Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0049984	09/30/2025
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) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a lack of policy and procedure and interview the laboratory failed to define a method to calculate acceptable ranges of coagulation control runs. Findings follow: A. The Coagulation Procedure Manual included "If any controls are outside the +/- 2SD range, the STA - Compact will audibly and visually alarm the operator." The manual did not state the parameters for acceptable control values. B. Coagulation control records from April 2025 showed +/-2SD being acceptable control results and +/-3SD being unacceptable. B. In an interview on 9/30/2025, at 12:05pm the technical

	supervisor confirmed that policies and procedures for defining acceptable coagulation controls were not available.