Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0703662	08/27/2024
Name of Provider or Supplier	**Street Address, City, State**	
Cascade Medical Center	402 Lake Cascade Pkwy, Cascade, 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
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of the bioMrieux Vidas 3 maintenance logs and an interview with the laboratory manager on 8/27/2024, the laboratory failed to perform maintenance as required by the manufacturer in 2022, 2023 and 2024. The findings include: 1. A review of the bioMrieux Vidas 3 maintenance logs identified that the laboratory failed to have documentation of semi annual maintenance performance (cleaning the housing, front cover, vials, tubes, disposables rack, reagent strip sections and touch screen) for 2022 as required by the manufacturer. 2. A review of bioMrieux Vidas 3 maintenance logs identified that the laboratory failed to perform monthly maintenance (cleaning the SPR block) in October 2022, November 2022, December 2022, February 2023, June 2023 and January 2024. 3. An interview with the laboratory manager on 8/27/2024 at 11:32 am confirmed the above findings. 4. The laboratory reports performing 296 tests on the bioMrieux Vidas 3 annually.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or

	baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a direct observation, lack of documentation and an interview with the laboratory manager on 8/27/2024, the laboratory failed to calibrate the pipette used for chemistry testing. The findings include: 1. During the laboratory tour on 8/27/2024 a direct observation identified an MLA adjustable volume pipette (50,100, 200 ul). 2. A lack of laboratory calibration documents identified that the laboratory failed to calibrate the pipette since the last inspection in September 2022. 3. An interview with the laboratory manager on 8/27/2024 at 12:53 pm confirmed that the laboratory had not calibrated the pipette. 4. The laboratory reports performing 41,501 chemistry tests annually.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of Quality Control (QC) documentation and an interview with the laboratory manager on 8/27/2024, the laboratory failed to successfully perform two levels of QC each day of patient testing for procalcitonin. The findings include: 1. A random record review of QC documents from the bioMrieux Vidas 3 for 2022, 2023 and 2024 identified that the laboratory failed to perform two levels of QC for procalcitonin on 1/25/2023, 12/18/2023 and 12/19/2023. The laboratory performed procalcitonin tests on one patient each of the preceding days (230250017, 233520003, 233530048). 2. An interview with the laboratory manager on 8/27/2024 at 12:40 pm confirmed the above finding. 3. The laboratory reports performing 70 procalcitonin tests annually.