Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D2068835	06/16/2025
Name of Provider or Supplier	**Street Address, City, State**	
Air St Luke's - Treasure Valley	4000 S Orchard St, Boise, 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	During an offsite 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 a lack of laboratory temperature and humidity logs and an interview with technical consultant 1 (TC1) on 6/16/2025, the laboratory failed to establish and monitor the testing temperature and humidity and storage temperature for the Siemens epoc Blood Analysis System in mobile units. The findings include: 1. A lack of the laboratory temperature and humidity logs identified the laboratory failed to establish and monitor testing temperature and humidity per the Siemens epoc Blood Analysis System requirements. 2. A lack of the laboratory temperature logs identified the laboratory failed to establish and monitor reagent storage temperature in the two ambulances per the Siemens epoc Blood Analysis System requirements. 3. An interview with TC1 on 6/16/2025 at 2:15 pm confirmed that the laboratory failed to monitor temperature and humidity on the ambulances. 4. The laboratory reports performing 1418 tests annually.

D6005	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c) (c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities. This STANDARD is not met as evidenced by: Based on a review of laboratory policies, a lack of documentation and an interview with technical consultant 1 (TC1) on 6/16/2025, the laboratory failed to establish and follow a policy for laboratory director on-site visits at least once every six months. the findings include: 1. A review of laboratory policies identified that the laboratory failed to establish a policy for laboratory director on-site visits every 6 months. 2. A lack of documentation identified that the laboratory failed to perform an on-site visit since the regulation went into effect on December 28, 2024. 3. An interview with TC1 on 6/16/2025 at 1:39 pm confirmed the above findings. 4. The laboratory reports performing 1,418 tests annually.