Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D2176567	09/14/2022
Name of Provider or Supplier	**Street Address, City, State**	
Webb Family Medical Clinic	1200 Central St, Water Valley, MS	

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: Based on review of the laboratory procedure manual and interview with the laboratory director/technical consultant (LD/TC) at 2:30 p.m. on 9/14/22, the laboratory did not have available written approved procedures that included all required elements. Findings include: 1. Observation of the laboratory procedure manual on the day of survey revealed the following procedures were not included: a. Requirements for patient preparation, storage, preservation, transportation, processing and referral; and criteria for specimen acceptability and rejection. b. Procedures to follow if the Cell Dyn Emerald hematology analyzer becomes inoperable. 2. The LD/TC confirmed in

	an interview at 2:30 p.m. on 9/14/22 that the laboratory manual did not include all required procedures.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of laboratory records since the Abbott Cell Dyn Emerald was installed on 1/14/22 and confirmation with the laboratory director/technical consultant (LD/TC) at 2:00 p.m. on 9/14/22, the laboratory failed to monitor and document the room temperature where hematology testing was performed. Findings include: 1. Observation of the laboratory room where hematology testing was performed revealed no thermometer to monitor the room temperature for optimal performance of the Cell Dyn Emerald hematology analyzer. 2. Cell Dyn Emerald manufacturer's instructions require: a). The Cell Dyn Emerald reagent, lyse and detergent should be stored at a temperature range of 18-32 degrees Celsius (C) b) Operating specifications for the Cell Emerald hematology analyzer require a room temperature of 18-32 degrees C. c). Quality control and calibration materials for the Cell Dyn Emerald must be allowed to come to room temperature before testing. 3. Interview with the LD/TC at 2:00 p.m. on 9/14/22 confirmed no room temperatures were being monitored and documented.