Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D2074775	02/24/2021
Name of Provider or Supplier	**Street Address, City, State**	
Fall River Family Medicine	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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a record review of proficiency testing (PT) from American Academy of Family Physicians (AAFP) and an interview with the laboratory lead on 2/24/2021, the laboratory failed to review PT and evaluate results that were less than 100% but greater than or equal to 80% for 2019 and 2020. The Findings include: 1. A review of PT records from AAFP for 2019 event A identified that the laboratory failed to evaluate the results for red blood cell count with and overall score of 80%. 2. A review of PT records from AAFP for 2020 event A identified that the laboratory failed to evaluate the results for cell identification/white blood cell differential with and overall score of 80%. 3. An interview with the laboratory lead on 2/24/2021 at 9:20 confirmed that the laboratory failed to evaluate PT results that were less than 100% but greater than or equal to 80% for 2019 and 2020. 4. The laboratory reports performing 5000 CBC tests annually.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

	This STANDARD is not met as evidenced by: Based on observation, record review of temperature logs and an interview with the laboratory lead on 2/24/21, the laboratory failed to document temperatures in their reagent and quality control (QC) storage refrigerator as required by the manufacturer for proper storage of reagents and QC. The findings include: 1. An observation of a refrigerator downstairs and review of temperature logs identified that the laboratory did not document temperatures for this refrigerator containing Cell-Dyn 18 plus controls, with a manufacturer storage requirement of 2C-10C, Piccolo reagents and A1C reagents. 2. An interview with the laboratory lead on 2/24/21 at 10:10 am confirmed that the laboratory failed to document the temperature of the reagent and QC storage refrigerator. 3. The laboratory reports performing 13,000 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 a review of temperature logs and an interview with the laboratory lead on 2/24/2021, the laboratory failed to document corrective actions for temperatures that were not documented or were not within the established performance specifications. The findings include: 1. Based on a random review of temperature logs for the refrigerator in the laboratory (upstairs refrigerator) the laboratory failed to document temperatures for fifteen (15) days in 2020 and no corrective actions were documented. 2. Based on a random review of temperature logs for the refrigerator in the laboratory (upstairs refrigerator) the laboratory failed to document corrective actions for the eleven (11) days that the recorded temperature was out of the established range of 36-46 F. 3. An interview with the laboratory lead on 2/24/2021 at 10:10 am confirmed that there were no corrective actions for the undocumented temperatures or for the temperatures that were out of the established range. 4. The laboratory reports performing 5000 CBC tests annually.