Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D2094414	10/03/2023
Name of Provider or Supplier	**Street Address, City, State**	
Westchester Medical Group Pllc	644 West Putnam Ave, Greenwich, 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	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 laboratory failed to establish normal reference ranges for the automated differential of the complete blood count test prior to patient testing in the specialty of hematology. Findings include: 1. Record review on 10/03/2023 of the 'CBC Act 2Diff Analyzer' standard operating procedure revealed lack of established normal ranges for the automated differential for the following white blood cell (WBC) types: a. Neutrophils. b. Lymphocytes. c. Monocytes. d. Eosinophil. e. Basophils. 2. Record review on 10/03/2023 of 2 of 2 patient final test reports revealed WBC differential reference ranges are being reported. 3. Staff

	interview on 10/03/2023 at 11:30 PM with the laboratory technical consultant confirmed the above findings. 4. The laboratory performs 328 complete blood count with automated differential tests in the specialty of hematology.