Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	35D0408755	08/12/2025
Name of Provider or Supplier	**Street Address, City, State**	
Carrington Health Center	800 4th St N, Carrington, ND	

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 and staff interview, the laboratory failed to develop written policies and procedures to describe the proper labeling of hematology staining containers used for 1 of 1 laboratory test (Manual Differential). The laboratory performed 39 patient manual differential tests since July 2024. Findings include: 1. Observation at 10:45 a.m. on 08/11/25 showed one filled container on a counter at the

	hematology bench with no identifying information. 2. During an interview at 7:41 a. m. on 08/12/25, a technical supervisor (#1) confirmed there is no policy on proper labeling of hematology staining containers.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation, staff interview and policy review, the laboratory failed to label 1 of 4 hematology staining containers (Fixative) observed. The laboratory performed 39 patient manual differential tests since July 2024. Findings include: 1. Observation at 10:45 a.m. on 08/11/25 showed one filled container on a counter at the hematology bench with no identifying information. 2. During an interview at 7:41 a.m. on 08/12 /25, a technical supervisor (#1) stated the unidentifiable container on the counter at the hematology bench contained fixative and confirmed the laboratory had not properly labeled the container. 3. Upon request on 08/12/25, the laboratory failed to provide a policy on proper labeling of hematology staining containers.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493. 1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: Based on record review, plan review, and staff interview, the laboratory failed to follow their Individualized Quality Control Plan (IQCP) for quality control performance for 8 of 8 months reviewed (January through August 2025) for pH (potential of hydrogen, scale used to measure acidity or alkalinity) , PO2 (partial pressure of oxygen, a measure of the amount of dissolved oxygen gas), and CO2 (carbon dioxide) testing on the EPOC. The laboratory performed 33 patient pH, PO2, and CO2 tests since July 2024. Findings include: 1. Reviewed on 08/11/25, the QC records for pH, PO2, and CO2 failed to include evidence of performance of two levels of controls in duplicate as stated in the laboratory's IQCP on the following days: 01/06 /25 02/03/25 02/17/25 03/03/25 04/07/25 05/05/25 05/13/25 06/06/25 07/07/25 08/04 /25 2. Reviewed on 08/11/25, the laboratory's "IQCP for Siemens Epoc for ABG [arterial blood gases]," dated 11/1/2020, stated, "Monthly: Two levels of External QC will be done once per month in duplicate." 3. During interview at 5:12 p.m. on 08/11

	/25, a technical supervisor (#1) confirmed the laboratory's IQCP for pH, PO2, and CO2 on the EPOC required performance of two levels of QC in duplicate each month and the laboratory performed two levels of QC (not in duplicate) each month.