Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0480653	06/21/2023
Name of Provider or Supplier	**Street Address, City, State**	
Scott J Zashin Md	8230 Walnut Hill Lane, Ste 614, Dallas, 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	An entrance conference was held with the laboratory representatives. The survey process was discussed and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in COMPLIANCE with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
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 on review of operator's manual for the Horiba ABX Micros hematology analyzer, laboratory policies, verification studies, patient final reports, laboratory records and confirmed in interview, the laboratory failed to ensure the normal ranges

	for male and female patients were defined and verified by the laboratory's studies, with patients from their patient population, for 13 of 13 analytes. Findings Included: 1. Review of operator's manual for the Horiba ABX Micros hematology analyzer (Reference: RAM625CUS) revealed the following: "3.6 Normal Ranges These normal ranges were established from a study performed in Somerville, N.J. (U.S.A) This study encompasses the central 95% of the values, in the distribution of 43 Normal, Healthy, and Drug Free individuals. These ranges are as follows: Male WBC: 4.7-9.6 (10^3/mm^3) Lymphocytes: 23-47 % Monocytes: 3-6 % Granulocytes: 49-74 % RBC: 4.37-5.63 (10^6/mm^3) HGB: 13.5-16.5 (g/dl) HCT: 41-50 % MCV: 83-101 (fm^3) MCH: 26.0-34 (pg) MCHC: 32-35 (g/dl) MPV: 7.3-9.0 (fm^3) RDW: 12-16 % PLT: 145-355 (10^3/mm^3) Female WBC: 4.9-12.3 (10^3/mm^3) Lymphocytes: 19-41 % Monocytes: 2-6 % Granulocytes: 53-79 % RBC: 3.90-5.10 (10^6/mm^3) HGB: 12-15 (g/dl) HCT: 37-45 % MCV: 84-96 (fm^3) MCH: 27-34 (pg) MCHC: 32-35 (g /dl) MPV: 8-10 (fm^3) RDW: 12-14 % PLT: 150-330 (10^3/mm^3) 2. Review of laboratory policy, "Laboratory Methods and Normals" (Reviewed in 2014) revealed the following: Horiba ABX Micros 60 Normals; Limits WBC: 4.0-12.0 (10^3/mm^3) RBC: 4.20- 6.30 (10^6/mm^3) HGB: 12.0-18.0 (g/dl) HCT: 36.0-51.0 % MCV: 80-99 (fm^3) MCH: 27.0-33 (pg) MCHC: 32-36 (g/dl) PLT: 150-450 (10^3/mm^3) MPV: 7.5-12.5 (fm^3) RDW: 11.5-14.5 % Lymphocytes: 18-44 % Monocytes: 4-19.8 % Granulocytes: 55-88 % The laboratory was asked to provide separate normal ranges for male and female patients, no ranges were provided. 3. Review of laboratory verification studies for the Horiba ABX Micros 60 hematology analyzer revealed the laboratory failed to define and verify separate normal ranges for male and female patients with patients from their patient population for 13 of 13 analytes. 4. Review of patient final reports revealed the following normal ranges printed on both male and female reports: WBC: 4.0-12.0 (10^3/mm^3) RBC: 4.20- 6.30 (10^6/mm^3) HGB: 12.0-18.0 (g/dl) HCT: 36.0-51.0 % MCV: 80-99 (fm^3) MCH: 25.0-35 (pg) MCHC: 32-36 (g/dl) PLT: 150-450 (10^3/mm^3) MPV: 7.5-12.5 (fm^3) RDW: 10-15 % Lymphocytes: 18-44 % Monocytes: 0.1-19.8 % Granulocytes: 55-88 % 5. Review of laboratory records revealed the laboratory's annual hematology test volume was 8,964 tests. 6. During an interview on 06/21/2023 at 11:15 a.m., in the facility hallway with Testing Person 3 (TP-3), after review of documentation, TP-3 stated separate male and female normal ranges were not defined and verified by the laboratory's verification studies. This confirmed the above findings.