Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D2163988	03/19/2026
Name of Provider or Supplier	**Street Address, City, State**	
Valley Lab, Llc	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
D0000	Based on record review and interview with the Technical Supervisor (TS1), the laboratory failed to notify HHS or its designee within 30 days on the Laboratory Director change. Findings include: 1. A review of the laboratory procedure on 3/19 /2026 at approximately 2:00 PM titled ' General Policies and Procedures ' states that the laboratory must notify HHS within 30 days of any changes to ownership, name, location or director. 2. An interview on 3/19/2026, at 1:03 PM, with TS1 confirmed the laboratory failed to notify the State Agency of the Laboratory Director change that occurred on 12/1/2025. The following deficiencies are a result of a desk review of proficiency testing scores obtained from the national database and verified with the proficiency testing company. The facility was found to be out of compliance with the conditions of the CLIA program. The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director; _
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: _ Based on a review of AAB-MLE proficiency testing records and an interview with the technical supervisor (TS) #1, the laboratory failed to have an attestation form signed by testing personnel for six of six proficiency testing events from January 2024 to January 2026. _ Findings include: 1. A review of AAB-MLE proficiency testing records revealed the absence of signed Attestation Statements for the following events: AAB-MLE Chemistry M1 2024, AAB-MLE Chemistry M2 2024, AAB-MLE Chemistry M3 2024, AAB-MLE M1 2025, AAB-MLE M2 2025, and AAB-MLE M3

	2025. 2. An interview with TS #1 on March 19, 2026, at 1:00 PM confirmed the laboratory did not obtain signed attestation forms from testing personnel for the six events listed above from January 2024 to January 2026. _
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: _ Based on a desk review of proficiency testing (PT) records from the Certification and Survey Provider Enhanced Reporting (CASPER) report and AAB-Medical Laboratory Evaluation (AAB-MLE) records, the laboratory failed to successfully participate in an approved proficiency testing program for each specialty, subspecialty, and analyte in which the laboratory is certified under CLIA. The laboratory failed to successfully participate in the subspecialties of Routine Chemistry and Endocrinology, resulting in unsuccessful performances. Refer to D2096, D2097, D2107, and D2108. _
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) (f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: _ Based on a desk review of the CASPER report and AAB-MLE evaluation records, the laboratory failed to achieve a satisfactory analyte performance score (80% or greater) for the same analyte in two consecutive testing events or two out of three consecutive testing events for 14 analytes in the subspecialty of Routine Chemistry, resulting in subsequent unsuccessful performances. _ Findings include: 1. Review of the CASPER report and AAB-MLE records revealed the following unsatisfactory analyte scores: o ALT: 2024-2 (0%), 2024-3 (0%) o Albumin: 2024-2 (0%), 2024-3 (0%) o ALK PHOS: 2024-2 (0%), 2024-3 (0%) o AST: 2024-2 (0%), 2024-3 (0%), 2025-3 (60%) o BILI, Total: 2024-2 (0%), 2024-3 (0%) o CA, Total: 2024-2 (0%),

	2024-3 (0%), 2025-1 (60%) o CL: 2024-2 (0%), 2025-1 (40%), 2025-3 (60%) o Creatinine: 2024-2 (0%), 2024-3 (0%), 2025-1 (0%), 2025-3 (40%) o Glucose: 2024-2 (0%), 2024-3 (0%), 2025-1 (60%), 2025-3 (60%) o K: 2024-2 (0%), 2025-1 (20%), 2025-3 (40%) o NA: 2024-2 (0%), 2025-1 (20%), 2025-3 (0%) o Total Protein: 2024-2 (0%), 2024-3 (0%), 2025-1 (60%) o TRIGL: 2024-3 (0%), 2025-3 (60%) o BUN: 2024-2 (0%), 2024-3 (0%), 2025-3 (40%) 2. Technical Supervisor #2 confirmed these findings on March 19, 2026, at approximately 11:30 AM. _
D2097	ROUTINE CHEMISTRY CFR(s): 493.841(g) (g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: _ Based on a desk review of the CASPER report and AAB-MLE evaluation records, the laboratory failed to achieve an overall satisfactory testing event score (80% or greater) for two consecutive testing events or two out of three consecutive testing events for the subspecialty of Routine Chemistry, resulting in subsequent unsuccessful performance. _ Findings include: 1. Review of the CASPER report and AAB-MLE records revealed the following overall subspecialty scores for Routine Chemistry: o 2024 Event 2: 17% o 2024 Event 3: 20% o 2025 Event 1: 74% o 2025 Event 3: 60% 2. Technical Supervisor 2 confirmed these findings during an interview on March 15, 2026, at approximately 11:30 AM. _
D2107	ENDOCRINOLOGY CFR(s): 493.843(f) (f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: _ Based on a proficiency testing desk review of the CASPER report and AAB-MLE evaluation records, the laboratory failed to achieve a satisfactory analyte performance score (80% or greater) for the same analyte or test in two consecutive testing events or two out of three consecutive testing events for the TSH analyte, resulting in unsuccessful performance. _ Findings include: 1. Review of the CASPER report and AAB-MLE records revealed the following unsatisfactory analyte scores for TSH: o 2025 Event 1: 20% o 2025 Event 3: 0% 2. Technical Supervisor #2 confirmed these findings during an interview on March 19, 2026, at approximately 11:30 AM. _
D2108	ENDOCRINOLOGY CFR(s): 493.843(g) (g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

	This STANDARD is not met as evidenced by: _ Based on a proficiency testing desk review of the CASPER report and AAB-MLE evaluation records, the laboratory failed to achieve an overall satisfactory testing event score (80% or greater) for two consecutive testing events or two out of three consecutive testing events for the subspecialty of Endocrinology, resulting in unsuccessful performance. _ Findings include: 1. Review of the CASPER report and AAB-MLE records revealed the following overall subspecialty scores for Endocrinology: o 2025 Event 1: 60% o 2025 Event 3: 50% 2. Technical Supervisor #2 confirmed these findings during an interview on March 19, 2026, at approximately 11: 30 AM. _
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: _ This CONDITION is not met as evidenced by: Based on a proficiency testing desk review of the CASPER report and AAB-MLE records, the laboratory director failed to provide overall management and direction of the laboratory services. The laboratory director failed to ensure that proficiency testing samples were tested as required and that successful participation was maintained. Refer to D6089. _
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under subpart H of this part; This STANDARD is not met as evidenced by: _ Based on a proficiency testing desk review of the CASPER report and AAB-MLE records, the laboratory director failed to ensure that proficiency testing samples were tested as required under Subpart H of this part, which resulted in the laboratory failing to achieve successful participation in an HHS-approved proficiency testing program. Refer to D2096, D2097, D2107, and D2130.