Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0939686	10/11/2021
Name of Provider or Supplier	**Street Address, City, State**	
Lakewood Health System - Motley Clinic	1233 Hwy 10, Motley, MN	

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 observation, document review and interview with laboratory personnel, the laboratory failed to include accurate Hematology reference ranges in the procedure manual for eight of nine reported parameters. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 12:05 p.m. on 10/11/21. 2. A Sysmex XP-300 hematology analyzer was observed as present and available for use during the tour of the laboratory. 3. Reference ranges for eight of nine reported parameters were inaccurate in the Sysmex XP-300 procedure, found in the LakeNet online protocols in

	Sharepoint and dated 11/11/19, when compared to a female patient test report from 03 /09/21. The inaccurate parameters were White Blood Cells (WBC), Hemoglobin (HGB), Hematocrit (HCT), Mean Corpuscular Volume (MCV), Mean Corpuscular Hemoglobin (MCH), Mean Corpuscular Hemoglobin Concentration (MCHC), Red Cell Distribution Width (RDW), and Platelets (PLT). See below. Parameter Procedure Report WBC 4.3-10 3.2-11.0 HGB 11.0-16.0 11.2-15.5 HCT 31-50 34.3-46.0 MCV 82-101 81.4-99.0 MCH 27-31 31.6-35.5 MCHC 32-37 31.6-35.5 RDW 11.5-14.5 11.3-14.6 PLT 150-450 130-375 4. In an interview at 1:50 p.m. on 10/11/21, the TC confirmed the above finding and indicated the reference ranges had been changed on 02/16/21 but the procedure had not been updated. .