Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D2021994	08/11/2022
Name of Provider or Supplier	**Street Address, City, State**	
Westmed Medical Group Immediate Care	1281 East Main St, Stamford, 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 provide a complete and an up to date procedure manual in the specialty of hematology. Findings include: 1. Record review of the 'CBC AcT Diff 2 Analyzer' standard operating procedure manual (SOP) on 08/11/2022 for complete blood count (CBC) test revealed the lack of the following procedures: a. Specimen requirements and stability. b. Specimen acceptance and rejection criteria. 2. Record review on 08/11/2022 of the 'CBC AcT Diff 2 Analyzer' SOP and patient test reports for CBC revealed the following discrepant reference ranges: Male: Analyte SOP Ranges Test Report WBC 4.8-10.8

	3.6-10.2 10^3mcL RBC 4.7-6.10 4.0-5.60 mil/mcL MCH 27-31 23.80-33.40 pg Female: Analyte SOP Ranges Test Report WBC 4.8-10.8 4.7-10.3 10^3/mcL HGB 11.1-15.3 12.0-14.50 g/dL HCT 33.3-45.9 35.7-43.0 % MCV 81-99 76.0-90.0 fL MCH 27-31 25.0-31.0 pg PLT 140-400 183-369 10^3/mcL 3. Staff interview with the technical consultant on 08/11/2022 at 12:10 PM confirmed the above findings. 4. The laboratory performs 1200 tests annually in the specialty of hematology.