Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0235470	04/26/2018
Name of Provider or Supplier	**Street Address, City, State**	
Allen Family Practice	658 Main Street Suite A, Rainelle, WV	

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
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 review of the laboratory's procedure manual and interview with Testing Personnel #1 (TP1), the laboratory failed to have a quality control procedure for the Cell DYN Emerald Hematology Analyzer which defined the type, number, frequency of controls and corrective actions to take when quality control is unacceptable. The findings include: 1. Review of the laboratory's procedure manual identified no quality control procedure for the Cell DYN Emerald Hematology Analyzer which defined the type, number, frequency of controls and corrective actions to take when quality control is a unacceptable. 2. On 4/26/18 at approximately 2:00 PM, TP1 confirmed the findings.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--

	Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the Cell DYN Emerald quality control records and interview with Testing Personnel #1 (TP1), the laboratory failed to verify that the recovered values for the Cell DYN 18 Plus Controls were within the table of expected results before the current lot number of Cell DYN 18 Plus Controls expired. Record review was from April 2016 to June 2018 The findings include: 1. Review of quality control records for the Cell DYN Emerald identified no records of new lot numbers of the Cell DYN 18 Plus Controls being verified prior to the current lot numbers of quality control expiring. 2. On 5//26/18 at approximately 2:00 PM, TP1 stated that they do not run the new lots of controls to verify values before the old lots of controls expired.