Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	30D2338846	09/01/2026
Name of Provider or Supplier	**Street Address, City, State**	
New England Lifeflight Inc	1 Garside Way - Hangar 2, Manchester, NH	

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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the lab's individualized quality control plan (IQCP), chemistry and hematology control records, patient records, and interview with testing personnel (TP1), the laboratory (lab) failed to follow the IQCP and perform two levels of controls for 1 of 2 new lots of blood gas electrolyte and metabolite (BGEM) test cartridges in 2026. Findings include: 1) Review on 9/1/2026 of the lab's IQCP revealed on page 2 under paragraph labeled "Liquid QC" instruction to perform control testing for "change in reagent lots, new shipment, change in storage condition, [and] replacement of any major part for instrumentation." The number of control material was not specified in the lab's IQCP. 2) Review on 9/1/2026 of the lab's chemistry and hematology quality control records completed in May 2026 revealed BGEM lot # 02-26052-80 revealed one level of control (level 3) was performed on 5/4 /2026 and two levels of controls (level 1 and level 3) was performed on 5/26/2026. 3) Review on 9/1/2026 of patient records from 5/4/2026 through 5/25/2026 revealed the lab tested and reported results for two patients (PT1, and PT2) using BGEM lot # 02-26052-80. PT1's reported test results on 5/4/2026 include measured analytes: hydrogen concentration (pH), partial pressure of carbon dioxide (pCO2), partial pressure of oxygen (pO2), sodium, potassium, calcium, glucose, lactate, hematocrit, chloride, creatinine, total carbon dioxide (TCO2), and blood urea nitrogen (BUN). PT2's reported rests results on 5/23/2026 include measured analytes: pH, pCO2, pO2, sodium, potassium, calcium, glucose, chloride, creatinine, TCO2, and BUN. BGEM lot # 02-26052-80 was the first reagent lot used by the lab for patient testing. 4)

	Interview on 9/1/2026 at 12:00 p.m. with TP1 confirmed the lab did not run level 1 control material on BGEM lot # 02-26052-80 before running the first patient test on 5 /4/2026. TP1 revealed the lab's procedure is to run two levels of controls (level 1 and level 3) for each new lot or shipment and monthly for BGEM test cards.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. This STANDARD is not met as evidenced by: Based on review of the laboratory's (lab) individualized quality control plan (IQCP) and interviews with Testing Personnel (TP1), the lab's IQCP failed to specify the number of control materials for the lab's chemistry and hematology test system used in 2026. Findings include: 1) Interview on 9/1/2026 at 12:00 p.m. with TP1 revealed the lab performed routine control testing using two liquid controls (Level 1 and Level 3) for each new reagent lot number, shipment, and monthly for the Epoc Blood Gas Electrolyte Metabolite (BGEM) test card (tests include: hydrogen concentration (pH), partial pressure of carbon dioxide (pCO2), partial pressure of oxygen (pO2), sodium, potassium, calcium, glucose, lactate, hematocrit, chloride, creatinine, total carbondioxide (TCO2), and blood urea nitrogen (BUN). 2) Review on 9/1/2026 of the lab's IQCP approved by the Lab Director (LD) on 3/30/2026 revealed the number of liquid control materials was not specified for the BGEM test card; there was no instruction to use two level of control materials for BGEM tests.