Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 30D0086483	**(X3) Date Survey Completed** 05/03/2023
Name of Provider or Supplier Littleton Hospital Association	**Street Address, City, State** 600 St Johnsbury Rd, Littleton, 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	The complaint survey was performed from 05/01/2023 through 05/03/2023. The laboratory was found out of compliance with the following CLIA Conditions: 493. 801; D2000: Proficiency Testing Enrollment and Testing of Samples 493.1487; D6168: High Complexity Testing Personnel The findings were reviewed with the laboratory director, general supervisor, chief medical officer, director of quality services, chief executive officer, chief operating officer/chief nursing officer, and chief financial officer.
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 Immunohematology testing in 2022. Subpart I defines an approved PT program for Immunohematology to include a minimum of five samples per testing event, and at least three testing events at approximately equal intervals per year. Findings include: 1. Review on 5/2/2023 of the lab's PT records for Immunohematology revealed it was enrolled in two programs (J-Survey and JAT-Survey) from the College of American Pathologists for ABO/Rh, antibody detection, antibody identification, and compatibility testing. J-Survey was used to assess Immunohematology testing using gel technology test system and the

	JAT-Survey was used to assess solid phase Immunohematology testing using the Echo instrument. The lab was enrolled in only two events per year for J-Survey and two events per year for JAT-Survey in 2022. 2. Interview with the Lab Manager on 5/2/2023 at 10:00 a.m. confirmed the above finding. The Lab Manager revealed that solid phase testing on the Echo was the lab's primary test method in 2022.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory (lab) failed to ensure positive identification throughout the Immunohematology testing process for 1 of 21 patient records reviewed from May 2022 through April 2023. Findings include: 1. Review on 5/3/2023 of Immunohematology records from 5/3/2022 to 4/26/2023 revealed 1 (Patient A) of 21 records reviewed had been labeled incorrectly with the wrong person's name. Specifically, patient A had an unexpected antibody detected, the antibody identification worksheet was labeled with another patient's specimen label (Patient B). The antibody workup identified 3 antibodies and Patient A had a history the previous week with the same antibodies identified. No blood product transfusions were received by either Patient A or Patient B and both Patient A's and Patient B's Immunohematology test results had been reported correctly. 2. Interview with the Lab Manager on 5/3/2023 at 10:30 a.m. confirmed the antibody identification workup for Patient A had been mislabeled with Patient B's specimen labels.
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 a record review, written policies and procedures, and interview with the general supervisor (GS), the laboratory failed to follow their written policy to assess the competency of the GS, based on the position responsibilities as listed in Subpart M, for one of one person serving as the general supervisor during the review period of January 2022 through December 2022. Findings include: 1. On 05/01/2023, review of the competency assessment policy 40367.40 titled, "EMPLOYEE COMPETENCY EVALUATION: INITIAL, ANNUAL, & REASSESSMENT" revealed under the "PURPOSE" section "The competency of each person to perform the duties assigned must be assessed following training, and at least annually thereafter.". 2. Review of the Form CMS-209 and personnel records for competency assessments performed from January 2022 through December 2022, revealed a competency assessment was not performed for the GS. 3. The GS confirmed the findings on 05/02/2023 at 03:21 p.m.

D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a record review and interview with the general supervisor (GS), the technical supervisor failed to ensure 1 of 7 testing personnel performing high complexity testing was evaluated at least semiannually during the first year of testing. Findings include: 1. On 05/01/2023, a review of personnel records for seven testing personnel who performed high complexity testing testing in 2021 and 2022 revealed there was no evidence a semi-annual evaluation was performed as follows: a. Testing Person #6 - The initial training was completed on 12/13/2021. There was no evidence a competency evaluation was performed between 12/13/2021 and 05/25/2023. 2. The GS confirmed the findings on 05/02/2023 at 02:40 pm.
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 interview with the general supervisor (GS) and human resource director, the laboratory failed to ensure 2 of 15 testing personnel met the required education qualifications to perform high complexity testing. Refer to 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 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 interview with the general supervisor (GS) and human resource director, the laboratory failed to ensure 2 of 15 testing personnel met the required education qualifications to perform high complexity testing. Findings include: 1. Interview with GS on 05/01/2023 at 10:30 am, confirmed Immunohematology (ABO group and D (Rho) typing, unexpected antibody detection, compatibility testing, and antibody identification) was performed in the laboratory by 15 testing personnel. 2. Review on 05/01/2023 of personnel records revealed the following for 2 of 15 testing persons: a. Testing person #1 was hired to perform high complexity testing on 07/03/2019. The testing person had earned a Bachelor of Science from Canada. There was no documentation to prove an evaluation of the person's credentials was performed, by a nationally recognized organization, to determine the equivalency of their education compared to an education obtained in the United States, as stated at 493.2 (d). b. Testing person #3 was hired to perform high complexity testing on 05/09/1994. The testing person had earned a Bachelor of Science from Canada. There was no documentation to prove an evaluation of the person's credentials was performed, by a nationally recognized organization, to determine the equivalency of their education compared to an education obtained in the

	United States, as stated at 493.2 (d). 3. The GS and human resource director confirmed the findings on 05/01/2023 at 03:15 pm.