Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	30D0703153	02/20/2019
Name of Provider or Supplier	**Street Address, City, State**	
Memorial Hospital-Cardiopulmonary	3073 White Mountain Highway, North Conway, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director or designee and testing personnel failed to attest to the routine integration of routine chemistry, toxicology and hematology proficiency testing samples into the patient workload using the laboratory's routine testing methods for 2 of 4 proficiency testing (PT) events reviewed. Findings include: 1) Review on 2/20/19 of the laboratory's PT records from 2018-2019 revealed the laboratory director or designee failed to sign the attestation statement for the 2018 Chemistry-Core 2nd Event and 1 of 5 testing personnel failed to sign the attestation statement for the 2019 Chemistry-Core 1st Event. Chemistry-Core events include PT samples for hydrogen concentration (pH), partial pressure of carbon dioxide pressure, partial pressure of oxygen, hemoglobin, carboxyhemoglobin, and methemoglobin. 2) Interview on 2/20/19 at 1:15 PM with the technical supervisor confirmed the above finding.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action

	when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory failed to successfully participate in a hematology proficiency testing program in 2018 and 2019. Refer to tag D2130 and D2131.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to achieve satisfactory performance for hemoglobin in two out of three consecutive testing events in 2018 and 2019. Findings include: 1) Review on 2/22/19 of American Proficiency Institute (API) evaluation reports revealed the laboratory failed to obtain satisfactory scores for hemoglobin proficiency testing included API Chemistry-Core events. The laboratory obtained a hemoglobin score of "0" for the 2018 Chemistry-Core 2nd Event and a hemoglobin score of "0" for the 2019 Chemistry-Core 1st Event. 2) Interview by phone on 2/25/19 at 1:00 PM with the technical consultant confirmed above finding.
D2131	HEMATOLOGY CFR(s): 493.851(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to obtain satisfactory performance scores in two out of three hematology proficiency testing events in 2018 and 2019. Findings include: 1) Review on 2/22/19 of American Proficiency Institute (API) evaluation reports revealed the laboratory failed to obtain satisfactory scores for hemoglobin proficiency testing included as part of the API Chemistry - Core events used for blood gas analysis. The laboratory obtained a score of "0" in the 2018 Chemistry - Core - 2nd Event and a score of "0" in the 2019 Chemistry - Core - 1st Event. 2) Review on 2/28/19 of CLIA 2) Interview by phone on 2/25/19 at 1:00 PM with the technical consultant confirmed above finding.

D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory failed meet analytic systems requirements for verification of performance specifications and calibration verification in 2017 and 2018. Findings include: 1) The laboratory failed to verify performance specifications for 4 of 4 new instruments received in 2017 to 2018 and used to perform routine chemistry, toxicology and hematology testing. Refer to tag D5421. 2) The laboratory failed to perform calibration verification for routine chemistry and toxicology analytes at least every six months in 2018 and 2019. Refer to tag D5439.
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 verify the accuracy, precision, and reportable range on 4 of 4 new instruments used for routine chemistry, hematology, and toxicology testing in 2017 and 2018. Findings include: 1) Review on 2/20/19 of instrument validations records revealed the following: Instrument #315252 was installed 10/4/17, taken out of use and sent back to manufacturer on 12/18/17, reinstalled on 1/16/18 and taken out of use on 4/2/18. Linearity studies were performed on 10/4/17 and 1/24/18. The linearity studies were not signed for review and evaluation by the laboratory director. There was no evidence the laboratory validated the accuracy or precision of the instrument. 2) Review on 2/20/19 of instrument validation records revealed the following: Instrument #307411 was installed on 12/18/17 and taken out of use on 4/10/18. A linearity study was performed but not dated or signed for review and evaluation by the laboratory director. There was no evidence the laboratory validated the accuracy or precision of the instrument. 3) Review on 2/20/19 of instrument validation records revealed the following: Instrument #303345 was installed on 4/5/18 and was taken out use on 5/18/18. There was no evidence that laboratory validated the accuracy, precision, or reportable range of the instrument. 4) Review on 2/20/19 of instrument validation records revealed the following: Instrument #316113 was installed on 5/8 /18. A linearity was performed on 5/14/18. An accuracy study was performed on 5/18

	/18. A precision study was performed on 6/6/18. The studies were not reviewed and signed for review and evaluation by the laboratory director. The first patient sample was run and results were reported on 5/28/18, prior to the precision study. 5) Observation on 2/20/19 at 10:15 AM revealed instrument #316113 was the instrument currently in use by the laboratory for patient testing. 6) Interview on 2/20/19 at 1:15 PM with the Technical Consultant confirmed the above findings and revealed that the linearity studies were not used to verify the reportable ranges in use by the laboratory. Interview also revealed that all of the above instruments were ABL 80 Flex Co-oximeter analyzers and used for testing of hydrogen concentration (pH), partial pressure of carbon dioxide, partial pressure of oxygen, hemoglobin, carboxyhemoglobin, and methemoglobin.
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 failed to perform calibration verification at least every 6 months for chemistry and toxicology analytes in 2018 and 2019. Findings include: 1) Review on 2/20/2019 of laboratory records revealed the most recent linearity study for the current blood gas analyzer (serial number 316113) was performed on 5/14/18 during verification of performance specifications. 2) Review on 2/20/2019 of the laboratory's procedure titled "Linearity Studies" revealed linearity studies would be done when needed. The procedure did not specify linearity or calibration verification must be done at least every 6 months. 3) Review on 2/20/2019 of laboratory records revealed no documentation of calibration verification for partial pressure of oxygen, carbon dioxide, pH, carboxyhemoglobin, methemoglobin, 4) Interview on 2/20/2019 at 1:15 PM revealed the laboratory did not perform calibration verifications for hydrogen concentration (pH), partial pressure of carbon dioxide, partial pressure of oxygen, hemoglobin, carboxyhemoglobin, and methemoglobin at least 6 months after the previous linearity study.
D5805	TEST REPORT

	CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure that the test report indicated when test results were below the laboratory's reportable range for 2 of 10 patient test reports reviewed (Patient identifier is #6). Findings include: 1) Review on 2/20/19 of patient test reports revealed that on 2/19/19 at 6:01 a.m., Patient #6's venous cord hydrogen concentration (pH) was reported as 6.55. On 2/19/19 at 6:03 a. m., Patient #6's arterial cord pH was reported as 6.52. 2) Review on 2/20/19 of laboratory linearity studies revealed the most current linearity was performed on 5/14 /18. The laboratory verified a range of 6.8 to 7.8 for pH. 3) Interview on 2/20/19 at 1: 15 PM the above findings and revealed that the laboratory did not perform a linearity for blood gases since 5/14/18 and did not use the linearity results to establish reportable ranges for any blood gas analyte.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory director failed to provide overall management and direction for routine chemistry, toxicology and hematology in 2017, 2018, and 2019. Findings include: 1) The laboratory director failed to ensure the procedures for verification of accuracy, precision and reportable range were adequate and performed prior to patient testing for 4 of 4 new instruments received in 2017 and 2018. Refer to tag D6013. 2) The laboratory director failed to ensure policies and procedures for assessing competency of testing personnel performing routine chemistry, toxicology and hematology testing were maintained annually. Refer to tag D6030.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance

	characteristics of the method; This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director failed to ensure in 2017 and 2018 that verification procedures used are adequate to determine the accuracy, precision, and reportable range of new instruments used for routine chemistry, toxicology and hematology. Findings include: 1) Review on 2/20/19 of instrument validations records revealed the following: Instrument #315252 was installed 10/4/17, taken out of use and sent back to manufacturer on 12/18/17, reinstalled on 1/16/18 and taken out of use on 4/2/18. Linearity studies were performed on 10/4/17 and 1/24/18. The linearity studies were not signed for review and evaluation by the laboratory director. There was no evidence the laboratory validated the accuracy or precision of the instrument. 2) Review on 2/20/19 of instrument validation records revealed the following: Instrument #307411 was installed on 12/18/17 and taken out of use on 4/10/18. A linearity study was performed but not dated or signed for review and evaluation by the laboratory director. There was no evidence the laboratory validated the accuracy or precision of the instrument. 3) Review on 2/20/19 of instrument validation records revealed the following: Instrument #303345 was installed on 4/5/18 and was taken out use on 5/18 /18. There was no evidence that laboratory validated the accuracy, precision, or reportable range of the instrument. 4) Review on 2/20/19 of instrument validation records revealed the following: Instrument #316113 was installed on 5/8/18. A linearity was performed on 5/14/18. An accuracy study was performed on 5/18/18. A precision study was performed on 6/6/18. The studies were not reviewed and signed for review and evaluation by the laboratory director. The first patient sample was run and results were reported on 5/28/18, prior to the precision study. 5) Observation on 2 /20/19 at 10:15 AM revealed instrument #316113 was the instrument currently in use by the laboratory for patient testing. 6) Interview on 2/20/19 at 1:15 PM with the Technical Consultant confirmed the above findings and revealed that the linearity studies were not used to verify the reportable ranges in use by the laboratory. Interview also revealed that all of the above instruments were ABL 80 Flex Co-oximeter analyzers and used for testing of hydrogen concentration (pH), partial pressure of carbon dioxide, partial pressure of oxygen, hemoglobin, carboxyhemoglobin, and methemoglobin.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director failed to ensure

	policies and procedures were established for monitoring testing personnel to assure they maintain competency to perform routine chemistry, toxicology and hematology testing in 2017 and 2018. Findings include: 1) Review on 2/20/2019 of personnel records revealed 8 testing personnel performed hydrogen concentration (pH), partial pressure of carbon dioxide, partial pressure of oxygen, hemoglobin, carboxyhemoglobin, and methemoglobin for greater than two years. Further review revealed 8 of 8 of these testing personnel records failed to include documentation of annual competency assessments in 2017 and 2018. 2) Interview on 2/20/2019 at 1:15 PM with the Technical Consultant revealed competency assessments are not done annually after the first year of hire.