

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D1026713	(X3) Date Survey Completed 08/29/2022
Name of Provider or Supplier Alex City Internal Medicine	Street Address, City, State 3368 Highway 280 Suite 220, Alexander City, 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	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of policies and procedures and an interview with the Laboratory Director, the laboratory failed to ensure the testing personnel were provided a policy and procedure manual that included preanalytic procedures, and a procedure to follow when imminently life threatening results or panic values were obtained. This was noted during the current survey for 2022. The findings include: 1. A review of laboratory records revealed the laboratory utilized the Beckman Coulter AcT Diff and Access 2 Operator's manuals as the procedure manuals. However, the manuals did not include preanalytical procedures (such as: specimen collection and labeling, and a</p>

criteria for specimen acceptability and rejection). The laboratory also failed to define panic values (imminently life threatening results), and a protocol to follow when testing personnel obtained these results. 2. During the exit summation on August 29, 2022, at 4:00 PM, the Laboratory Director confirmed the above findings.

D6031

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(13)

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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:
Based on a review of policies and procedures and an interview with the Laboratory Director, the Laboratory Director failed to ensure the testing personnel were provided a policy and procedure manual that included preanalytic procedures, and a procedure to follow when imminently life threatening results or panic values were obtained. This was noted during the current survey for 2022. The findings include: 1. Refer to D5403.