on the McKesson Helicobacter pylori (H. pylori) test kit since the last survey on October 10, 2017. Findings: 1. A review of personnel records revealed 7 out of 9 testing personnel failed to meet the education requirement for high-complexity testing of the H. pylori test kits. 2. A review of 2 out of 2 personnel training documents and 2 out of 2 patient test reports, revealed the testing personnel failed to have documented training prior to reporting patient H. pylori test results. 3. The laboratory performed approximately 85 H. pylori tests in 2018. 4. An interview with the technical supervisor on July 16, 2019, at 9:50 AM, confirmed the laboratory failed to ensure the testing personnel met the education and training requirements for high-complexity H. pylori tests.

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, the laboratory failed to ensure that prior to reporting patient Helicobacter pylori (H. pylori) tests that 7 out of 9 testing personnel met the education qualification requirements for high-complexity testing since the last survey on October 10, 2017. Refer to 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 technical supervisor, 7 out of 9 testing personnel failed to meet the education qualification requirements for high-complexity testing personnel under 493.1489 since the last survey on October 10, 2017. Findings: 1. A review of personnel records revealed 7 out of 9 testing personnel performing high-complexity H. pylori failed to meet the education qualification requirements. 2. An interview with the technical supervisor on July 16, 2019, at 9:50 AM, confirmed the laboratory failed to ensure the testing personnel met the education and training requirements for high-complexity H. pylori tests.