Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2002212	04/19/2024
Name of Provider or Supplier	**Street Address, City, State**	
Valley Day And Night Clinic	1214 Dixieland Rd Ste 8, Harlingen, TX	

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	The following deficiencies are a result of a desk review of proficiency testing scores obtained from the CMS (Centers for Medicare and Medicaid Services) national database and verified with the proficiency testing company, American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE). The laboratory was found to be NOT in compliance with the conditions of participation of the CLIA program based on the following CONDITION LEVEL DEFICIENCIES: 493.803 Successful participation [proficiency testing] 493.1403 Laboratories performing moderate complexity testing; laboratory director
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a desk review of proficiency testing records obtained from the CMS (Center for Medicare Services) national database and verified with the proficiency testing company, American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE), the laboratory had not successfully participated in a proficiency testing program approved by HHS, for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. The laboratory had unsuccessful participation in the specialty of hematology for the analyte White Blood Cell differential (refer to D2130).

D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive 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 CMS 155 report and proficiency testing records from American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE), the laboratory failed to successfully participate for the same analyte in two consecutive testing events or two out of three consecutive testing events in the specialty of Hematology for the analyte White Blood Cell Differential resulting in an initial proficiency testing failure. The findings include: 1. A review of the CMS 155 report revealed the laboratory received the following unsatisfactory scores (passing = >80%) for the analyte White Blood Cell Differential: Third testing event 2023 73% First testing event 2024 67% 2. A desk review of the laboratory's American Association of Bioanalysts Medical Laboratory Evaluation's (AAB-MLE) results from the third event of 2023 and the first event of 2024 confirmed the proficiency testing scores: Third testing event 2023 73% First testing event 2024 67%
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a desk review of laboratory proficiency testing performance, the laboratory director failed to provide overall management and direction of the laboratory services (refer to D6016).
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that 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 desk review of proficiency testing results, the laboratory director failed to ensure the overall quality of the laboratory services provided. The laboratory director failed to ensure successful participation in an HHS approved proficiency testing program (refer to D2130).