Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	20D2163591	10/20/2021
Name of Provider or Supplier	**Street Address, City, State**	
Mainehealth Dba Maine Medical Center	84 Campus Dr, Scarborough, 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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and staff interview, the laboratory failed to test PT samples in the same manner as routine patient samples in the specialty of Chemistry. Findings include: 1. Record review on 10/20/2021 of the laboratory's 2020 American Proficiency Institute (API) Chemistry PT attestation sheets revealed: a. 2020 API Chemistry Event 1 - Testing personnel (TP)1 and TP2 participated in the event. b. 2020 API Chemistry Event 2 - TP1 and TP2 participated in the event. c. 2020 API Chemistry Event 3 - TP1, TP2 and TP3 participated in the event. d. No PT event samples were tested by 8 of 11 TP in 2020. 2. Staff interview with the technical consultant and the laboratory director on 10/20/2021 at 11:00 AM confirmed PT was not rotated amongst all TP. 3. The laboratory performs 16 tests a year in the specialty of Chemistry.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two

	years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on record review, lack of documentation and staff interview the laboratory failed to retain a copy of all proficiency testing (PT) records in the specialty of Chemistry. Findings include: 1. Record review on 10/20/2021 of the laboratory's 2020 American Proficiency Institute (API) PT records revealed: a. Chemistry Event 3 - The laboratory did not retain a copy of all records for the event. b. The API PT Performance Evaluation is the only record retained for 2020 Event 3. 2. Staff interview on 10/20/2021 at 11:00 AM with the technical consultant and the laboratory director confirmed the laboratory did not retain all records for API PT 2020 Event 3. 3. The laboratory performs 16 tests per year in the specialty of Chemistry.
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on record review, lack of documentation and staff interview the laboratory failed to take remedial action when unacceptable Proficiency Testing (PT) scores are received. Findings include: 1. Record review on 10/20/2021 of the laboratory's American Proficiency Institute (API) PT 2020 Chemistry Event 1 records revealed: a. Overall pO2 test score of 80%. Specimen BG-01 was unacceptable. The expected result was 16-34 mmHg. The laboratory reported 105 mmHg . b. "Attribute error due to air contamination," was handwritten under the results. c. Remedial action, staff training or a corrective action plan was not documented for the above unacceptable results. 2. Record review on 10/20/2021 of the Maine Medical center 'POCT API Survey Routing Form' 2020 Chemistry Core 1st event revealed: a. The box beside "No problems or lack of consensus indicated." was checked off. b. The form was signed by the LD. 3. Record review on 10/20/2021 of the laboratory's American Proficiency Institute (API) PT 2020 Chemistry Event 3 records revealed: a. Overall pO2 test score of 80%. Specimen BG-13 was unacceptable. The expected result was 19-31 mmHg. The laboratory reported 54 mmHg . b. In the Performance review and corrective action section: "Results reviewed. Passed." was handwritten. c. The Performance review and corrective action section was signed by the technical consultant (TC). d. Investigation, remedial action or a corrective action plan was not documented for the above unacceptable results. 4. Staff interview with the LD and the TC on 10/20/2021 at 11:00 AM confirmed the laboratory did not take remedial action when unacceptable Proficiency Testing (PT) scores are received. 5. The laboratory performs 16 tests per year in the specialty of Chemistry.
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 staff interview, it was determined that the reference range for Sodium (Na) on the laboratory's final patient test report failed to correlate with the reference range in the laboratory's procedure manual. Findings include: 1. Record review on 10/20/2021 comparing final patient test report's reference range for patient #1 (P1) with the laboratory's Radiometer ABL 90 procedure manual revealed the following: Test P1 Final Report Procedure Na 133-145 mmol/L 113-145 mmol/L 2. During interview on 10/20/2021 at 11:00 AM, the technical consultant and the laboratory director confirmed the above reference range does not match. 3. The laboratory performs 16 tests annually in the specialty of Chemistry.