

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2121737	(X3) Date Survey Completed 07/23/2019
Name of Provider or Supplier Afc Urgent Care	Street Address, City, State 5050 N Broadway, Knoxville, TN	
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 review of the Operator's Manual for the Complete Blood Count (CBC) analyzer being used as the laboratory's CBC procedure manual, lack of required number of control materials to run, troubleshooting of controls, lack of CBC reporting to include reference ranges for different age groups tested, critical value reporting and upon interview with Center Administrator, it was determined that the CBC Operator's Manual was not sufficient for the CBC procedure manual. The findings include: 1. Review of the CBC analyzer Operator's Manual being used as the laboratory's CBC procedure manual. 2. Lack of</p>

control plan to include required number of control materials. 3. Lack of troubleshooting of controls. 4. Lack of CBC reporting to include reference ranges for different age groups tested. 5. Lack of critical value reporting. 6. Interview at approximately 3:45 p.m. July 23, 2019 with Center Administrator, confirmed the Operator's Manual for the CBC analyzer being used as the CBC procedure manual lacks pertinent information required for controls, reporting, troubleshooting, reference ranges, and critical value reporting. =====

D6004

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(a)(b)

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:
===== Based on review of the laboratory's competency evaluations and upon interview with Center Administrator, it was determined that laboratory director did not document 2018 annual competency for Technical Consultant. The findings include: 1. Review of laboratory's annual competency evaluation results were not documented in 2018 for Technical Consultant. 2. Interview with Center Administrator at approximately 3:45 p.m. July 23, 2019 confirmed no annual competency evaluation in 2018 was documented for Technical Consultant. =====