Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0049984	06/12/2019
Name of Provider or Supplier	**Street Address, City, State**	
Stone County Medical Center	2106 East Main Street, Mountain View, 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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Through a review of the Hematology Procedure Manual, the Chemistry Procedure Manual, the Laboratory General Procedure Manual, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to have written policies for corrective actions when control results are unacceptable for four of five analyzers in use. Survey findings include: A. A review of the Hematology Procedure Manual, the Chemistry Procedure Manual, and the Laboratory General Procedure Manual revealed that there were no written procedures for documenting corrective actions in the event that Chemistry (Dimension EXL 200 and Vidas) or

	Hematology (Sysmex XS-100i and Sysmex XP-300) quality control results were unacceptable. B. In an interview at 9:34 a.m. on 6/12/2019, laboratory employee #3 (as listed on the form CMS-209) confirmed the laboratory failed to have written policies for corrective actions for quality control failures.