Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	30D0086768	12/17/2019
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
D3021	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(c)(1) Blood and blood products storage and distribution. If a facility stores or maintains blood or blood products for transfusion outside of a monitored refrigerator, the facility must ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product. This STANDARD is not met as evidenced by: A. Based on record review and staff interview, the laboratory failed to monitor refrigerated storage temperatures for red blood cell units on 2 days in May 2018. Findings include: 1) Review of Immunohematology refrigerator temperature logs on 12/17/2019 from January 2018 through November 2019 revealed no temperature (digital or internal) was documented on 5/26/18 and 5/27/18 for the refrigerator used to store red blood cell units. 2) Interview on 12/17/2019 at 10:15 a.m. with the Technical Supervisor (TS1) confirmed temperatures were not recorded on the Immunohematology refrigerator temperature logs for 5/26/18 and 5/27/18. B. Based on record review and staff interview, the laboratory and failed to ensure room temperature storage conditions were within acceptable limits for 11 of 12 plateletpheresis (platelet) units in 2018 and 2019. Findings include: 1) Review of the laboratory's policy titled "Apheresis Platelets" on 12/17/2019 revealed the acceptable storage temperature for platelet units is 20-24 degrees Celsius. 2) Review of "Plateletpheresis Temperature Log" on 12/17/2019 from January 2018 through December 17, 2019 revealed the laboratory received and stored 12 platelet units during this period. Further review revealed temperatures recorded on days the laboratory stored platelets fell below 20 degrees Celsius for 11 of 12 platelet units. 3) Interview on 12/17/2019 at 10:15 a.m. with the Technical Supervisor (TS1) confirmed the above findings.
D3041	RETENTION REQUIREMENTS

	CFR(s): 493.1105(a)(6) Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting. This STANDARD is not met as evidenced by: Based on review of patient test reports for the period of March 2018 through December 2019 and staff interview, the laboratory failed to maintain copies of original patient test reports for at least two years after the reports were issued from the Merge Laboratory Information System (LIS). Findings include: 1. Record review conducted on 12/16/2019 of patient test reports for the period of 03/27/2018 through 12/16/2019 revealed copies of the original patient test reports issued from the MERGE LIS between the period of 03/27/2018 through 01/29/2019 were not maintained for at least 2 years after the reports were issued. 2. Record review conducted on 12/17/2019 of the Quality Management Program, version 4.0, effective 05/31/2017, stated the following on page 7 under Section Records H, "test reports - retain or be able to retrieve a copy of the original report (including preliminary, final, and corrected) for a minimum of two years." 3. The General Supervisor (GS1) stated during an interview on 12/17/2019 at 1:00 p.m. that copies of the original test reports that were issued from the Merge LIS and faxed to outside clients were not maintained by the laboratory. The interview further revealed that the Merge LIS went "live" on 03 /27/2018 and was then replaced with a new HARVEST LIS on 01/29/2019.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (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's calibration verification procedures for blood gases in November 2019 failed to cover the laboratory's

	reportable range. Findings include: 1) Review on 12/17/2019 of calibration verification for blood gases performed in November 2019 revealed the following ranges had been verified: Hydrogen concentration (pH) = 6.529-7.895 Oxygen partial pressure (pO2) = 17 - 428 mmHg Carbon dioxide partial pressure (pCO2) = 19.4 - 93.4 mmHg 2) Review on 12/27/2019 of the laboratory's procedure titled 'iSTAT Cartridge and Test Information" revealed the following reportable ranges: pH = 6.5 - 8.2 pO2 = 5 - 800 mmHg pCO2 = 5 - 130 mmHg 3) Interview on 12/17/2019 at 11:25 a.m. with the Technical Consultant (TS1) confirmed the calibration verification performed in November 2019 for pH, pO2, and pCO2 did not fully verify the laboratory's reportable ranges. 4) This is a repeat deficiency from the initial survey completed 6/14/2018.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and staff interview with the Testing Personnel (TP1) and the General Supervisor (GS1), the laboratory failed to check each batch of media for sterility, ability to support and/or inhibit growth, and produce a biochemical response in 2019. Findings include: 1. Review conducted on 12/17/2019 of quality control (QC) records from September 2019 through December 2019 of Columbia CAN w/5% Sheep Blood, MH Agar w/ 5% Sheep Blood, Blood Agar 5% Sheep Blood, Haemophilus ID Quad, Thio Med w/Dex, Hemin, Vit K, and MacConkey agar plates, revealed that media batches were not checked for sterility, ability to support and/or inhibit growth or produce a biochemical response. 2. Record review conducted on 12/17/2019 of the Quality Control and Quality Assurance Program, effective 03/29/2017, stated the following on page 2: "Before, or concurrent with initial use: Check each batch of media for sterility if sterility is required for testing, Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response, Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer." 3. TP1 and GS1 stated during interview on 12/17/2019 at 11:45 a.m. that certain commercially prepared media were only visually inspected and the manufacturer's quality control certificate was kept on file when each batch was received.
D5503	BACTERIOLOGY CFR(s): 493.1261(a)(2) (a) The laboratory must check the following for positive and negative reactivity using control organisms: (a)(2) Each week of use for gram stains. This STANDARD is not met as evidenced by:

	Based on record review and staff interview with the General Supervisor (GS1) and Technical Supervisor (TS1), the laboratory failed to document quality control of Gram stain each week of use in 2019. Findings include: 1. Record review conducted on 12 /17/2019 of Bacteriology quality control records for the period of October 2019 through December 2019 revealed that the laboratory failed to document checking Gram stain reagents with positive and negative reference organisms with each new batch of stains and each week of patient testing. 2. Interview with the TS1 at 12/17 /2019 at 12:10 p.m. and with the GS1 at 12/17/2019 at 1:15 p.m. confirmed the findings above.
D5543	HEMATOLOGY CFR(s): 493.1269(a)(d) (a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to perform control testing for 3 manual cell counts performed in 2018 and 2019. Findings include: 1) Review on 12/16/2019 of manual body fluid cell count proficiency testing (PT) records from 2018 and 2019 revealed no quality control (QC) testing was documented for 2 of 3 PT samples (BFM-1 and BFM-3) in event 2018-Chem&HemeQA1. The attestation was signed in April and May 2018 for these PT samples. 2) Review on 12 /17/2019 of records titled "Body Fluid Patient QC Form" from January 2018 through December 17, 2019 revealed 1 patient cerebral spinal fluid (CSF) cell count performed on 9/14/19. No QC testing was documented on the QC form. The laboratory was unable to provide quality control testing performed on 9/14/19 at the time of survey. 3) Interview on 12/17/2019 at 12:30 p.m. with the Technical Supervisor (TS1) confirmed the manual cell count control testing for the 2 PT samples and 1 patient sample were not documented. 4) This is a repeat deficiency cited on the initial survey completed on 6/14/2016 and again on the recertification survey completed 1/10/2018.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to follow their established procedures to monitor, assess and correct problems identified for testing performed in the specialties of bacteriology, chemistry and hematology. Findings include: 1) The laboratory's calibration verification procedures failed to cover the laboratory's reportable ranges for blood gases. Refer to tag D5439. 2) The laboratory failed to check each batch of media for sterility and its ability to support and/or inhibit growth. Refer to tag D5477. 3) The laboratory failed to ensure gram stain control

	testing was documented. Refer to tag D5503 4) The laboratory director failed to ensure control testing was performed for manual cell counts. This is a repeat deficiency from the initial survey completed on 6/14/2016 and the recertification survey completed 1/10/2018. Refer to tag D5543. 5) Interview on 12/17/2019 at 12:30 p.m. with Testing Personnel (TP3) revealed TP3 reviewed the patient manual cell count mentioned above for accuracy of the calculation and manual entry into the reporting system. TP3 confirmed control testing was not part of the review of the "Body Fluid Patient QC Form".
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director failed to ensure 1 of 7 new testing personnel met educational qualifications and received appropriate training prior to testing patients' specimens in 2018. Findings include: 1) Review on 12 /16/2019 of personnel records revealed 1 of 7 (TP1) new testing personnel failed to include educational qualifications for performing high complexity testing. Cross reference D6171. Further review of TP1's record on 12/16/2019 revealed incomplete training for blood gas testing and cell identification; there was no documentation of training for all other specialties and testing performed by TP1 who worked on third shift. 2) Interview on 12/16/2019 at 12:30 p.m. with TS1 confirmed the above finding and revealed testing personnel on third shift perform all testing in all specialties except bacteriology culture workups using the Vitek2.
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 record review and staff interview, the technical supervisor failed to perform competency assessments semiannually within the first year for 4 new testing personnel in 2018 and 2019. Findings include: 1) Review of 7 new testing personnel records on 12/16/2019 revealed 4 of 7 have performed testing for 1 year or more. Further review of of the 4 personnel records revealed semiannual competency assessments were not documented within the first year for the following: TP2: 1 competency assessment for Immunohematology procedures and 2 competency assessments for Chemistry, Hematology, and Microbiology test systems were not documented. TP3: 1 competency assessment for all Immunohematology procedures, manual body fluid cell counts, complete blood counts (CBC) coagulation testing on the CA 600 analyzer, chemistry procedures on the Dimension EXL, and Vitek2 analyzer. TP4: 1 competency assessment for manual body fluid counts, CBC, manual

	cell differentials, coagulation testing on the CA 600 analyzer, chemistry procedures on the Dimension EXL; and 2 competency assessments for gram stains, urine sediment, and Vitek2 analyzer. TS1: 1 competency assessment for procedures for Alere analyzer (d-dimer and brain natriuretic peptide), chemistry procedures on the Dimension EXL; and 2 competency assessments for Vitek2 analyzer. 2) Interview on 12/16/2019 at 12:30 p.m. with the Technical Supervisor (TS1) revealed the missing semiannual competency assessments listed above had not been performed.
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, 1 of 12 laboratory personnel performing high complexity testing from January 2018 to June 2018 failed to meet educational qualification requirements. Refer to tag D6171. Based on record review and staff interview, 1 of 12 testing personnel failed to follow control procedures for blood gas testing. Refer to tag D6177.
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, 1 of 7 new laboratory personnel performing high complexity testing from January 2018 to June 2018 failed to meet educational qualification requirements. Findings include: 1) Review of the laboratory personnel form (CMS-209) on 12/16/2019 revealed 7 of 12 testing personnel were hired since the previous recertification survey. 2) Review of 7 new testing personnel records on 12/16/2019 revealed 1 (TP1) of 7 records failed to include educational qualifications. 3) Interview on 12/17/2019 at 9:00 a.m. with the Director of Radiation and Laboratory Services revealed TP1 was employed by the laboratory from January 2018 to June 7, 2018. 4) Interview on 12/16/2019 at with Technical Supervisor (TS1) confirmed TP1's record did not include education qualifications. TS1 revealed TP1 was performing patient testing on 3rd shift in all specialties.
D6177	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3) Each individual performing high complexity testing must 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, the testing personnel failed to follow the laboratory's quality control (QC) policies for routine chemistry testing in October 2019. Findings include: 1) Review of the laboratory's policy titled "Quality Control and Quality Assurance Program" on 12/17/2019 revealed on page 3 "Corrective Action on invalid QC results must be performed and controls must be valid prior to

	reporting patient results..." 2) Review of the blood gas QC records on 12/17/2019 from September 2019 through November 2019 revealed QC Level 1 run on 10/19 /2019 failed to fall within the laboratory's acceptable criteria for Oxygen partial pressure (pO2). There was no record that QC Level 1 had been repeated for Level 1. 3) Review on 12/17/2019 of patient results from 10/19/2019 revealed 2 patient pO2 results had been reported. 4) Interview on 12/17/2019 at 11:25 a.m. with TS1 (technical supervisor) revealed if a QC result(s) fall outside the acceptable range, the result(s) is invalid. TS1 confirmed QC must be acceptable prior to reporting patient results.