Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	20D0089092	09/06/2022
Name of Provider or Supplier	**Street Address, City, State**	
Mainehealth	Administration, Norway, 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: Based on record review and staff interview, it was determined that the reference range for Blood Gas on the laboratory's final patient test report did not correlate with the reference range in the laboratory's procedure manual. Findings include: 1. Comparison of the final patient test report's Blood Gas reference range on 9/6/2022 for patient #1 (PT1) with the laboratory's procedure for Blood Gas revealed the following: a. Final report (PT1): -pH 7.34-7.42 -pCO2 32-41 mmHg -pO2 62-92 mmHg b. Procedure manual: -pH Less than 7.20, greater than 7.60 -pCO2 Less than 20, greater than 60 -pO2 Less than 50, greater than 125 2. Staff interview with the

	Senior Director of Operations on 9/6/2022 at 10:00am confirmed the reference range for Blood Gas did not correlate with the reference range on the final patient test report. 3. The laboratory performs 1959 tests annually in the specialty of Chemistry.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on lack of documentation and interview with Senior Director of Operations (SDO), the laboratory director (LD) failed to ensure that an approved procedure manual was available to testing personnel. Findings include: 1. Record review of the laboratory online testing manual on 9/6/2022 revealed the LD had not signed the lab manual. 3. Interview with the senior SDO on 9/6/2022 at 9:00am confirmed the above finding. 4. The laboratory performs 1959 tests annually in the specialty of Chemistry.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the Senior Director of Operations (SDO) the technical consultant (TC) failed to document semiannual competency of new testing personnel (TP) to assess the knowledge and skills necessary to perform moderate complexity laboratory testing in the specialty of Chemistry. Findings include: 1. Record review on 9/6/2022 of the CMS form 209 revealed 10 of 10 TP perform moderate complexity testing. 2. Record review on 9/6/2022 or the laboratory's "Competency Evaluations" policy revealed the statements: "The department Manager or Lead Therapist shall give... an annual competency evaluation", and "The evaluation shall be given with the employees ' initial department orientation and annually thereafter". 3. During interview with (SDO) on 9 /6/2022 at 9:15 AM, (SDO) stated that "one competency" was being performed in the first year for each new employee. 4. The laboratory performs approximately 1959 tests per year under the Chemistry specialty.