Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0480653	11/25/2019
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	Entrance and exit conferences were held with the laboratory representative. 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 representative at the entrance and exit conferences. The laboratory representative was 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.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on direct observation, review of manufacturer's instructions and staff interview, it was revealed the laboratory failed to ensure that 3 of 3 vials of in-use Horiba Minotrol 16 Tri-Level (quality control) material were labeled with new expiration dates according to the manufacturer. Findings included: 1. Observed in the laboratory refrigerator on 11//25/2019 at 1115 hours were 3 vials of Horiba Minotrol 16 Tri-

	Level QC material (Lot numbers MX420H, MX420L, and MX420N; expiration date 01/05/2020). The vials were open and in use. The vials were not labeled with the new expiration date according to the manufacturer. 2. The manufacturer's instructions for Horiba Minotrol 16 Tri-Level QC material (IS421-004 Rev. 07/15) stated the following: "Opened tubes are stable for 16 days provided they are handled properly and provided the instructions in section 'Instructions for use' are followed." The laboratory failed to label in use control material with the new expiration date. 3. During an interview with Testing Person #2 on 11/25/2019 at 1151 hours in the breakroom, the above findings were confirmed.
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 the laboratory's verification studies for the Horiba ABX Micros 60 hematology analyzer (Serial Number 809CS97961), and staff interview, it was revealed the laboratory failed to have documentation of verifying reference ranges (normal values) for the laboratory's patient population. Findings included: 1. Review of the verification studies for the Horiba ABX Micros 60 hematology analyzer (performed 02/08/2019) revealed the laboratory failed to have documentation of verifying Complete Blood Count (CBC) reference ranges. 2. In an interview on 11/25/2019 at 1151 hours in the breakroom, Testing person #2 was asked for to provide documentation of verification of patient reference ranges. No documentation was provided. This confirmed the above findings.