Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2144744	01/08/2025
Name of Provider or Supplier	**Street Address, City, State**	
Etch Primary Care Center Inc	10857 Hardin Valley Rd, Knoxville, TN	

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) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 of the laboratory, review of patient test reports, review of the laboratory procedure manual, and staff interview, the laboratory procedure manual failed to include correlating reference ranges (normal values) for hematology analytes. The findings include: 1. Observation of the laboratory on 01.08.2025 at 9:30 a.m. revealed a Sysmex XP300 instrument (serial number B9735) in use for Complete Blood Count (CBC) patient testing. 2. A review of four final patient test reports, #1 (09.26.2023), #2 (03.05.2024), #3 (10.15.2024), and #4 (12.11.2024), revealed the

	following CBC analyte reference ranges used for patient evaluation in the medical record. -White Blood Cell count (WBC): 4.6-14.5 -Red Blood Cell count (RBC): 3.9-5.2 -Hemoglobin (HGB): 11.0-14.0 -Hematocrit (HCT): 32.0-41.0 -Platelet count (PLT): 150-550 -Mean corpuscular volume (MCV): 70-90 -Mean corpuscular hemoglobin (MCH): 23.0-30.0 -Mean corpuscular hemoglobin concentration (MCHC): 31.5-36.0 -Red cell distribution width (RDW-CV): 11.5-15.5 -Absolute neutrophil count (NEUT#): 1.3-7.4 -Relative neutrophil count (NEUT%): 30-65 -Absolute lymphocyte count (LYM#): 1.5-9.5 -Relative lymphocyte count (LYM%): 30-64 -Absolute mixed count (MXD#): 0.5-2.0 -Relative mixed count (MXD%): 4.0-14.0 3. A review of the Normal Values laboratory procedure revealed the following ranges that differed from those on the final patient test report in the medical record. -White Blood Cell count (WBC): 4.3-11.0 -Red Blood Cell count (RBC): 4.6-6.2 (male) 4.2-6.4 (female) -Hemoglobin (HGB): 14-18 (male) 12-16 (female) -Hematocrit (HCT): 40-54 (male) 38-47 (female) -Platelet count (PLT): 150-375 -Mean corpuscular volume (MCV): 80-94 (male) 82-100 (female) -Mean corpuscular hemoglobin (MCH): 26-33 -Mean corpuscular hemoglobin concentration (MCHC): 31-36 -Red cell distribution width (RDW-CV): no reference range present -Absolute neutrophil count (NEUT#): no reference range present -Relative neutrophil count (NEUT%): 50-70 -Absolute lymphocyte count (LYM#): no reference range present -Relative lymphocyte count (LYM%): 25-40 -Absolute mixed count (MXD#): no reference range present -Relative mixed count (MXD%): no reference ranged present 4. The findings were confirmed by an interview with the laboratory lead on 01.08.2025 at 11:00 a.m.