

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D0856060	(X3) Date Survey Completed 03/10/2026
Name of Provider or Supplier Oregon State University Student Health Laboratory	Street Address, City, State 850 Sw 26th Street, Corvallis, OR	
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	Validation survey A validation survey was performed on March 10, 2026 with the following standard level deficiency cited.
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, manufacturer's labeling, and interview with the Laboratory Director, the laboratory failed to ensure reagents were monitored for room temperature as defined by the manufacturer's instructions for three of three reagents found in draw room 120B as evidenced by: 1. In direct observation at 0918 in draw room 120B the following reagents were not monitored for room temperature according to manufacturer's temperature requirements (manufacturer's requirements were labeled on each package): a. 12 -Copan aerobic collection and penetration swabs lot #260219 expiration date: 2026 07-17 . The manufacturer's label stated, "store at 5-25 degrees C". b. 8-Griener Vacquette K3EDTA tubes (purple top) lot #B2504334 expiration date: 08-01-2026. The manufacturer's label stated, "store at 4-25 degrees C". c. 8- Griener Sodium Citrate tube (blue top) lot #5293024 expiration date: 07-31-2026. The manufacturer's label stated, "store at 4-25 degrees C." 2. In interview with the Laboratory Director at 0920 he confirmed that room 120B draw station was not monitored for temperature.</p>