Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	30D0002728	04/30/2025
Name of Provider or Supplier	**Street Address, City, State**	
Concord Hospital - Laconia	80 Highland St, Laconia, 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
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 gram stains in 2025. Findings include: 1. Review on 4/29/2025 and 4/30/2025 of PT records for gram stains revealed the lab performed a gram stain on 1 sample for Event 1 of 2025. 2. Interview on 4/30/2025 at 9:40 a.m. with the Microbiology Technical Supervisor confirmed the above finding and revealed the lab had not enrolled in a PT program that included 5 samples per event, 3 events per year.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by:

	Based on record review and staff interview, the laboratory (lab) failed to establish and follow written policies and procedures to assess the Technical and General Supervisor competency in 2023 and 2024. Findings include: 1. The lab was not able to provide a policy and procedure used to assess competency of the Technical and General Supervisors upon request by the surveyor on 4/30/2025. 2. Interview on 4/30/2025 at 10:40 a.m. with the Director of Laboratory Services revealed there was no policy and procedure in place to access competency of the Technical and General Supervisors. Interview further revealed competency assessments had not been performed for Technical and General Supervisors in 2023 and in 2024.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) (b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory (lab) failed to perform function checks for equipment used for Immunohematology testing in 2024 and 2025. Findings include: 1. Review on 4/30/2025 of the lab's "Blood Bank Maintenance Log" for 2024 revealed no function checks had been performed in 2024 for 2 refrigerators and 1 freezer used to store blood products and reagents, 1 water bath used to thaw frozen plasma products, 3 centrifuges, an incubator, heating block, and pipettes used for patient testing. Further review revealed certain function checks were scheduled to be done each month. There was no "Blood Bank Maintenance Log" for 2025. 2. Interview on 4/30/2025 at 10:00 a.m. with the Blood Bank Supervisor confirmed the maintenance outlined on the "Blood Bank Maintenance Log" had not been performed in 2024 and 2025 and revealed it was the Supervisor's responsbility to ensure it was completed.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the

	reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory (lab) failed to perform calibration verification for routine chemistry and toxicology analytes in 2023 and 2024. Findings include: 1. Review on 4/30/2025 of calibration verification records from 2023 and 2024 revealed calibration verification performed in December 2024 failed to include 26 of 39 routine chemistry and toxicology analytes; calibration verification performed in June 2024 failed to include 13 of 29 routine chemistry and toxicology analytes; calibration verification performed twice in 2023 each failed to include 28 of 39 and 26 of 39 routine chemistry and toxicology analytes. 2. Interview on 4/30/2025 at 12:10 p.m. with the Technical Supervisor confirmed calibration verifications from 2023 and 2024 failed to include all the analytes.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) (b)(3) Adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed; This STANDARD is not met as evidenced by: Based on record review and staff interview, testing personnel failed to adhere to the laboratory's (lab) approved control procedure for routine chemistry and toxicology testing in 2025. Findings include: 1. Review on 4/30/2025 of the lab's procedure titled "Laboratory Quality Control Policy Core Laboratory Laconia and Franklin," approved 1/10/2025, revealed quality control (QC) instruction on page 3: "Chemistry assays with 2 or fewer calibrators have three levels of QC run twice a day." 2. Review on 4/30/2025 of calibration verification records revealed 39 routine chemistry and toxicology analytes with 2 or fewer calibrators. Analytes include: acetaminophen, albumin, alkaline phosphatase, alanine aminotransferase, ammonia, amylase, aspartate transaminase, blood urea nitrogen, calcium, cholesterol, creatine kinase, carbon dioxide, carbamazapine, creatinine, c-reactive protein, direct bilirubin, ethanol, gentamicin, gamma-glutamyl transferase, glucose, high density lipoprotein, high sensitivity c-reactive protein, lactate dehyrdogenase, microalbumin, magnesium, phosphate, phenytoin, salicylate, total bilirubin, tobramycin, total protein, triglyceride, urinary/cerebral total protein, valproic acid, vancomycin, uric acid, sodium, chloride, and potassium. 3. Review on 4/30/2025 of control records from January through April revealed three control materials had been tested once per day from 1/9/2025 to 2/16/2025 for routine chemistry analytes using the "multi-qual" QC material and from 1/9/2025 to 2/17/2025 for toxicology analytes using the "IA Plus" QC material. Two routine chemistry controls were run once a day after 2/16/2025, and two toxicology controls were run once a day after 2/27/2025, through 4/30/2025. 4. Interview on 4/30/2025 at 12:10 p.m. with the Technical Supervisor confirmed the control procedure for the analytes listed above had not been followed.