Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D2068835	06/21/2023
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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, competency assessment records and an interview with technical consultant 1 (TC1) on 6/21/2023, the laboratory failed to follow written policies and procedures to assess testing personnel competency in 2022. The findings include: 1. The CMS 209 identified thirteen (13) testing personnel performing testing on the Siemens EPOC which includes the following analytes: pH, pCO2, pO2, TCO2, ionized calcium, creatinine, chloride, glucose, potassium, sodium, hematocrit and lactic acid. 2. A review of competency assessment records identified seven (7) of thirteen (13) testing personnel failed to have an annual competency assessment for 2022. 3. An interview with TC1 on 6/21/2023 at 11:50 am and by email on 6/23/2023 confirmed the above finding. 4. The laboratory reports performing 1600 tests annually on the Siemens EPOC analyzers.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a

	minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of Siemens EPOC calibration verification documents and an interview with the point of care testing (POC) manager on 6/21/2023, the laboratory failed to verify the reportable range at least once every six months for their two Siemens EPOC analyzers for 2022 and 2023. The findings include: 1. A review of calibration verification documents identified that the laboratory failed to perform verifications of the reportable ranges for pH, pCO2, pO2, TCO2, ionized calcium, creatinine, chloride, glucose, potassium, sodium, hematocrit and lactic acid on one (1) of two (2) EPOC analyzers (27766, 28040) every six months in 2022 and 2023. 2. An interview with the POC manager on 6/21/2023 at 10:13 am confirmed that the laboratory had not performed verifications of reportable range for analytes at least once every six months on both EPOC analyzers. 3. The laboratory reports performing 1600 tests annually on the Siemens EPOC analyzers.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on a lack of documentation and an interview with the point of care testing (POC) manager on 6/21/2023, the laboratory failed to evaluate results for analytes performed on multiple analyzers to ensure that they are within the allowed acceptable difference between analyzers. The finding include: 1. A lack of documentation for analyte result comparison between the laboratories two Siemens EPOC analyzers identified that the laboratory failed to evaluate test results for pH, pCO2, pO2, TCO2, ionized calcium, creatinine, chloride, glucose, potassium, sodium, hematocrit and lactic acid to ensure that they were within the allowed acceptable difference between the two analyzers. 2. An interview with the POC manager on 6/21/2023 at 10:32 confirmed that the laboratory failed to compare analyte results between analyzers to ensure accurate patient testing. 3. The laboratory reports performing 1600 tests annually on the Siemens EPOC analyzers.