

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 13D2047419	<b>(X3) Date Survey Completed</b> 11/20/2025
<b>Name of Provider or Supplier</b> Raise The Bottom	<b>Street Address, City, State</b> 9196 W Barnes St, Boise, ID	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5413</b>	<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 a lack of laboratory temperature logs, a review of the Sciex 4500 user manual and an interview with the technical supervisor on 11/20/2025, the laboratory failed to establish and monitor the testing temperature and humidity for the Sciex 4500. The findings include: 1. A lack of room temperature and humidity logs for the Sciex 4500 identified the laboratory failed to establish and monitor testing temperature and humidity per manufacturer requirements. 2. A review of the Sciex 4500 user manual identified an operating temperature of 5-40 C and an operating humidity of 20-80%. 3. An interview with the technical supervisor on 11/20/2025 at 3: 18 pm confirmed that the laboratory failed to monitor temperatures and humidity for the Sciex 4500.</p>
<b>D5429</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p>

This STANDARD is not met as evidenced by:

Based on a review of Beckman Coulter AU480 maintenance logs and an interview with the technical supervisor on 11/20/2025, the laboratory failed to perform maintenance as required by the manufacturer. The findings include: 1. A review of the Beckman Coulter AU480 maintenance logs identified that the laboratory failed to document daily maintenance performance which included: inspecting the syringes for leaks; inspect the wash solution roller pump for leaks; inspect, clean and prime the sample probe, reagent probe and mix bars; inspect and replenish the wash solution from September 13, 2023 to November 3, 2025. 2. A review of the Beckman Coulter AU480 maintenance logs identified that the laboratory failed to document weekly maintenance performance which included: cleaning the sample probe and the mix bars; perform a W2; perform a photocal; clean the pre-dilution bottle from September 13, 2023 to September 1, 2025. 3. A review of the Beckman Coulter AU480 maintenance logs identified that the laboratory failed to document monthly maintenance performance which included: cleaning the sample probe and reagent probe wash wells; cleaning the mix bar wash wells; cleaning the wash nozzle unit and checking the tube mounting joints and cleaning the DI water tank, DI filter, and sample probe filter from September 2023 to January 2025. 4. An interview with the technical supervisor on 11/20/2025 at 2:43 pm confirmed that maintenance performance had not been documented. .