Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D0058598	02/20/2023
Name of Provider or Supplier	**Street Address, City, State**	
Humboldt General Hospital Laboratory	118 E Haskell St, Winnemucca, NV	

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	This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on 2/07-08/2023 and a complaint investigation conducted remotely on 2/09-20/2023. The complaint submitted on 2/09 /2023 alleged that the same patient samples tested on the two blood gas analyzers in the respiratory therapy department produced significantly different results which would affect patient care. The allegation was substantiated. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) records, review of instrument print outs of patient results, review of laboratory policies and procedures, and interview with the administrative respiratory director, the laboratory failed to ensure that the PT samples were tested the same number of times that it routinely tests patient samples. Findings include: 1. Review of the instrument records for blood gas PT testing for the first event of 2023 revealed that the PT samples were tested on both Stat Profile Prime Plus analyzers. 2. Review of the instrument records for blood gas PT testing for the third event of 2022 revealed that PT samples were tested on the Rapidpoint 500 and Stat Profile Prime Plus analyzers. 3. Review of the instrument records for blood gas PT testing for the third event of 2021 revealed that PT samples were tested on both Rapidpoint 500 analyzers. 4. Review of the instrument print outs of patient results from 1/30/2023 through 2/09/2023 revealed that not all patient

	samples were tested on both Stat Profile Prime Plus analyzers. Six of twelve patient samples were tested on both instruments. 5. The administrative respiratory director interviewed on 2/08/2023 at approximately 9:30 AM indicated that PT samples were tested on both instruments because patient samples were tested on both instruments according to the recommendation of the instrument technical representatives. However, the respiratory director indicated that not all staff members tested patient samples on both analyzers. 6. The respiratory director confirmed that there were no policies and procedures approved by the laboratory director to test patient samples on both analyzers. 7. On 2/16/2023, the respiratory director submitted a revised policy still to be approved by the laboratory director. The policy, "Reporting Blood Gas Values," states, "I. Each blood sample is to be processed through the primary machine. A. If the primary machine is not available or inoperable, samples should be run through the secondary machine." The laboratory performs approximately 1165 blood gas tests annually.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of American Association of Bioanalysts' (AAB) evaluation of proficiency testing (PT) results submitted by the laboratory from 2021 through 2022, the absence of laboratory instrument printouts of PT results, the absence of the PT program report forms and attestation statements for the first AAB PT events for 2022 (Q1 2022), and an interview with the administrative laboratory director, the laboratory failed to maintain a copy of all records, including the laboratory instrument printouts of PT results, PT program report forms used by the laboratory to record PT results and the attestation statements provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens. Findings include: 1. A review of the laboratory's PT documentation from 2021 and 2022 revealed that the only documents available for Q1 2022 were AAB's evaluations of the PT results. 2. The laboratory was unable to provide the laboratory instrument printouts of PT results, the proficiency testing program report forms used by the laboratory to record proficiency testing results, and the attestation statements provided by the PT program, signed by the analyst(s) and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens. 3. The administrative laboratory director confirmed these findings in an interview on 2/7/2023 at approximately 3:00 PM. The laboratory performs approximately 3,190 microbiology tests, 5 general immunology tests, 210,462 chemistry tests, 165,734 hematology tests, and 1,920 immunohematology tests annually.

D3035	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(ii) In addition, the laboratory must retain immunohematology records, blood and blood product records, and transfusion records as specified in 21 CFR 606.160(b)(3)(ii), (b)(3)(iv), (b)(3)(v), and (d). This STANDARD is not met as evidenced by: Based on review of emergency transfusion release records and an interview with the administrative laboratory director, the laboratory failed to ensure retention of immunohematology records for the emergency release of blood as required. Findings include: 1. The emergency transfusion release records for 2022 were reviewed. The laboratory was unable to locate the emergency transfusion release for patient LS from July 20, 2022. 2. The administrative laboratory director confirmed these findings in an interview on February 8, 2023 at approximately 2:30 PM. The laboratory performs approximate 1,920 immunohematology tests per year.
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 review of laboratory policies and procedures, review of patient test reports from the hospital medical records and analyzers, and interview with the administrative respiratory director and blood gas analyst, the laboratory failed to meet the applicable analytic systems requirements: 1. The laboratory failed to compare the results from the two blood gas analyzers in use in the respiratory department at least twice a year (refer to D5775). 2. The laboratory failed to take corrective actions for unacceptable quality control results prior to testing patient samples (refer to D5783). 3. The laboratory failed to establish a quality assessment program (refer to D5791).
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 a review of American Association of Bioanalysts (AAB) proficiency testing (PT) results and corrective actions from 2021 through 2022, a review of the laboratory procedures, and an interview with the laboratory manager, the laboratory failed to ensure that a procedure was in place for referring abnormal white blood cells to a pathologist for further review and identification. Findings include: 1. A review of the AAB PT results for 2021 and 2022 revealed that in the second event for 2022 (Q2 of 2022) that the laboratory had unacceptable results for white blood cell identification specimens eight and ten for Q2. The laboratory identified these cells as abnormal lymphocytes. The expected results were a myelocyte and promyelocyte for specimens eight and ten, respectively. 2. A review of the corrective action for the AAB PT event Q2 of 2022 revealed that the laboratory's finding was that the specimens were reported incorrectly, as the laboratory practice was to reflex all abnormal white blood cells to a pathologist for further review. 3. A review of the director approved laboratory procedures titled "Peripheral Blood Smear, Wright's Stain Protocol" and "Blood Smear and Wright Stain" found that the process for reflexing of abnormal blood cells to a pathologist was not included in these procedures. 4. An interview with the administrative laboratory director on 2/8/2023 at approximately 10:00 AM confirmed these findings. The laboratory performs approximately 165,734 hematology tests annually.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of policies and procedures in the respiratory department for blood gas analysis, review of the manufacturer's operations manual for blood gas analysis, and interview with the administrative respiratory director, the laboratory failed to ensure that laboratory director approved, signed, and dated these documents and manual prior to use. Findings include: 1. Review of the respiratory department's policy dated 8/05/2002, "Reporting Blood Gas Values," revealed that the laboratory director had not approved, signed, and dated this document prior to use. 2. Review of the operations manual for the Stat Profile Prime Plus blood gas analyzer during the on-site survey on 2/07/2023 revealed that the laboratory director had not approved, signed, and dated the manual prior to use. 3. The administrative respiratory director indicated that the operations manual was used as the procedure manual for performing blood gas analysis and confirmed on 2/08/2023 at approximately 9:45 AM that the original policy from 8/05/2002 and the operations manual had not been approved, signed, and dated by the laboratory director . 4. Review of the revised policy, "Reporting Blood Gas Values," submitted to the surveyor on 2/16/2023 by email, with a reviewed date of 2/16/2023 by the administrative respiratory director, revealed that

	the laboratory director had not approved, signed, and dated this document prior to use. The laboratory performs approximately 1165 blood gas tests annually.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of refrigerator temperature records for the Respiratory Department from 1/01/2022 through 3/31/2022 and review of Stat Profile Prime Plus Auto QC Cartridge storage requirements revealed that the refrigerator temperature was not monitored daily and the acceptable refrigerator temperature was not defined on the temperature log sheets. Findings include: 1. Review of refrigerator temperature logs from 1/01/2022 through 3/31/2022 revealed that temperatures were not recorded on 12 of 31 days in January, 14 of 28 days in February, and 16 of 31 days in March of 2022. 2. Review of Stat Profile Prime Plus Auto QC Cartridge product insert indicated the storage temperature as 2-8 degrees Celsius. The laboratory performs approximately 1165 blood gas tests annually.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on an observation of reagents stored in the laboratory's refrigerators and an interview with the administrative laboratory director, the laboratory failed to ensure that laboratory reagents were not available for patient testing beyond the manufacturer's expiration date. Findings include: 1. During the on-site survey on 2/8 /2023, observation of reagents stored in the laboratory's refrigerators revealed the following expired reagents for chemistry and microbiology, which were available for use in patient testing. a. Sample Diluent with lot numbers IKD652 and IMD659 with expiration dates of 10/1/2022 and 12/1/2022, respectively b. CA Clean II detergent with lot number A2001 and expiration date 1/25/2023 c. Thyroxine Uptake calibrator with lot number: 28D004 and an expiration date of 2/1/2023 d. Alkaline phosphatase calibrator with lot number 2AD023 with an expiration date of 2/1/2023 e. MacConkey plates with lot number 589433 with an expiration date of 2/6/2023 2. The administrative laboratory director confirmed the findings during the survey on 11/08 /2022 at approximately 1:00 PM. The laboratory performs approximately 210,462 chemistry test and 3190 microbiology tests annually.
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 review of laboratory verification studies for the new blood gas analyzers, Nova Stat Profile Prime Plus, review of the manufacturer's instruction manual, and interview with the administrative respiratory director, the laboratory failed to verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. Findings include: 1. Review of the laboratory verification studies revealed that there was no documentation that the reference intervals had been verified against the values of the laboratory's patient population for venous, arterial and capillary blood gases. 2. Review of the Stat Profile Prime Plus instruction manual stated in section A.8 Reference Values, "Each laboratory should establish and maintain its own reference values. The values shown in Table A-29 should be used only as a guide." 3. The administrative respiratory director confirmed the finding during the on-site survey on 2/08/2023 at approximately 9:00 AM. The laboratory performs approximately 1165 blood gas tests annually.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, review of patient test reports from the hospital medical records and analyzers, and interview with the administrative respiratory director and blood gas analyst, CMS 209 personnel #11, the laboratory failed to have a system in place that twice a year evaluates and defines the relationship between test results using the two Stat Prime Profile Plus blood gas analyzers and the RapidPoint 500. Based on review of laboratory documentation of laboratory inter-instrument comparisons from 2021 and 2022 in the clinical laboratory and an interview with the administrative laboratory director, the laboratory failed to ensure that the twice annual inter-instrument comparisons were performed for the troponin assay and the method comparisons for the automated versus manual differentials of white blood cells in 2021 and 2022. Findings include: Respiratory Department 1. A review of laboratory policies and procedures for blood gas analysis for 2021 and 2022 and interview with the administrative respiratory director on 2/08/2023 at approximately 9:45 AM revealed that the laboratory did not have a system to compare the two blood gas analyzers in use at least twice a year and define the relationship between the test results from the different analyzers, the two RapidPoint 500

	analyzers in 2021 and 2022 and the two Stat Prime Profile Plus analyzers in 2022. 2. Blood gas analyst, CMS 209 personnel #11, interviewed on 2/08/2023 at approximately 2:30 PM indicated that when patient samples are tested on both analyzers, the results from the first analyzer used to test the sample are entered in the hospital information system. 3. A complaint investigation was conducted remotely from 2/09/2023 through 2/20/2023, for the allegation received on 2/09/2023, that blood gas test results did not correlate between the two analyzers and "patients were being neglected or wrong mode of treatment is ordered due to the results the machine is giving." Patient reports from 1/31/2023 through 2/09/2023 from the hospital records and from the instruments were reviewed. 4. Six of twelve patient samples were tested on both analyzers between 1/31/2023 and 2/09/2023. Three of six patient samples tested on both analyzers had comparable results. Three of six patient samples tested on both analyzers had significant differences in the results. See these three reports below. 5. Venous blood gas tested for patient with Medical Record Number (MRN) 53189 on 2/07/2023 at 5:25 and 5:26 AM had the following instrument results. The report from the test performed at 5:26 AM, analyzer PP13220360C, was entered into the hospital information system. Analyzer PP13220360C PP13220010C pH 7.452 7.511 PCO2 59.9 69.2 mmHg PO2 85.7 110.6 mmHg HCO3 42.17 55.89 mmol/L O2 Sat 96 97 % Base 18.0 32.7 mmol/L Excess MetHb 0.4 1.0 % COHb 1.7 0.5 % O2Hb 94.2 96.0 % tHb 15.5 16.0 g/dL Tested at 5:26 AM 5:25 AM 6. Venous blood gas tested for patient with MRN 53189 on 2/08/2023 at 5:31 and 5:34 AM had the following instrument results. The report from the test performed at 5:31 AM, analyzer PP13220360C, was entered into the hospital information system. Analyzer PP13220360C PP13220010C pH 7.575 7.585 PCO2 45.6 53.5 mmHg PO2 110.3 117.0 mmHg HCO3 42.67 51.23 mmol/L O2 Sat 99 99 % Base 20.5 29.2 mmol/L Excess MetHb 0.4 0.9 % COHb 1.7 0.4 % O2Hb 96.7 97.5 % tHb 16.5 16.5 g/dL Tested at 5:31 AM 5:34 AM 7. Arterial blood gas tested for patient with MRN 30568 on 2/04/2023 at 12:09 and 12:10 AM had the following instrument results. The report from the test performed at 12:10 AM, analyzer PP13220010C, was entered into the hospital information system.: Analyzer PP13220360C PP13220010C pH 6.985 7.001 PCO2 102.9 120.7 mmHg PO2 77.9 75.0 mmHg HCO3 24.73 30.13 mmol/L O2 Sat 88.0 88.0 % Base -7.0 -1.3 mmol/L Excess MetHb 0.4 0.5 % COHb 1.2 0.4 % O2Hb 86.6 87.1 % tHb 10.3 10.1 g/dL Tested at 12:09 AM 12:10 AM 8. The administrative respiratory director interviewed on 2/08/2023 at approximately 10:00 AM indicated that there was no set policy on which test results were reported if the patient samples were tested on both analyzers although the first set of results was generally accepted due to possible sample deterioration. Clinical Laboratory 9. Review of laboratory documentation of laboratory inter-instrument comparisons from January 2021 through December 2022, revealed that the troponin assay had been compared between instruments in April 2021. There was no second comparison in 2021 and there were no comparisons in 2022. 10. Review of laboratory documentation of laboratory inter-instrument comparisons from January 2021 through December 2022, revealed that automated versus manual blood cell differentials had been compared in April 2021 and May 2022. There was no second comparison in 2021 and 2022. 11. The administrative laboratory director confirmed these findings in an interview on 2/8 /2023 at approximately 1:30 PM. The laboratory performs approximately 1165 blood gas tests, 165,734 hematology tests, and 210,462 chemistry tests annually.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or

	both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records for the Stat Profile Prime Plus blood gas analyzer and patient reports from 1/31/2023 through 2/09/2023 and lack of documentation of corrective actions, the laboratory failed to document corrective actions taken when QC results were flagged as high and evaluate patient test results to determine if patient results had been adversely affected. Findings include: 1. Review of QC records for the Stat Profile Prime Plus blood gas analyzer PP132200010C from 1/31/2023 through 2/09/2023 revealed that Auto QC 1 for PCO2 was flagged as high on 2/04/2023 through 2/08/2023. 2. Review of QC records for the Stat Profile Prime Plus blood gas analyzer PP132200010C from 1/31/2023 through 2/09/2023 revealed that Auto QC 2 for PCO2 was flagged as high on 2/05/2023 and 2/06/2023. 3. There were no corrective actions documented for the unacceptable QC results and whether the blood gas analysts had identified the unacceptable QC results. 4. Review of the patient reports for blood gases from 1/31/2023 through 2/09/2023 revealed that a patient sample, MRN 35068, had been tested on 2/04/2023 with results reported from analyzer PP132200010C. The laboratory performs approximately 1165 blood gas tests annually.
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 review of the Respiratory Department's policies and procedures, review of quality control (QC) reports, review of patient reports, and interview with the administrative respiratory director, the laboratory failed to establish a quality assessment (QA) system to monitor, assess and when indicated correct problems identified in the analytic systems. Findings include: 1. The laboratory did not have a QA system established for analytic systems for blood gas testing performed in the Respiratory Department. There was no on-going mechanism to monitor, evaluate, identify problems, and perform corrective actions for: a. testing and reagent storage conditions, b. quality control performance and detection of control failures, shifts and trends, c. verification of calculated results reported in the patient reports including Bicarbonate (HCO3) and Base Excess, d. and the comparison of test results between the two blood gas analyzers, e. and the documentation of these activities on a regular basis. 2. Review of the refrigerator temperature logs revealed missing temperature records from the daily log and no corrective actions were documented. Refer to D5413. 3. Review of the quality control report for the Stat Profile Prime Plus analyzer PP132200010C from 1/31/2023 through 2/09/2023 revealed unacceptable results for Auto QC 1 for PCO2 from 2/04/2023 through 2/08/2023 and Auto QC 2 for PCO2 on 2/05/2023 and 2/06/202. There was no documentation that the QC records were

	reviewed and corrective actions were taken for the unacceptable QC results and the shift in the Auto QC 1 results from 2/04/2023 through 2/08/2023. Refer to D5783. 4. Review of the new instrument verification studies for the two Stat Profile Prime Plus analyzers installed in September 2022 did not include assessments of the calculated test results reported in the patient reports including HCO3 and Base Excess for accuracy. The administrative respiratory director responded in an email on 2/20/2023, "No HCO3 and base excess are not compared in the comparison, these parameters are calculated not measured parameters," when questioned whether these two parameters were verified for accuracy during the new instrument verification process. 5. A complaint investigation for the allegation that the significant differences in patients' blood gas test results from the two analyzers was affecting patient care, was conducted and the allegation was substantiated. Patient test reports from 1/31/2023 through 2/09/2023 from the two blood gas analyzers were reviewed. There were significant differences found in the patient test results for three out of six patients for specimens analyzed on the two analyzers used in the department. Refer to D5775. 6. The administrative respiratory director interviewed on 2/08/2023 at approximately 9: 45 AM indicated that the department did not have any procedure manuals and used the manufacturer's instrument operation manual as the procedure manual for the Stat Profile Prime Plus. The manufacturer's instrument operation manual did not have instructions for the reporting of patient test results when the analyzed results differed from one instrument to the other. The administrative respiratory director indicated that the first set of results obtained were usually reported. The laboratory performs approximately 1165 blood gas tests annually.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on observation and interview with testing personnel #11 on CMS Form 209, the laboratory did not have a system in place to ensure test results and other patient-specific data were accurately and reliably sent from the point of data entry to final report destination. Findings include: 1. Testing personnel #11 on CMS Form 209 demonstrated manual entry of blood gas results into the hospital information system from the blood gas analyzer patient report printout on 2/08/2023 at approximately 2: 30 PM. 2. There were no internal audits performed on manually entered test results for accuracy. The testing personnel confirmed the finding during the on-site survey on 2 /08/2023 at approximately 2:30 PM. The laboratory performs approximately 1165 blood gas tests annually.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:
Based on review of American Proficiency Institute (API) and American Association of Bioanalysts' (AAB) proficiency testing (PT) evaluations, review of laboratory PT records, and an interview with the administrative respiratory director and with the administrative laboratory director, the laboratory director failed to ensure that the appropriate staff evaluated the laboratory's performance and identified problems that required corrective actions. Findings include: Respiratory Department 1. Review of the laboratory's PT records and API PT evaluations revealed the following: a. There was no documentation that the PT evaluations for blood gas performance for the first and second events of 2022 were reviewed by the appropriate staff. b. The corrective action documented for the third event of 2021 did not identify what problems may have caused the failed PO2 with a score of 40% and the unacceptable PCO2 result with a score of 80%. c. The laboratory PT documentation failed to identify what caused the failure with a score of 0% for total hemoglobin from the third event of 2022. The administrative respiratory director interviewed on 2/08/2023 at approximately 9:30 AM indicated that upon further investigation at a later date, the laboratory had reported the incorrect hemoglobin result from the instrument printout. There was no documentation of this investigation and corrective actions to prevent the recurrence of this failure. The laboratory performs approximately 1165 blood gas tests annually. Clinical Laboratory Findings include: 1. Review of AAB's evaluation of PT results from 2021 through 2022 revealed the following unacceptable results for the first event of 2022 (Q1 2022): a. In the subspecialty of Routine Chemistry, specimen one for acetone had an unacceptable result causing an overall score of 80% for the analyte. b. In the subspecialty of Mycology, the specimen for potassium hydroxide (KOH) skin prep had an unacceptable result causing an overall score of 0% for the analyte. c. In the subspecialty of Hematology, the specimen for nasal eosinophils had an unacceptable result causing an overall score of 0% for the analyte. d. In the subspecialty of Hematology, specimen one for white blood cell (WBC) differential counts for monocytes and abnormal white blood cells had unacceptable results, causing a score of 50% for each analyte. e. In the subspecialty of Bacteriology, specimen two, which was a gram negative organism had an incorrect response, resulting in a score of 50% for the specimen and an overall score of 91% in bacteriology. 2. The laboratory was unable to provide documentation of investigation or corrective action for the unacceptable analytes from the Q1 2022 events. 3. Review of AAB's evaluation of PT results from 2021 through 2022 revealed the following unacceptable results for the second event of 2022 (Q2 2022): In the subspecialty of Toxicology, specimens six, eight, and ten for phenobarbital had unacceptable results, causing an unsatisfactory score of 40% for the analyte. 4. Review of the laboratory's investigation and corrective action for the unacceptable Q2 Chemistry 2022 samples six, eight, and ten for phenobarbital, revealed that the investigation and corrective action had been started, but not completed. The following areas were incomplete: a. The classification of PT failure was not chosen. b. There were no findings noted, although the corrective action stated "Phenobarbital QC passed 2 levels. No patient affected due to PT failure." c. The section for calibration was partially completed stating that a calibration problem had been noted, but the document did not describe

	the problem, the date of last calibration, the date of the last calibration verification, or the frequency of calibration required. d. The date of the last competency assessment for the testing personnel was also incomplete. 5. Review of AAB's evaluation of PT results from 2021 through 2022 revealed the following unacceptable results for the third event of 2022 (Q3 2022): a. In the subspecialty of Toxicology, specimen eleven for theophylline had an unacceptable result, causing a score of 80% for the analyte. b. In the subspecialty of Endocrinology, specimen thirteen had an unacceptable result, causing a score of 80% for the analyte. 6. The laboratory was unable to provide documentation of investigation or corrective action for these unacceptable analytes from the Q3 2022 events. 7. The laboratory manager confirmed these findings in an interview on 2/8/2023 at approximately 9:00 AM. The laboratory performs approximately 3,190 microbiology tests, 165,734 hematology tests, and 210,462 chemistry tests annually.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Review of API PT attestation forms and interview with the administrative respiratory director revealed that the laboratory director failed to specify in writing, the administrative respiratory director as the designee approved to sign the PT attestations forms for blood gas testing. Findings include: 1. Review of the API PT attestation forms for the second and third events of 2021 for blood gases revealed no laboratory director's signature. 2. The administrative respiratory director interviewed on 2/08 /2023 at approximately 9:00 AM indicated that the forms were signed electronically when the PT results were submitted to API by the the laboratory and confirmed that there was no written designee assignment approved by the laboratory director. The laboratory performs approximately 1165 blood gas tests annually.
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 review of personnel training and competency records and interview with the administrative respiratory director, the technical consultant failed to ensure that the semi-annual competency evaluation was performed and documented for the testing

	personnel who began employment in 2021. Findings include: 1. Review of the personnel training and competency records for 2020 through 2022 of eight blood gas analysts revealed that there was no semi-annual competency evaluation documentation for the blood gas analyst # 11 on CMS Form 209, who began employment in 2021. 2. The administrative respiratory director confirmed the finding during the on-site survey on 2/08/2023 at approximately 9:00 AM. The laboratory performs approximately 1165 blood gas tests annually.
D6054	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 annually, after the first year. This STANDARD is not met as evidenced by: Based on review of personnel training and competency records and interview with the administrative respiratory director,the technical consultant failed to ensure that testing personnel's training and performance evaluations were performed and documented at least annually and when the new blood gas analyzers, Stat Profile Prime Plus, were installed for operation in September 2022. Findings include: 1. Review of personnel training and competency records for 2020 through 2022 revealed that five of eight blood gas analysts did not have the annual competency documentation for 2021. 2. There were no training and performance evaluations documented for seven of eight blood gas analysts to operate and report test results from the new blood gas analyzers, Stat Profile Prime Plus, installed for operation in September 2022. 3. The administrative respiratory director interviewed on 2/08/2022 at approximately 9:00 AM confirmed the findings. The laboratory performs approximately 1165 blood gas tests annually.
D6064	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(a) Each individual performing moderte complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required. This STANDARD is not met as evidenced by: Based on review of the laboratory personnel roster, review of Nevada State personnel certification records, and interview with the administrative respiratory director, three of eight blood gas analysts did not have a current personnel certification issued by the State of Nevada. Findings include: 1. Review of Nevada State personnel certification records revealed one of eight blood gas analysts' certification as a general supervisor in blood gas expired on 5/06/2015. No reinstatement application was submitted to date. 2. Review of Nevada State personnel certification records revealed one of eight blood gas analysts' certification as a blood gas technologist expired on 3/19/2022. An application for a general supervisor for blood gas was submitted on 2/03/2023. 3. Review of Nevada State personnel certification records revealed oneof eight blood gas analysts' certification as a blood gas technologist expired on 11/06/2022. A reinstatement application was submitted on 2/05/2023. 4. The administrative respiratory director confirmed the findings on 2/08/2023 at approximately 9:30 AM. The laboratory performs approximately 1165 blood gas tests annually.

D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on review of laboratory quality control (QC) records, review of laboratory policies and procedures, and interview with the administrative respiratory director, the technical supervisor failed to establish a quality control program and establish the parameters for acceptable levels of analytic performance. Findings include: 1. Review of quality control records for the Stat Profile Prime Plus blood gas analyzers from 1/31 /2023 through 2/09/2023 revealed that three levels on on-board controls were tested every 24 hours of operation. 2. Review of the laboratory's policy, "Reporting Blood Gas Values," dated 8/05/2002, revealed that there were no parameters established for acceptable quality control performance. a. The policy did not state how many levels of the three levels of QC performed were required to pass before patient samples could be tested. b. The policy failed to indicate any requirements for the testing of external quality control materials. 3. The administrative respiratory director interviewed on 2 /08/2023 indicated that the three levels of on-board controls were tested at approximately 3:00 AM daily for blood gas analysis. The laboratory performs approximately 1165 blood gas tests annually.