

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2163988	(X3) Date Survey Completed 06/13/2024
Name of Provider or Supplier Valley Lab, Llc	Street Address, City, State 4460 So Highland Drive, Salt Lake City, UT	
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
D6018	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing (PT) records review, lack of documentation and document review of the laboratory procedure manual, the laboratory director failed to ensure all proficiency tests are reviewed to evaluate the laboratory's performance for 2 of 3 testing events in 2023 for event 2 and event 3 for hematology and routine chemistry. Findings include: 1. Record review on 6/13/2024 at approximately 12:11 PM, revealed the American Association of Bioanalysts (AAB) PT reports review failed to include documentation the director reviewed the reports to evaluate test performance for event 2 and event 3 for the year 2023. 2. An interview with the compliance manager on 6/13/2024 at approximately 12:11 PM, confirmed that the laboratory director failed to include documentation the director reviewed the reports to evaluate test performance for event 2 and event 3 for the year 2023 for hematology and routine chemistry . 3. A review of the laboratory procedure manual revealed the laboratory failed to follow their procedure as stated on page 20, "All attestation forms will be signed by the testing personnel and the laboratory director."</p>