Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0466478	10/21/2021
Name of Provider or Supplier	**Street Address, City, State**	
Morrilton Medical Clinic, P A	#10 Hospital Drive, Morrilton, AR	

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
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: Through a review of laboratory policies and procedures, a review of quality control documentation, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to document establishment of acceptability ranges for quality control. Survey findings include: A. During a review of the policy and procedure manual it was determined the quality control policy is based on ranges set using two and three standard deviations. B. A review of quality control documentation revealed that ranges in use for both hematology and chemistry quality control were wider than calculated standard deviations for the analytes for five of eight chemistry tests reviewed and for all three constituents of the white blood cell differential. C. In an interview, at 11:24 on 10/21/2021, the technical consultant (listed as #5 on the form CMS-209) stated there was no documentation of establishing the standard deviations for hematology. In an interview at 11:49 on 10/21/2021, the technical consultant stated that the chemistry ranges changed with a software upgrade on 2/11

	/2021 and that there was no documentation of establishing the ranges in use since the upgrade.