Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0935096	04/14/2026
Name of Provider or Supplier	**Street Address, City, State**	
Primary Care Specialists	110 Vista Dr, Pocatello, 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
D0000	Based on an off-site paper revisit the laboratory was found to be in compliance with CLIA regulations (42 CFR Part 493, effective April 24, 2003), all previous deficiencies found were corrected.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 review of manufacturer's instructions, direct observation, a review of laboratory temperature logs and an interview with the technical consultant on 4/14 /2026, the laboratory failed to monitor room temperature in the laboratory where Afinion 2, Sofia 2 and other waived test kits were being stored and tested and the patient sample storage refrigerator temperature since the previous inspection on 5/14 /2024. The findings include: 1. A review of the Sofia 2 Flu + SARS Antigen FIA manufacturer instructions for use (IFU) identified storage temperatures of 59- 86 F. A review of the Afinion manufacturer's instructions identified an operating temperature of 59-89 F. A review of the Consult hCG urine tests and the Consult mononucleosis test IFUs identified a storage temperature of 36-86 F. A review of the Consult Immunochemical Fecal Occult test IFU identified a storage temperature of 59-86 F. 2. A direct observation in the patient sample collection room at 1:58 on 4/14/2026 identified a patient sample refrigerator. 3. A direct observation at 1:59 pm on 4/14

	/2026 in the laboratory identified the following: a. Quidel/Ortho Sofia 2 analyzer b. Afinion 2 analyzer c. Consult hCG urine test kits lot #0001141312, expiration 6/22 /2027 d. Consult Immunochemical Fecal Occult Blood test kits lot # 0425171-1, expiration 2/28/2027 e. Consult Mononucleosis test kits lot #224J11A, expiration 9/30 /2026 f. Sofia Flu+ SARS Antigen FIA lot #226505, expiration 10/29/2026 4. A review of laboratory temperature logs identified the laboratory failed to monitor the patient sample refrigerator temperature and the laboratory room temperature since the last inspection on 5/14/2024. 5. An interview with the technical consultant on 4/14 /2026 at 1:59 pm confirmed the above findings. 6. The laboratory reports performing 2,348 moderate complexity and waived tests annually.