Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2002212	09/12/2024
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 laboratory was surveyed and failed to meet the following conditions of the CLIA regulations found at CFR 42 493.1 through 493.1780. The condition cited was: 493. 1421 Condition: Laboratories Performing Moderate Complexity Testing; Testing Personnel
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, review of patient test records from July 2024, and staff interview, the laboratory failed to have documentation of following its procedure for resolving flags on 11 of 11 patient hematology results. The findings were: 1. A review of the laboratory's policy titled "CBC Flags and Panic Values (Medonic M Series)" (effective date: 07/2024) determined: "Corrective Actions on Flagged Results a. Check for clots and agglutination by ringing the sample with applicator stick. b. Remix the sample and rerun or redraw the specimen. If result is the same invalidate flagged results by replacing results with DNR (Do not report) and put a comment verified by repeat analysis. c. Upon the Provider's request, send out specimen to the reference laboratory. d. Document that specimen was sent-out for verification, date, time and initial." 2. A review of patient results from July 1, 2024 to July 24, 2024 identified 11 of 11 patient results where the laboratory failed to follow its policy for corrective actions on flags. The following patient results were reported with flags: a) 07/01/2024 Patient: 608718 Flags: BD b) 07/01/2024 Patient: 608990 Flags: BD c) 07/10/2024 Patient: 435816 Flags: OM d) 07/10/2024 Patient: 603923 Flags: BD e) 07/11/2024 Patient: 279931 Flags: BD f) 07/13/2024 Patient: 467564

	Flags: BD g) 07/15/2024 Patient: 594419 Flags: OM h) 07/17/2024 Patient: 474067 Flags: OM i) 07/20/2024 Patient: 467564 Flags: OM j) 07/20/2024 Patient: 474067 Flags: OM k) 07/24/2024 Patient: 558689 Flags: OM 3. The technical consultant confirmed the findings in an interview conducted on 09/12/2024 at 1100 hours in the laboratory.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, review of the laboratory's hematology control records from May 2024 to August 2024, and staff interview, the facility failed to have documentation of verifying 3 of 3 new lots of quality control material. The findings included: 1. A review of the laboratory's procedure titled "QC Verification" (approved 06/26/2016) determined: "Purpose: To verify CBC Quality Control materials before use. Procedure: Whenever a new lot of controls are put into use, do the following days before the old lot expires. 1. Use a new QC file. 2. Edit all parameters in accordance with the package insert. 3. Run low, normal, high at least 10 times within 7 days (within the life if [sic] the control opened). 4. Print out the Levy-Jennings of the 10 runs and label 'parallel study' and file in the CBC Control Binder including a package insert of the same lot of controls. 5. Use the mean of the printout to change the settings on each level of controls which corresponds to the assay value. 6. Change Labdaq settings only when the new lot of controls is ready for use." 2. A review of the laboratory's hematology control records from May 2024 to August 2024 identified 3 of 3 lots were put into use without documentation of QC verification being performed. They were: a) CDS Boule Con-diff control lot number: 22401-3K put into use: 05/28/2024 b) CDS Boule Con-diff control lot number: 22404-3K put into use: 06/10/2024 c) CDS Boule Con-diff control lot number: 22407-3K put into use: 08/26/2024 3. The technical consultant confirmed the findings in an interview conducted on 09/12/2024 at 1015 hours in the trauma exam room. She stated the manufacturer's technical support informed her verification of new quality control lots was not required. Key QC - quality control CBC - complete blood count
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 procedures, review of patient test records from July 2024, and staff interview, the laboratory failed to have documentation of documenting the notification of 4 of 4 panic values. The findings were: 1. A review of the laboratory's policy titled "CBC Flags and Panic Values (Medonic M Series)" (effective date: 07/2024) determined: "Corrective Action on Panic Values a. Check fort clots and agglutination by ringing the sample with applicator stick. b. Remix and rerun the sample or redraw the patient. If results are the same, place a comment verified by repeat analysis. c. Notify the Provider immediately, document who was notified, date/time of notification and the MA's initials." 2. Further review of the policy determined the laboratory defined panic values as: WBC: less than 2 and greater than 20 HGB: less than 7.5 and greater than 18 HCT: less than 25 and greater than 55 PLT: less than 50 and greater than 800 3. A review of patient test records from July 2024 identified 4 of 4 panic values without documentation of the notification of the provider. They were: a) 07/13/2024 Patient: 467564 Critical Values: HGB: 19.0 HCT: 57.2 b) 07/17/2024 Patient: 474067 Critical Value: PLT: 42 c) 07/20/2024 Patient: 467564 Critical Value: HGB: 18.4 d) 07/20/2024 Patient: 474067 Critical Value: WBC: 25.3 4. The technical consultant confirmed the findings in an interview conducted on 09/12/2024 at 1100 hours in the laboratory. Key MA - medical assistant WBC - white blood cell HGB - hemoglobin HCT - hematocrit PLT - platelet
D6055	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's instrumentation, review of the job description for the technical consultant, review of the laboratory's personnel records, and staff interview, the laboratory failed to have documentation of competency assessments being performed when new instrumentation was placed into use for 4 of 5 testing personnel. The findings included: 1. A review of the laboratory's instrumentation determined the laboratory placed new instrumentation into use in May 2024. It was: Medonic M-series Hematology analyzer Serial number: 62347 2. A review of the job description for the technical consultant identified: "Specifically the technical consultant is responsible for: i. evaluating and documenting the performance of individuals responsible for moderate-complexity testing at least semi-annually during their first year. Thereafter, evaluations must be performed annually unless the methodology or instrumentation changes, in which case before reporting any patient results, the individual's performance must be re-evaluated to include the new methodology or instrumentation." 3. A review of the laboratory's personnel records determined the laboratory failed to have documentation of competency assessments being performed on 4 of 5 testing personnel prior the reporting of patient results. They were (as listed on Form CMS 209): a) Testing personnel number 1 Training date: 04 /10/2024 Competency assessment performed: 03/2024 b) Testing personnel number 3

	Training date: 04/10/2024 Competency assessment performed: 03/09/2024 c) Testing personnel number 4 Training date: 04/10/2024 Competency assessment performed: 06 /2024 d) Testing personnel number 5 Training date: 05/29/2024 Competency assessment performed: 07/2024 4. The technical consultant confirmed the findings in an interview conducted on 09/12/2024 at 0934 hours in the trauma exam room.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's CMS 209, review of personnel records and staff interview, the laboratory failed to have documentation to qualify 1 of 15 testing personnel (refer to D6065).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS 209 Form, review of personnel records and staff interview, the laboratory failed to have documentation to qualify 1 of 15 testing personnel. The findings included: 1. A review of the laboratory's CMS 209 Form determined the laboratory identified 15 testing personnel. 2. A review of the laboratory's personnel records determined the facility failed to have documentation of education to qualify 1 of 15 testing personnel to perform moderate complexity testing. Testing personnel number 15 was educated in a foreign country and did not have documentation of a foreign credentialing evaluation being performed to determine the equivalency in the United States. 3. The technical consultant confirmed the findings in an interview conducted on 09/12/2024 at 0928 hours in the trauma exam room.