Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2003905	01/02/2023
Name of Provider or Supplier	**Street Address, City, State**	
Valley Day And Night Clinic	5502 North San Bernardo Ste 600, Laredo, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended.
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Association of Bioanalysts' (AAB) proficiency testing records from 2022, review of the laboratory's policies, and staff interview, it was revealed the laboratory failed to test proficiency samples the same number of times as patient samples. The findings include: 1. A review of the laboratory's American Association of Bioanalysts' (AAB) proficiency testing records from 2022 (Q1, Q2, and Q3) revealed proficiency testing samples were tested in duplicate for each event. 2. A review of the laboratory's policies revealed the laboratory would repeat testing on any sample which had flagged results. 3. The following proficiency testing results did not have flagged results and therefore, should not have been tested in duplicate: a) Q1 sample: 33333 sample: 555 b) Q3 sample: 131313 4. An interview with the technical consultant on 01/02/2023 at 1350 hours in the conference room - after her review of the records- confirmed the findings.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where

	the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a random review of patient test reports from 2021 and 2022, and staff interview, it was revealed the laboratory failed to include the interpretation identifying results as panic values on 6 of 6 reports. The findings include: 1. A sampling of patient test records from 2021 and 2022 revealed the following 6 of 6 records with panic values: date: 10/25/2021 Patient ID: 517972 HGB: 22.0 HCT: 66.3 date: 11/15 /2021 Patient ID: 338582 HGB: 23.4 HCT: 68.1 PLT: 43 date: 03/02/2022 Patient ID: 209862 HGB: 23.0 HCT: 66 date: 04/06/2022 Patient ID: 534079 HGB: 18.6 HCT: 55.2 date: 05/18/2022 Patient ID: 428228 HGB: 5.0 HCT: 44.0 date: 07/06/2022 Patient ID: 464177 HCT: 56.9 2. A review of the patient test results for the identified specimens revealed the values listed were not identified as "panic" on 6 of 6 report. 3. An interview with the technical consultant on 01/02/2023 at 1535 hours in the conference room - after her review of the records- confirmed the findings. KEY WBC - white blood cell HGB - hemoglobin HCT - hematocrit PLT - platelet
D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, a random review of patient test records from 2021 and 2022, and staff interview, it was revealed the laboratory failed to have documentation of the notification of 6 of 8 panic values. The findings include: 1. A review of the laboratory's policy titled "CBC Flags and Panic Values" revealed: "Notify the Provider immediately, document who was notified, date and time that person was notified and the MA's initials." 2. A review of the laboratory's policy titled "Panic Values" revealed the laboratory had the following defined ranges for panic values: WBC - under 2 or over 20 HGB - under 7.5 or over 18 HCT - under 25 or over 55 PLT - under 50 or over 800 3. A sampling of patient test records from 2021 and 2022 revealed the following 6 of 8 records with panic values where the laboratory failed to have documentation of the notification of the provider: date: 10/25/2021 Patient ID: 517972 HGB: 22.0 HCT: 66.3 date: 11/15/2021 Patient ID: 338582 HGB: 23.4 HCT: 68.1 PLT: 43 date: 03/02/2022 Patient ID: 209862 HGB: 23.0 HCT: 66 date: 04/06/2022 Patient ID: 534079 HGB: 18.6 HCT: 55.2 date: 05/18/2022 Patient ID: 428228 HGB: 5.0 HCT: 44.0 date: 07/06/2022 Patient ID: 464177 HCT: 56.9 4. The laboratory was asked to provide documentation of the notification of the panic values. No documentation was provided. 5. An interview with the technical consultant on 01/02/2023 at 1535 hours in the conference room - after her review of the records- confirmed the findings. KEY WBC - white blood cell HGB - hemoglobin HCT - hematocrit PLT - platelet