Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 05D0554022	**(X3) Date Survey Completed** 09/24/2025
Name of Provider or Supplier Los Angeles Hematology	**Street Address, City, State** 3650 East South St, Ste 212, Lakewood, CA	
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**
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of 2023-2025 laboratory proficiency testing records, routine hematology test records, and Personnel Report-CLIA (CMS209, 9/15/25); and interview with laboratory personnel, it was determined that the laboratory failed to include proficiency samples with the routine patients workload. Findings included: a. The laboratory participated in AAB/MLE's Hematology proficiency testing for RBC (Red Blood Cell) Count, WBC (White Blood Cell) Count, HCT (Hematocrit), HGB (Hemoglobin), Platelets count, and Automated Differential. b. For 2023-2025, only Testing Person-1 Attested to testing all the proficiency testing samples, as follows: Dates of proficiency testing: 2023 2024 2025 ---------- 2/13 /23 2/20/24 2/11/25 5/25/23 5/14/24 5/28/25 9/27/23 9/19/24 9/17/25 c. Review of routine hematology test records for 2023 - 2025 documented three testing persons. d. The 2025 Personnel Report named two testing personnel. e. Testing Person-2 affirmed (9/24/25 at 12:00 PM) testing patients only. f. Testing Person-1 affirmed ((9/24/25 at 12:00 PM) testing all the proficiency samples and the aforementioned findings. g. The reliability and quality of hematology results reported by other Testing Personnel could not be assured during this Survey. Patients test results were reported, as follows: Date Testing Person ---------- 2/10/23 YV; Testing Person-2 2 /14/23 YV 5/24/23 YV 5/26/23 Testing Person-2 9/27/23 YV 2/20/24 Testing Person-2, 5/13/24 Testing Person-2 9/18/24 Testing Person-2 2/11/25 Testing Person-2 5/29 /25 Testing Person-2 9/17/25 Testing Person-1 h. The Testing Personnel reported 7,000 hematology results annually (CMS116, 9/15/25). .

D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: . Based on observation of the Medonic hematology analyzer (serial number 49874), review of laboratory records verifying calibrations, the lack of laboratory records, and interview with laboratory personnel, it was determined the laboratory failed to perform calibration verification at least once every 6 months in 2023. Findings included:. a. Records documented Medonic calibrations were verified in 2022-2023, as follows: 11/04/22 ... 12/07/23 b. The laboratory failed to have records for verifying calibrations any date after 11/04/22 until 12/07/23. c. Testing Person-1 affirmed (9/24 /25 at 12:00PM) the aforementioned findings and that calibration verification had not been performed at least once every 6 months as required. d. The laboratory reported 7,000 hematology results annually. The reliability and quality of hematology results reported during the timeframe June 2023 - November 2023 could not be assured during this Survey. Dates of testing selected for review are as follows: Date Patient tested ---------- 6/02/23 2572 7/03/23 2782 8/01/23 2958 9/05/23 3176 10/02/23 3386 11/20/23 3721 .