Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	30D0086768	11/14/2025
Name of Provider or Supplier	**Street Address, City, State**	
Cottage Hospital	90 Swiftwater Rd, Woodsville, 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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 record review, observation, and staff interview the laboratory (lab) failed to follow manufacturer's defined acceptable humidity criteria for operation of the lab's Cobas Pure chemistry test system for 31 out of 45 days reviewed in October and November 2025. Findings include: 1. Review on 11/14/2025 of the operators manual for the Cobas Pure chemistry analyzer revealed on page 231 environmental conditions during operation for ambient (room) humidity must be between 30-85%. 2. Review on 11/14/2025 of the lab's humidity logs from October 1, 2025 through 11/13/2025 revealed the lab's room humidity fell below 30% on 30 out of 44 days reviewed. 3. Observation on 11/14/2025 at 10:00 a.m. of the lab's ambient humidity revealed the humidity was 25%. The lab was performing chemistry testing using the Cobas Pure at the time of observation. 4. Interview on 11/14/2025 at 10:30 a.m. with the Technical Supervisor (TS1) confirmed the above findings and revealed the lab continued to perform chemistry testing using the Cobas Pure analyzer in October and November 2025 on the days identified in the logs when humidity fell outside the manufacturer's acceptable range. 5. Review on 11/14/2025 of the lab's test list revealed the Cobas Pure analyzer is used to test for the following analytes: acetaminophen, albumin, alkaline phosphatase, aspartate aminotransferase, ammonia, amylase, alanine

	aminotransferase, blood urea nitrogen, calcium, carbon dioxide, chloride, cholesterol, creatine kinase, creatinine, c-reactive protein, protein, digoxin, dilantin, direct bilirubin, direct low density lipoprotein, ethyl alcohol, ferritin, folate, free thyroxine, glucose, human chorionic gonadotropin, high density lipoprotein cholesterol, hemoglobin A1C, iron, lactic acid, lactate dehydrogenase, lipase, lithium, magnesium, microalbumin, phosphorus, potassium, pro-B-type natriuretic peptide, prostate specific antigen, salicylate, sodium, total bilirubin, total protein, unsaturated iron binding capacity, triglycerides, troponin-I high sensitivity, thyroid stimulating hormone, uric acid, valproic acid, vancomycin, vitamin B12, vitamin D (25-hydroxy), and carbamazepine.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on record review, observation, and staff interview; the laboratory (lab) failed to label 3 of 3 opened vials of hematology quality control (QC) material in 2025. Findings include: 1. Review 11/14/2025 of the package insert for complete blood count (CBC) QC material (QC1, QC2, and QC3) revealed "Open vials and vials which have been sampled by cap piercing will retain stability for 15 days if stored at 2-8 degrees Celsius after being re-capped". QC1, QC2, and QC3 are used for control testing of CBC analytes: white blood cell count, red blood cell count, platelet count, hemoglobin, hematocrit, and white blood cell differential. 2. Observation at 11/14 /2025 at 9:30 a.m. of QC1, QC2, and QC3 vials revealed the caps were pierced and no revised expiration date was documented on the 3 vials. 3. Interview on 11/14/2025 at 9:30 a.m. with the Technical Supervisor (TS1) confirmed the above findings.