Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0477839	10/29/2019
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	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.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observation and in interview with staff, the laboratory failed to ensure Cell Dyn 1700 hematology CDS Lytic reagent was not used beyond the expiration date. Findings included: 1. During a tour of the laboratory on 10/29/2019 at 1010 hours, the following reagent was observed to be open and in use on the Cell Dyn 1700 hematology analyzer: CDS Lytic Reagent; Lot number 7571; Expiration date 09/30 /2019 2. During an interview on 10/29/2019 at 1012 hours, testing person # 1 agreed that the reagent was expired. This confirmed the findings.

D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on review of the laboratory policies and confirmed in staff interview, it was revealed the laboratory failed to have documentation to define critical values for white blood cells (WBC), Hematocrit (HCT), Hemoglobin (HGB), and Platelet hematology analytes. Findings included: 1. Review of the laboratory policies revealed the laboratory failed to establish a policy to define critical values for white blood cells (WBC), Hematocrit (HCT), Hemoglobin (HGB), and platelet hematology analytes and to document notification of the patient's provider. 2. The laboratory was asked to provide documentation of critical values for white blood cells (WBC), Hematocrit (HCT), Hemoglobin (HGB), and platelet hematology analytes. No documentation was provided. 3. During an interview on 10/29/2019 at 1015 hours in the laboratory, testing person #1 confirmed the above findings.