Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0670715	02/20/2019
Name of Provider or Supplier	**Street Address, City, State**	
Medical Associates Of Carter	8707 Asheville Hwy, 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	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's procedure for Complete Blood Count's (CBC's) on 2/20/2019 and upon interview with the Technical Consultant, determined the laboratory failed to have written procedures to include specimen identification, labeling and reporting, operation and troubleshooting of CBC machine, defined normal patient values and course of action if test system becomes inoperable. The findings include: 1. A review of the laboratory's procedures on 2/20/2019 for testing CBC"s failed to include specimen identification and labeling, reporting results, operation and troubleshooting of CBC

	machine, normal patient values and course of action to take if CBC machine becomes inoperable. 2. An interview with the Technical Consultant at approximately 11:30 a. m. February 20, 2019 confirmed the laboratory did not have a complete procedure manual for testing and reporting of CBC's. ==========