Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	30D0085999	11/06/2025
Name of Provider or Supplier	**Street Address, City, State**	
New London Hospital	273 County Road, New London, 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
D0000	
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory (lab) failed to enroll in an approved proficiency testing (PT) program for Cell ID in 2025. Findings include: 1. Review on 11/6/2025 of CASPER report 0155D for the lab's regulated analyte PT scores in 2022 through 2025 revealed no reported scores for Cell ID in 2025. 2. The laboratory could not provide documentation during the survey that it was enrolled in an approved PT program for Cell ID at the start of 2025. 3. Interview on 11/7/2025 at 9:45 a.m. with the Technical Supervisor (TS) revealed the lab did not renew enrollment in Cell ID PT when it renewed PT enrollment for 2025 and did not participate in a PT program for Cell ID in 2025.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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, the laboratory's (lab) procedure manual for arterial and venous blood gases failed to include reportable ranges verified by the lab. Findings include: 1. Review on 11/5/2025 of the lab's procedure titled "Blood Gas RP500 Series Procedure - New London Hospital" approved 3/21/2025 revealed the RapidPoint 500e instrument ranges and verified ranges for hydrogen concentration (pH), partial pressure of carbon dioxide (pCO2), partial pressure of oxygen (pO2), total hemoglobin (tHb), sodium (Na), potassium (K), ionized calcium (iCA), chloride (Cl), glucose (Gluc), and lactate (L) as follows [instrument range / verified range]: pH: 6.5-7.8 / 6.5-7.8 pCO2: 5.0-200 / 0.15-180 mmHg pO2: 10-700 / 20-620 mmHg tHb: 2-25 / 2-25 Na: [no instrument] / 100 - 200 mMol/L K: [no instrument] / 1.0 - 13.0 mMol/L iCA: [no instrument] / 0.40 / 3.5 mMol/L Cl: [no instrument] / 65-140 mMol/L Gluc: [no instrument] / 20-750 mg/dL L: [no instrument] / 0-25 mMol/L 2. Review on 11/5/2025 of the lab's verification of performance specifications for RapidPoint 500e analyzer revealed the lab did not verify or establish the instrument or verified ranges published in the procedure manual. Refer to D5421. 3. Interview on 11/5/2025 at 2:00 p.m. with the Technical Supervisor (TS) and General Supervisors (GS1 and GS2) confirmed the blood gas analyte ranges in the procedure manual were not verified by the lab.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory (lab) failed to verify performance specifications for a new blood gas instrument before testing patient

	samples in May 2024. Findings include: 1. Review on 11/5/2025 of the verification of performance specifications for the lab's new instrument RapidPoint 500e revealed the accuracy, precision and reportable range studies were performed by the instrument manufacturer representative. The lab could not provide documentation of verifications studies performed by laboratory personnel for the following analytes tested on the RapidPoint 500e: hydrogen concentration (pH), partial pressure of carbon dioxide (pCO2), partial pressure of oxygen (pO2), total hemoglobin (tHb), oxyhemoglobin (FO2Hb), carboxyhemoglobin (FCOHb), methemoglobin (FMetHb), sodium (Na), potassium (K), ionized calcium (iCA), chloride (Cl), glucose (Gluc), and lactate (L). 2. Interview on 11/5/2025 at 11:30 a.m. with the Technical Consultant (TC1) confirmed the lab's personnel did not perform testing to verify performance specifications for accuracy, precision and reportable range for the analytes listed above tested. 3. Review on 11/5/2025 of the lab's test list revealed the following annual test volumes for the blood gas analytes: pH: 516 pCO2: 514 pO2: 514 tHb: 486 FO2Hb: 514 FCOHb: 514 FMetHb: 514 Na: 514 K: 514 iCA: 516 Cl: 514 Gluc: 514 L: 496
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory (lab) failed to verify education qualifications for 4 of 7 testing personnel reviewed. Refer to tag D6171.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; or (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures

	training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory (lab) failed to verify and maintain qualifications for 4 of 7 testing personnel reviewed. Findings include: 1. Review on 11/5/2025 of 7 testing personnel files revealed 4 (TP1, TP2, TP3, and TP4) of 7 files failed to include the education qualifications. 2. Review on 11/5/2025 of Form CMS-209 (Personnel Form) completed by the lab and signed by the Laboratory Director 5/11/2025 revealed TP1, TP2, TP3, and TP4 performed moderate and high complexity testing. 3. Interview on 11/5/2025 at 9:30 a.m. with a General Supervisor (GS1) revealed the lab did not obtain and maintain a copy of TP1, TP2, TP3, and TP4's educational qualifications before hiring as temporary testing personnel (traveling technologists).