Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2144466	01/21/2020
Name of Provider or Supplier	**Street Address, City, State**	
Holtville Family Practice, Llc	213 Lightwood Road, Suite 1, Deatsville, AL	

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 a review of the policy and procedure manual, and an interview with Testing Personnel (TP) #1 and the Certified, Registered Nurse Practitioner (CRNP), the surveyor determined the laboratory failed to establish a written policy and procedure to instruct staff how to address alert and panic values of Complete Blood Count (CBC) testing. This affected the survey period, 6/06/2018 (initial survey) to current survey date. The findings include: 1. A review of the policy and procedure manual revealed the laboratory did not have a written policy and procedure, outlining how staff should address alert and panic values. 2. During an interview at 4:00 PM on

	January 21, 2020, the CRNP stated the nursing staff (also the testing personnel) were expected to follow nursing standards in determining if patient CBC results were panic values; and how to address reporting and recording. The CRNP further stated it is the practitioner's responsibility to instruct the testing personnel on the steps of confirming the results. The CRNP confirmed the laboratory did not have a written policy and procedure for this process.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of the policies and procedures, a review of the calibration records for the Beckman Coulter Act-diff 2 Hematology analyzer, a lack of documentation of routine maintenance for the Hematology analyzer, and an interview with the Certified Registered Nurse Practitioner (CRNP) and Testing Personnel (TP) #1, the surveyor determined the Laboratory Director (also the Technical Consultant) failed to ensure the Quality Assurance program was maintained in a manner to ensure: 1) Calibrations were performed when needed. This affected the survey review period of June 2018 - June 2019. 2) Routine maintenance was addressed for the Hematology analyzer. This affected the survey review period of June 2018 - current survey. 3) Staff followed the policy to perform quality control lot to lot verifications. This affected the survey review period of June 2018 - current survey. The findings include: 1. A review of the calibration records for the Beckman Coulter Act-diff 2 revealed the analyzer was calibrated on 6/13/2019 and 11/04/2019, after the initial installation in March of 2018. The analyzer was not calibrated until more than one year after the initial calibration was performed, when the analyzer was installed. 2. During an interview on January 21, 2020 at 3:30 - 4:00 PM, the surveyor inquired of TP #1 how often the analyzer should be calibrated. TP #1 stated the calibration should be performed every six months. TP #1 also stated she was not aware the instrument should be calibrated every six months until after the laboratory experienced a proficiency testing failure in March of 2019, when service was called. 3. A review of the maintenance file for the Act -diff 2 revealed a service invoice, dated 11/18/2019 from Beckman Coulter. During an interview on January 21, 2020 at 3:30 - 4:00 PM, the surveyor inquired of TP #1 if any routine maintenance was required for the Act-diff 2. TP #1 stated the analyzer should be decontaminated once per month. TP #1 also confirmed the maintenance was not being done, because the staff was not aware of this requirement. The staff did not realize any maintenance should be performed until the analyzer was not operating optimally and service was called. 4. A review of the policies and procedures revealed the following: "Assay values of a new lot of Hematology controls should be confirmed before it is put into routine use. The new lot of control material should be assayed in parallel with the current lot in use before the expiration of the current lot..." 5. During the interview on January 21, 2020 at 3:30 - 4:00 PM, the surveyor asked TP #1 if she had documentation of the quality control lot to lot verifications. TP #1 stated she did not, because the laboratory was not performing the quality control verifications, as the policy instructed.