Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0503800	06/03/2024
Name of Provider or Supplier	**Street Address, City, State**	
Valley Day And Night Clinic	305 E Expressway 83, Mission, 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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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 upon review of the laboratory's verification study for the Medonic M series hematology analyzer (Serial Number 62348), patient test records and interview of facility personnel, the laboratory failed to verify the reference ranges for the parameters of the Complete Blood Count (CBC) using the Medonic analyzer were appropriate for the patient population before testing patient specimens. The laboratory reported an annual volume of 13,518 Hematology tests. The findings included: 1. Review of the laboratory's verification study found no verification of reference ranges for the Medonic M series hematology analyzer (Serial Number 62348) installed May 2024. Further review found in the letter dated April 12, 2024 (from Medonic) to the Technical Consultant and Laboratory Director :"It is also the responsibility of the Laboratory Director to determine whether the manufacturer's published reference ranges are acceptable for your lab's patient population. I have included a worksheet for you to use. Instructions for evaluation are included in the worksheet." 2. Review of the method validation instructions provided by the manufacturer found: "3. Reference Range Validation: The Laboratory Director must examine all reference ranges provided by the manufacturer and determine if they are appropriate for the lab's patient population. This can be done empirically, or by using the methods outlined in the CLSI Document C28-A2E "How to Define and Determine Reference Intervals in

	the Clinical Laboratory." 3. Review of final patient reports printed from the LIS for male and female patients found the following reference ranges to be the same for both sexes: WBC 3.2 - 10.2 x10^3 RBC 4.08 - 5.48 x10^6 Hgb 12.2 - 16.2 g/dL Hct 37.7 - 47.9 % MCV 80 - 97 fL MCH 27.0 - 31.2 pg MCHC 31.8 -35.4 g/dL RDW 11.5 - 14.5 % Plt 142 - 424 x10^3 MPV 0.0 - 50.0 fL Gran % 37 - 92 % Lymph % 10.0 - 50.0 % Mid % 0.1 - 24.0 % 4. During interview of the technical consultant conducted June 3, 2024, at 3:24 PM, she stated that the reference ranges in the LIS were obtained from a nearby hospital and she did not verify ranges for the new analyzer.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based upon review of the laboratory's verification study for the Medonic M series hematology analyzer (Serial Number 62348), patient test records and interview of facility personnel, the laboratory director failed to ensure the reference ranges for the parameters of the Complete Blood Count (CBC) using the Medonic analyzer were appropriate for the patient population before testing patient specimens. (See D 5421)