Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D0537383	05/09/2019
Name of Provider or Supplier	**Street Address, City, State**	
Frank A English Md	313 W Country Club Rd #4, Roswell, NM	

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	The following deficiency was cited as the result of a recertification survey on 05/09 /19 for 42 CFR part 493 Laboratory Requirements.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of 2017-2018 quality control records, laboratory policy, manufacturer instructions and interview with the Technical Consultant, the laboratory failed to have a quality control policy that monitored the accuracy and precision of the Coulter AcT Diff 10 hematology analyzer. Findings are: A. Review of 11/26/18-12/31 /18 quality control records revealed no documentation indicating that the laboratory established or verified the manufacturer's quality control ranges prior to use. 1. Review of the laboratory's quality assurance and quality control policies dated 08/03 /18 did not refer to any procedures for establishing quality control ranges or verifying the manufacturer's ranges. 2. Review of the quality control manufacturer's instructions for Coulter 4C-ES Cell Control, revised on 09/2018, indicated: "Before your current cell control lot(s) expire, perform the following on your new lot(s): Confirm that recovered values are within the TABLE OF EXPECTED RESULTS OR Establish

	your own laboratory mean." 3. Review of 11/26/18-12/31/18 (22 days) quality control records and manufacturer assay sheets revealed the laboratory's calculated means and ranges differed from the manufacturer. Platelet count a. Low control Lot 68600 Manufacturer mean = 78 resulted in an acceptable range of 58-98. Laboratory's calculated mean over 22 days = 72 and would have resulted in an acceptable range of 64-80. One day, 12/17/18, had a platelet result of 81, outside of the calculated range. b. Normal control Lot 78600 Manufacturer mean = 216 resulted in an acceptable range of 176-256. Laboratory's calculated mean over 22 days = 206 would have resulted in an acceptable range of 192-220. c. High control Lot 86800 Manufacturer mean = 388 resulted in an acceptable range of 328-448. Laboratory's calculated mean over 22 days = 377 would have resulted in an acceptable range of 357-397. 4. During interview on 05/09/19 at 11:27 am, the Technical Consultant confirmed that she had always used the manufacturer's ranges. B. Review of 2017-2019 quality control records for the Beckman Coulter AcT Diff 10 used to perform CBC (Complete Blood Cell count) testing had no documentation of charts, such as Levy-Jennings, (used to plot quality control values) or calculations of the mean, standard deviation or coefficient of variation used for tracking trends or shifts in quality control values. 1. Review of the AcT Diff 10 instruction manual revealed that the analyzer did not have built-in quality control charts or statistical files for tracking trends and shifts in the quality control data that may require corrective actions. The manufacturer offered an Interlaboratory Quality Control Program but there was no documentation showing that the laboratory was enrolled. 2. Review of the laboratory's quality assurance and quality control policies dated 08/03/18 did not refer to any procedures for tracking trends or shifts in quality control data. 3. During interview on 05/09/19 at 09:53 am, the Technical Consultant stated she had never tracked quality control trends.