Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1047501	10/28/2025
Name of Provider or Supplier	**Street Address, City, State**	
Valley Day And Night Clinic	1755 W Price Rd, Brownsville, 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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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 policies, a review of patient test records from August 2025 and September 2025, and staff interview, the laboratory failed to have documentation of suppressing the values of flagged CBC results for 2 of 6 samples reviewed. The findings included: 1. A review of the laboratory's policy to address flags on CBC (complete blood count) results determined the laboratory was to manually suppress the flagged results to ensure they were not reported to the provider. 2. A review of flagged CBC results from August 2025 and September 2025 identified 2 of 6 results were flagged values were not suppressed and subsequently reported to the provider. They were: a) August 25, 2025 ID: 24472 b) September 25, 2025 ID: 640093 3. Technical consultant number 1 (as listed on Form CMS 209) confirmed the finding in an interview conducted on 10/28/2025 at 1030 hours in the laboratory.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal

	values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's verification studies for the Medonic M-series hematology analyzer performed in September 2024 and staff interview, the laboratory failed to have documentation of verifying 2 of 3 sets of patient normal ranges. The findings included: 1. A review of the laboratory's verifications studies for the Medonic M-series hematology analyzer performed in September 2024 identified the laboratory implemented 3 sets of patient normal ranges. The laboratory failed to have documentation of verifying 2 of the 3 sets. They were: a) Normal range (6 months - 6 years) White blood cell 5 - 15 Lymphocyte Absolute count 0.6 - 4.1 Mid Absolute count 0 - 1.8 Granulocyte Absolute count 2 - 7.8 Lymphocyte percent 10 - 58.5 Mid Cells percent 0.1 - 24 Granulocyte percent 37 - 92 Red blood cell 4.2 -6.3 Hemoglobin 10.7 - 12.5 Hematocrit 31 - 36 Mean Corpuscular volume 80 - 97 Mean Corpuscular hemoglobin 26 - 32 Mean Corpuscular hemoglobin concentration 31 - 36 Red cell distribution width 11.5 - 14.5 Platelet 150 - 350 Mean Platelet volume 0 - 50 b) Normal Range (6 years - 18 years) White blood cell 4.5 - 13.5 Lymphocyte Absolute count 0.6 - 4.1 Mid Absolute count 0 - 1.8 Granulocyte Absolute count 2 - 7.8 Lymphocyte percent 10 - 58.5 Mid Cells percent 0.1 - 24 Granulocyte percent 37 - 92 Red blood cell 4.2 -6.3 Hemoglobin 11.5 - 16.0 Hematocrit 35 - 45 Mean Corpuscular volume 80 - 97 Mean Corpuscular hemoglobin 26 - 32 Mean Corpuscular hemoglobin concentration 31 - 36 Red cell distribution width 11.5 - 14.5 Platelet 150 - 350 Mean Platelet volume 0 - 50 2. Technical consultant number 1 (as listed on Form CMS 209) confirmed the findings in an interview conducted on 10/28/2025 at 0930 hours in the office.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on review of the laboratory's records February 2025 to September 2025 and staff interview, the laboratory director failed to ensure the monthly quality assessments were reviewed for 8 of 8 months. The findings included: 1. A review of the laboratory's Quality Assurance Plan (approved on 02/01/2025) under the section titled "Quality Assurance Review" determined: "Our laboratory uses this Quality Assurance Program to improve the laboratory services we provide to our physicians and patients. We will perform a quality review at least monthly and review the results with the Laboratory Director or Technical Consultant for their approval.... The record of our Quality Assurance review are filed with this plan and are available for review by the Director, Consultant, staff and Laboratory Surveyors. All records are dated and initialed by the staff performing the review, by the Technical Consultant and by the Laboratory Director." 2. A review of the laboratory's records from February 2025 to September 2025 identified the laboratory failed to have documentation of the laboratory director reviewing 8 of 8 quality assurance monthly reports. They were: February 2025 March 2025 April 2025 May 2025 June 2025 July 2025 August 2025

	September 2025 3. Technical consultant number 1 (as listed on Form CMS 209) confirmed the findings in an interview conducted on 10/28/2025 at 1130 hours in the office.