Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	20D0697398	02/02/2022
Name of Provider or Supplier	**Street Address, City, State**	
Maine Health Nephrology - Portland	1600b Congress St, Portland, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on record review and staff interview with the laboratory manager (LM), the laboratory director (LD) failed to sign the attestation sheet for the American Proficiency Institute (API) proficiency testing (PT) samples in the specialties of Hematology and Chemistry. Findings include: 1. Record review on 2/2/2022 of the laboratory's PT attestation sheets for API Hematology and Chemistry Surveys for the 2nd and 3rd events 2020, and the 1st, 2nd, and 3rd, events of 2021, revealed the LD did not sign the attestation sheets. The attestation sheet was signed by the LM who does not qualify as a technical supervisor. 2. Staff interview on 2/2/2022 at 11:30 AM with the LM confirmed the above findings. 3. The laboratory performs 21,141 tests annually in the specialty of Hematology and 100,676 tests annually in the specialty of Chemistry.
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 interview with the laboratory manager (LM), the laboratory failed to include complete blood count (CBC) normal ranges in the laboratory's procedure manual in the specialty of Hematology. Findings include: 1. Record review on 2/2/2022 of the laboratory's procedure manual revealed, the manual did not include normal ranges for male and female CBC. 2. Staff interview with the LM on 2/2/2022 confirmed the laboratory's procedure manual did not contain normal ranges for male and female CBC. 3. The laboratory performers 21, 141 tests per year in the specialty of Hematology.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on surveyor observation, record review and interview with the laboratory manager (LM), the laboratory failed to follow manufacturer's instructions for calibrator and control storage in the specialty of Chemistry. Findings include: 1. Surveyor observation of the contents of the Chemistry freezer on 2/2/2022 at 11:30 AM revealed: a. 1 box of 6 x 5 mL Liquichek Level 1 ImmunoAssay Control Lot # 60291, expiration date 8/31/2022 with storage requirements of minus 20 to minus 70 degrees Celsius. b. 1 box of 6 x 5 mL Liquichek Level 3 ImmunoAssay Control Lot # 60293, expiration date 8/31/2022 with storage requirements of minus 20 to minus 70 degrees Celsius. 2. Record review on 2/2/2022 of the laboratory's 'Chemistry Freezer Temperature Log' revealed: a. Acceptable range of minus 18 degrees Celsius or greater which is outside of the manufacturer's acceptable range for the controls referenced in 1a and 1b above. b. Temperature recorded was outside of the acceptable range for the controls referenced in 1a and 1b above for 122 of 258 working days in 2020 and 83 of 233 working days in 2021. 3. Staff interview with the LM on 2/2/2022 at 11:30 AM, confirmed the acceptable range on the laboratory temperature chart was outside of the manufacturer's required storage parameters for the above referenced controls. 4. The laboratory performs 100,676 Chemistry tests annually.

D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory manager (LM), it was determined that the reference ranges on the laboratory's final patient test report did not correlate with the reference ranges in the laboratory's procedure manual (PM) in the specialty of Chemistry. Findings include: 1. Comparison of male (M) and female (F) final patient test reports with the laboratory PM's reference ranges on 2/2/2022 revealed, the reference ranges on the final patient test report for Iron (Fe), Total Iron Binding Capacity (TIBC), Magnesium, (Mg)2, Blood Urea Nitrogen (BUN), Creatinine (Creat), Sodium (Na), Potassium (K), Chloride (Cl), Carbon Dioxide (CO2), Glucose (Gluc), Calcium (Ca), Phosphorus (Phos), Total Protein (TP), Albumin (Alb), Alkaline Phosphatase (ALP), Aspartate Aminotransferase (AST), Total Bilirubin (TBili), Protein Urine (U Prot), and Creatinine Urine (U Creat) did not match the reference ranges in the PM. Test Final Patient Report M, F Iron 30-160 ug /dL TIBC 250 - 450 ug/dL Mg 1.6 - 2.8 mg/dL BUN 6.0 - 19.0 mg/dL Creat 0.5-1.2 mg/dL Na 133 - 145 meq/L K 3.3 - 5.3 meq/L Cl 96 - 108 meq/L CO2 22 - 29 meq/L Gluc 70 - 99 mg/dL Ca 8.4 - 10.4 mg/dL Phos 2.6 - 4.5 mg/dL TP 5.9 - 8.4 g/dL Alb 3.2 - 5.2 g/dL Alk Phos 39 - 117 U/L AST 0 - 37 U/L TBili 0.0 - 1.0 mg/dL Test PM Iron, F 37-170 ug/dL Iron, M 49-181 ug/dL TIBC, F 265 - 497 ug/dL TIBC, M 262 - 462 ug/dL Mg 1.6 - 2.3 mg/dL BUN, F 7.0 - 17.0 mg/dL BUN, M 9.0 - 20.0 mg/dL Creat, F 0.52-1.04 mg/dL Creat, M 0.66-1.25 mg/dL Na, F, M 137 - 145 meq/L K, F, M 3.5 - 5.1 meq/L Cl, F, M 98 - 107 meq/L CO2, F, M 22 - 30 meq/L Gluc. F, M 74 - 106 mg/dL Ca, F, M 8.4 - 10.2 mg/dL Phos, F, M 2.5 - 4.5 mg/dL TP F, M 6.3 - 8.2 g /dL Alb, F, M 3.5 - 5.0 g/dL ALP, F, M 38 - 126 U/L AST, F 14 - 36 U/L AST, M 17 - 59 U/L AST, Adult 15 - 46 U/L TBili, F, M 0.2 - 1.3 mg/dL 2. During interview on 2 /22/2022 at 11:00 AM, the LM confirmed the above reference ranges did not match. 3. The laboratory performs 100,676 tests per year in the specialty for Chemistry.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the laboratory manager (LM), the laboratory director (LD) failed to document new moderate complexity testing personnel (TP) training prior to testing patient samples. Findings include: 1. Record review on 2/2/2022 of the laboratory's CMS 209 form revealed 2 new TP. 2. Record

	review on 2/2/2022 of the laboratory's training records revealed, the laboratory failed to document training on the Beckman Coulter Access II prior to reporting test results on patient samples for the 2 new TP referenced in #1 above 3. During interview on 2/2/2022 at 11:00 AM the LM: a. Stated TP2 was hired on 10/4/2021 and TP3 was hired on 11/29/2021. b. Confirmed that training on the Beckman Coulter Access II prior to reporting test results on patients was not documented. 4. The laboratory performs 1,317 Ferritin, 2,811 Vitamin D 25 OH and 3,400 Parathyroid Hormone tests annually on the Beckman Coulter Access II.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on record review and staff interview, the technical consultant failed to evaluate the competency of all testing personnel (TP) to perform moderate complexity testing in the specialties of Hematology and Chemistry. Findings include: 1. Record review on 2/2/2022 of the laboratory's 2020 and 2021 TP competency records revealed 1 of 3 moderate complexity TP did not have competency records. 2. Staff interview with the laboratory manager on 2/2/2022 at 11:00 AM confirmed the above findings. 3. The laboratory performs 21,141 tests annually in the specialty of Hematology and 100,676 tests annually in the specialty of Chemistry.