

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0683963	(X3) Date Survey Completed 01/17/2018
Name of Provider or Supplier Ccs Medical Pllc	Street Address, City, State 626 Frankhauser Road, Williamsville, NY	
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 surveyor's review of the laboratory procedure manual, hematology analyzer Sysmex XS 1000i operator's manual and an interview the laboratory manager, the laboratory failed to establish a written policy to backup the data files for the Sysmex XS 1000i computer. FINDINGS: The laboratory manager confirmed on 01/17/18 at approximately 10:00 AM that the laboratory did not have a procedure to backup the data which includes Quality Control (QC) results, calibration and maintenance for the Sysmex analyzer. The laboratory did not backup the data for the analyzer from 09/26 /2016 through survey date.</p>