

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D2074775	(X3) Date Survey Completed 09/11/2024
Name of Provider or Supplier Fall River Family Medicine	Street Address, City, State 21 Winn Dr, 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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 a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, training and competency assessment records and an interview with the laboratory lead on 9/11/2024, the laboratory failed to follow written policies and procedures to assess testing personnel competency in 2023 and 2024. The findings include: 1. The CMS 209 form identified eight (8) testing personnel (TP) performing moderate complexity testing of which five (5) were new since the last inspection on 12/1/2022. 2. A review of training and competency assessment records identified that the laboratory failed to have initial training for five (5) of five (5) new TP. 3. A review of training and competency assessment records identified that the laboratory failed to have an annual competency assessment for one (1) TP in 2023. 4. A review of training and competency assessment records identified that the laboratory failed to have an annual competency assessment for one (1) TP in 2024. 6. An interview with the laboratory lead on 9/11/2024 at 8:40 am confirmed the above findings. 7. The laboratory reports performing 25,000 moderate complexity tests annually.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p>

This STANDARD is not met as evidenced by:
Based on a review of proficiency testing (PT) documentation from Wisconsin State Laboratory of Hygiene (WSLH), and an interview with the laboratory lead on 9/11/2024, the laboratory director or delegated designee failed to review PT results in 2023. The findings include: 1. A review of PT documents for 2023 from WSLH identified that the laboratory director failed to review results for Hematology event three. 2. An interview with the laboratory lead on 9/11/2024 at 9:20 am confirmed that the laboratory director failed review the above PT results. 3. The laboratory reports performing 25,000 tests annually.

D5781

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(1)

(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.

This STANDARD is not met as evidenced by:
Based on review of temperature logs and an interview with the laboratory lead on 9/11/2024, the laboratory failed to document corrective actions when refrigerator temperatures were out of the established range in 2024. The findings include: 1. A review of the laboratory temperature logs for 2023 and 2024 identified that the laboratory failed to document corrective actions for 7 of 30 days in April 2024 and 2 of 31 days in May 2024 when the refrigerator temperatures were out of the established range of 2-8 C. 2. An interview with the laboratory lead on 9/11/2024 at 9:46 am confirmed the above finding. 4. The laboratory reports performing 25,000 tests annually.