Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0477839	03/30/2023
Name of Provider or Supplier	**Street Address, City, State**	
Lab Of Drs Mathieu, Daniel, Poole	3601 North Star, Richardson, 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.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of the Drew 3 hematology analyzer operator's manual, laboratory procedure manual, random review of patient records (01/2023), and confirmed in interview, the laboratory failed to follow manufacturer's instructions for 9 of 9 flagged CBC (Complete Blood Count) results reviewed in 01/2023. Findings Included: 1. Review of the Drew 3 Operator's Manual (Revision 1.06) revealed the following: "9.5.3. Erythrocyte and HGB Flags R1= CR1: Elevated number of microcytes at the

	left side of the peak R2=CR2: Elevated number of macrocytes at the right side of the peak The hematology flags listed above are non-specific and the meaning of each message is only a suggestion of the cause of possible abnormality. Always verify flagged Erythrocytes and HGB results according to your laboratory's protocol." 2. Review of laboratory procedure manual revealed no protocol for verifying erythrocyte flags on patient specimens. 3. Review of patient records in 01/2023, revealed the following 9 of 9 patients resulted with erythrocyte flags: a. Performed on: 01/06/2023 at 03:47 p.m. Patient ID: 12010623 Flags: R1 No documentation of result verification. b. Performed on: 01/13/2023 at 10:51 a.m. Patient ID: 311323 Flags: R1 No documentation of result verification. c. Performed on: 01/13/2023 at 11:27 a.m. Patient ID: 411323 Flags: R1 No documentation of result verification. d. Performed on: 01/13/2023 at 11:30 a.m. Patient ID: 611323 Flags: R1 No documentation of result verification. e. Performed on: 01/16/2023 at 10:18 a.m. Patient ID: 7011623 Flags: R1 No documentation of result verification. f. Performed on: 01/16/2023 at 10: 59 a.m. Patient ID: 12011623 Flags: R1 No documentation of result verification. g. Performed on: 01/16/2023 at 02:45 p.m. Patient ID: 19011623 Flags: R1 No documentation of result verification. h. Performed on: 01/26/2023 at 12:50 p.m. Patient ID: 912623 Flags: R1 No documentation of result verification. i. Performed on: 01/30/2023 at 11:39 a.m. Patient ID: 4013023 Flags: R1 No documentation of result verification. The laboratory failed to follow manufacturer's instructions for 9 of 9 flagged CBC (Complete Blood Count) results reviewed in 01/2023. 4. During an interview on 03/30/2023 in a patient room at 11:04 a.m., with Testing Person 1 (TP-1), TP-1 stated the laboratory did not have a protocol for verifying erythrocyte flags on patient specimens. This confirmed the above findings. Word Key HGB-Hemoglobin ID- Identification