Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	20D2206486	11/21/2024
Name of Provider or Supplier	**Street Address, City, State**	
Mid Coast Hospital	123 Medical Center Drive, Brunswick, ME	

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: 1. Surveyor observation of the laboratory testing area on 11/21/2024 at 12:30pm revealed 2 Avoximeter 4000 Hematology analyzers. 2. Record review on 11/21/2024 of the laboratory Avoximeter procedure manual revealed the procedure manual did not include documentation outlining the process for switching between the two Avoximeters on a monthly basis. 3. Staff interview on 11/21/2024 at 11:30am with the QD: a. Confirmed the laboratory switches between instruments on a monthly

	basis. b. Confirmed the Avoximeter procedure did not include documentation outlining the process for switching between the two Avoximeters on a monthly basis. 4. The laboratory performs 500 tests per year in the specialty of Hematology.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the quality director (QD), the laboratory failed to document routine monthly maintenance and function checks on the two Avoximeter 4000 (AV 1, AV 2) hematology analyzers in use. Findings include: 1. Record review on 11/21/2024 of the laboratory's maintenance charts for the AV 1 and AV 2 revealed the following monthly maintenance is required: a. Check Avox Supplies and outdates b. Temp track daily summary report printed / reviewed end of month 2. Record review of the AV 1 and AV 2 maintenance documentation on 11/21/2024 revealed no monthly maintenance for the following: a. 2023: February (AV 1), June (AV 2), and August (AV 2). b. 2024: January (AV 1), February (AV 2), March (AV 1), April (AV 2), and May (AV 1). 3. Interview with the QD on 11/21 /2024 at 11:30am confirmed the findings above. 4. The laboratory performs 500 tests per year in the specialty of hematology.