

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0856441	(X3) Date Survey Completed 09/01/2021
Name of Provider or Supplier Western Connecticut Medical Group	Street Address, City, State 95 Locust Ave, Danbury, CT	
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 record review and staff interview the laboratory failed to provide a complete procedure manual in the specialty of hematology. Findings include: 1. Record review of the "WCMG Oncology Lab Testing Procedure & Competency" binder on 9/1/2021 revealed the lack of the following procedures: a. Specimen requirements and stability. b. Specimen acceptance and rejection criteria. c. Step by step performance of the complete blood count (CBC) procedure utilizing Sysmex XN-1000 Automated Hematology Analyzer. d. Calibration and calibration verification procedures. e. Corrective action to take when calibration or control results fail to meet the</p>

laboratory's criteria for acceptability. f. Reportable range for test results. g. Instrument maintenance procedures. h. Quality control acceptability criteria. i. Procedure when the system becomes inoperable. 2. Staff interview with the technical consultant (TC) on 9/1/2021 at 11:00 AM confirmed the SOP manual in the specialty of hematology is incomplete and needs to be updated. 3. The laboratory conducts 11,928 CBC tests annually in the specialty of hematology.