Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	30D0995902	02/01/2018
Name of Provider or Supplier	**Street Address, City, State**	
Core Physicians Laboratory Services	1 Hampton Rd, Exeter, NH	

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 record review and staff interview, the hematology procedure manual failed to include the reportable range of hematology complete blood count (CBC) test results. Findings include: 1. Review on 1/31/18 of the laboratory procedure titled "Sysmex XS 1000" dated January 20, 2016 revealed "The procedure manual for the Sysmex XS 1000 is the manufacturer's manual..." and did not include reportable ranges for CBC results. Review of the manufacturer's manual for the Sysmex XS 1000 revealed no reportable ranges for CBC test results for white blood count, red blood count, platelet count, hemoglobin, and hematocrit. 2. Interview on 1/31/18 at 11:

	15 a.m. with the general supervisor confirmed the reportable ranges for CBC test results were not included in the laboratory's procedure manuals. 3) The laboratory performs an estimated 17, 774 CBC tests annually.