Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	30D0002728	06/02/2023
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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (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 procedure failed to include the verified reportable range for a new hematology test system implemented 3 /7/2023. Findings include: 1. Review on 6/1/2023 of the laboratory's verification of performance specifications for erythrocyte sedimentation rate (ESR) revealed the reportable range verified was 7.0 - 120 mm/hr. 2. Review on 6/1/2023 of the laboratory's reportable range settings in the LIS (referenced inthe procedure) revealed the reportable range for ESR was 1.0 - 130 mm/hr. 3. Interview on 6/1/2023 at 9:40 a. m. with the technical consultant confirmed the above findings.

D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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 failed to perform their own studies to verify the manfuacturer's performance specifications for new hematology, chemistry, and toxicology test systems in implemented in 2023. Findings include: 1. Review on 5/31/2023 of documentation for verification of manufacturer's performance specifications for 2 new Sysmex XN-550 instruments and 2 new GEM5000 instruments revealed the verification procedures had been performed by the manufacturer's representative. The 2 XN-550 instruments were put into use in March 2023 and the 2 GEM5000 instruments were put into use 5/8/2023. 2. Interview on 5/31/2023 at 1:00 p.m. and again at 2:00 p.m. with the general supervisor (GS) confirmed the above findings and revealed the laboratory did not perform their own studies to verify accuracy, precision and reportable ranges for these 4 instruments. 3. The XN-550 instruments are used to perform complete blood counts (white blood cell, red blood cell, hemoglobin, platelet, and white cell differential) and body fluid cell counts (white blood cell, red blood cell). The 2 GEM5000 instruments are used to test chemistry analytes (ionized calcium, chloride, glucose, potassium, lactate, sodium, partial pressure of oxygen, partial pressure of carbon dioxide, hydrogen concentration, and oxygen saturation), toxicology analytes (methemoglobin, carboxyhemoglobin, deoxyhemoglobin) and hematology analytes (hematocrit and total hemoglobin).
D5609	HISTOPATHOLOGY CFR(s): 493.1273(e)(f) (e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on observation and staff interviews, the laboratory failed to document control procedures when assessing the quality of slides derived from frozen section histopathology procedures in 2021, 2022 and 2023. Findings include: 1. Observation by the surveyor on 6/2/2023 at 9:30 a.m. revealed a Cryostat machine located in the grossing area of the laboratory. 2. Interview on 6/2/2023 at 9:30 a.m. with the pathology assistant (PA) revealed the Cryostat was used to prepare frozen sections of tissue as part of the slide making procedure. 3. Interview on 6/2/2023 at 9:45 a.m. with the laboratory director (LD) revealed the LD assessed the quality of slides for each frozen section case but did not document this anywhere. 4. The laboratory's annual test volume for frozen setions is 79.
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, the laboratory's procedures for monitoring manually entered cerebrospinal fluid (CSF) cell counts failed to identify reporting errors in May 2023. Findings include: 1. Review on 6/1/2023 of CSF manual cell count records from January 2023 through May 2023 revealed 1 (Patient 1) of 20 cell counts were entered into the laboratory's LIS incorrectly. Specifically, the number of squares counted for Patient 1's CSF red blood cell (RBC) count was reported as 9 and Patient 1's worksheet documented only 1 square had been counted. The final RBC count reported was 396 cells per microliter; the RBC count using the correct number of squares counted is 3,565 cells per microliter. Further review of the worksheet for Patient 1 revealed it had been initialed as being reviewed for accuracy. 2. Interview on 6/1/2023 with testing personnel confirmed the number of squares counted had been entered wrong for Patient 1's CSF RBC cell count.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on record review and staff interview, the technical consultant (TC) failed to ensure new 1 of 2 new testing personnel performing routine chemistry testing in the operating room (OR) in 2022 and 2023 received competency assessments semiannually in the first year of patient testing. Findings include: 1. Review on 5/31 /2023 of the CMS-209 personnel form and personnel records revealed no documentation of a second semiannual competency assessment for 1 of 2 (TP2) testing personnel whom had been performing routine chemistry and hematology patient testing for at least 1 year. Chemistry and hematology testing using the i-STAT CG8+ test cartridge includes oxygen partial pressure, carbon dioxide partial pressure, hydrogen concentration, sodium, potassium, ionized calcium, glucose, hemoglobin and hematocrit. There was no documentation of training for TP2; there was documentation of a 6 month competency assessment having been completed in July 2022. 2. Interview on 5/31/2023 at 9:40 a.m. with the TC overseeing the OR confirmed the above findings. 3. The laboratory performed 117 tests annually using the i-STAT in the OR.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed.

	This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory failed to obtain documentation of qualifications for 7 of 8 new testing personnel performing moderately complex chemistry and hematology testing in 2021, 2022, and 2023. Refer to D6065. This is a repeat deficiency cited from the recertification survey completed in May 2019.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to obtain documentation of qualifications for 7 of 8 new testing personnel performing moderately complex chemistry and hematology testing in 2021, 2022, and 2023. Findings include: 1. Review on 5/31/2023 of the CMS-209 Personnel Form revealed 8 new testing personnel performing moderately complex testing. 2. Review on 5/31 /2023 of the personnel records for revealed no documentation of educational qualifications for 7 of the 8 new testing personnel. Further review revealed the 7 testing personnel were trained to performed moderately complex testing in chemistry and hematology. 3. Interview on 5/31/2023 at 10:25 a.m. with the General Supervisor confirmed the above findings. 4. This deficiency was previously cited during the recertificaiton survey completed on 5/8/2019.
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 failed to ensure qualifications were met for 1 of 4 new testing personnel performing high complexity hematology, immunohematology, and microbiology testing in 2021, 2022, and 2023. Refer to D6171. This is a repeat deficiency from the recertification survey completed in May 2019.
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 have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (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; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

	This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure qualifications were met for 1 of 4 new testing personnel performing high complexity hematology and immunohematology testing in 2021, 2022, and 2023. Findings include: 1. Review on 5/31/2023 of the CMS-209 Personnel Form revealed 4 new testing personnel performing high complexity testing. 2. Review on 5/31/2023 of the personnel records revealed no documentation of educational qualifications for 1 (TP1) of 4 of these new testing personnel. Further review revealed that TP1 was trained to performed high complexity testing in hematology and immunohematology; as well as moderate complexity testing in chemistry and microbiology. 3. Interview on 5/31 /2023 at 10:25 a.m. with the General Supervisor confirmed the above findings. 4. This deficiency was previously cited during the recertificaiton survey completed on 5/8 /2019.
D6175	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(1) Each individual performing high complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on record review and staff interview, testing personnel performing cerebrospinal fluid (CSF) manual cell counts failed to report results accurately in May 2023. Findings include: 1. Review on 6/1/2023 of CSF manual cell count records from January 2023 through May 2023 revealed 1 (Patient 1) of 20 cell counts were entered into the laboratory's LIS incorrectly. Specifically, the number of squares counted for Patient 1's CSF red blood cell (RBC) count was reported as 9 and the worksheet documented only 1 square had been counted. The final RBC count reported was 396 cells per microliter; the RBC count using the correct number of squares counted is 3,565 cells per microliter. 2. Interview on 6/1/2023 with testing personnel confirmed the number of squares counted had been entered wrong for Patient 1's CSF RBC cell count.