Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D0058598	11/10/2020
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 11/10/2020. 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.
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 review of the attestation statement page for the American Proficiency Institute 2020 Chemistry-Core-First and Second Events and interview with the clinical laboratory administrative director, the laboratory director failed to ensure that the attestation form was signed by the testing personnel and the laboratory director. Findings include: Review of the American Proficiency Institute attestation statement page for 2020 Chemistry-Core-First and Second Events revealed that the testing personnel and the laboratory director did not sign the form attesting to the routine integration of the samples into the patient workload using the laboratory's routine methods to test for blood gases, pCO2, pH, pO2, and carboxyhemoglobin, hemoglobin, methhemoglobin, and oxyhemoglobin. The clinical laboratory administrative director confirmed the finding during the on-site survey on 11/10/2020 at approximately 2:00 PM. The laboratory performs approximately 149,353 chemistry tests and 57,095 hematology tests annually.
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 review of federal database CASPER Report 155D, American Association of Bioanalysts (AAB) proficiency testing (PT) evaluation forms, and interview with the clinical laboratory administrative director, the laboratory did not successfully participate in a proficiency testing program. The laboratory's failure to achieve an overall satisfactory proficiency testing event performance for two out of three testing events for the third testing event of 2019 and the second testing events of 2020 with a score of 0% in each event resulted in unsuccessful proficiency testing performance for Anti-HIV. Findings include: The laboratory failed to maintain successful participation with the AAB PT program shown by the unsuccessful performance for Anti-HIV for the third testing event of 2019 and the second testing events of 2020. Refer to D2084.
D2084	GENERAL IMMUNOLOGY CFR(s): 493.837(f) Failure to achieve satisfactory performance for the same analyte or test in 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 desk review of federal database CASPER Report 155D, American Association of Bioanalysts (AAB) proficiency testing (PT) evaluation forms, and interview with the clinical laboratory administrative director, the laboratory did not successfully participate in a proficiency testing program. The laboratory's failure to achieve an overall satisfactory proficiency testing event performance for two out of three testing events for the third testing event of 2019 and the second testing events of 2020 with a score of 0% in each event resulted in unsuccessful proficiency testing performance for Anti-HIV. Findings include: The laboratory failed to maintain successful participation with the AAB PT program shown by the unsuccessful performance for Anti-HIV in the third testing event of 2019 and the second testing events of 2020 with a score of 0% in each event..

D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of federal database CASPER Report 155D and review of the performance summary from the American Proficiency Institute (API), the laboratory failed to attain a score of at least 80 percent of acceptable responses for blood gas pO2 for the third event of 2019. Findings include: Review of CASPER Report 155D and the performance summary from API revealed that the laboratory scored a 60% in the third event of 2019 for blood gas pO2. The laboratory performs approximately 149,353 chemistry tests annually.
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on desk review of federal database CASPER Report 155D and review of the performance summary from API, the laboratory failed to take and document remedial action and maintain the documentation for two years from the date of participation in the proficiency testing event. Findings include: 1. Review of CASPER Report 155D and the performance summary from API revealed that the laboratory scored a 60% in the third event of 2019 for blood gas pO2. 2. The blood gas analysts interviewed during the on-site survey on 11/10/2020 at approximately 1:00 AM and the quality services director were unable to locate and submit documentation of the corrective actions taken for the failed testing event. The laboratory performs approximately 149,353 chemistry tests annually.
D2173	COMPATIBILITY TESTING CFR(s): 493.863(a) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on desk review of federal database CASPER Report 155D and interview with the clinical laboratory administrative director, the laboratory failed to attain an overall testing event score of at least 100 percent resulting in unsatisfactory performance. Findings include: 1. Review of CASPER Report 155D revealed that the laboratory scored a 40% in the third event of 2018 for compatibility testing. 2. The clinical

	laboratory administrative director interviewed during the on-site survey on 11/10 /2020 at approximately 11:00 AM confirmed the finding. The laboratory performs approximately 1,755 immunohematology tests annually.
D2179	COMPATIBILITY TESTING CFR(s): 493.863(d) (1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on desk review of federal database CASPER Report 155D, lack of documentation of corrective action, and interview with the clinical laboratory administrative director, the laboratory failed to take and document remedial action and maintain the documentation for two years from the date of participation in the proficiency testing event. Findings include: 1. Review of CASPER Report 155D revealed that the laboratory scored a 40% in the third event of 2018 for compatibility testing. 2. The clinical laboratory administrative director interviewed during the on-site survey on 11/10/2020 at approximately 11:00 AM was unable to locate documentation of the corrective actions taken for the failed testing event. The laboratory performs approximately 1,755 immunohematology tests annually.
D3029	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(2) Test procedures. Retain a copy of each test procedure for at least 2 years after a procedure has been discontinued. Each test procedure must include the dates of initial use and discontinuance. This STANDARD is not met as evidenced by: Based on review of laboratory procedures and interview with the clinical laboratory administrative director, the laboratory failed to ensure that discontinued procedures included the dates of initial use and discontinuance. Findings include: Review of laboratory procedure, Alere Determine HIV 1/2 Ag/Ab Combo, revealed that the procedure did not include the date when the laboratory discontinued the test. The clinical laboratory administrative director interviewed during the on-site survey on 11 /10/2020 at approximately 11:00 AM indicated that the procedure was discontinued in the beginning of 2019. The laboratory performs approximately 146 general immunology tests annually.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by:

	Based on review of the CASPER Report 155D and the API performance summary for the third event of 2019 and through the second event of 2020 and the performance review and corrective action forms, the Respiratory Care blood gas laboratory failed to evaluate, take, and document corrective action for the unacceptable PT results for hemoglobin, methemoglobin, and oxyhemoglobin for the third event of 2019 and oxyhemoglobin for the first event of 2020. Findings include: 1. Review of the CASPER Report 155D and the API performance summary for the third event of 2019 and through the second event of 2020 revealed scores of 80% for hemoglobin, methemoglobin, and oxyhemoglobin for the third event of 2019 and oxyhemoglobin for the first event of 2020. 2. Review of the performance review and corrective action forms revealed the forms were not completed and there was no documentation of the review of the unacceptable results and corrective actions taken for the unacceptable results. The laboratory performs approximately 57,095 hematology 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 observation and interview with the clinical laboratory administrative director, the laboratory failed to ensure laboratory reagents were not used after their expiration date. Findings include: 1. A tour of the microbiology section revealed a tube of oxidase reagent which expired on 6/19/2020 and a tube of H2O2 which expired in 9/2020 available for use in the refrigerator. 2. A tour of the Respiratory Care laboratory revealed an opened box of calibration verification material, lot # 35081, which expired on 4/30/2020 available for use in the refrigerator. 2. The clinical laboratory administrative director interviewed during the on-site survey on 11/10 /2020 at approximately 12:00 PM confirmed the findings. The laboratory performs approximately 2,972 microbiology tests and 149,353 chemistry 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 observation, lack of documentation and interview with the blood gas analysts, the Respiratory Care laboratory performing blood gas analysis on the RapidPoint 500 failed to verify the performance specifications of the test before reporting patient test results. Findings include: 1. A tour of the Respiratory Care laboratory revealed two RapidPoint 500 blood gas analyzers. 2. Interview with the blood gas analysts during the on-site survey on 11/10/2020 at approximately 1:30 PM

	revealed that the two analyzers were installed in July of 2018 and April of 2019. 3. There was no documentation of verification studies conducted for accuracy, precision, reportable range, and the reference intervals before the laboratory began testing patient samples and reporting results from the newly installed RapidPoint 500 blood gas analyzers. The laboratory performs approximately 149,353 chemistry 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 instrument comparison reports and interview with the clinical laboratory administrative director, the laboratory failed to ensure that when two instruments are used to perform the same test, the laboratory evaluates and defines the relationship between test results using the different instruments twice a year. Findings include: 1. Review of the comparison reports for the two Sysmex CA-600 performing coagulation tests revealed that the laboratory had performed one comparison study for 2019. The clinical laboratory administrative director interviewed during the on-site survey on 11/10/2020 at approximately 12:00 PM confirmed the finding. 2. The blood gas analysts in the Respiratory Care laboratory who perform blood gas analysis and the quality services director were unable to locate the comparison studies for the two RapidPoint 500 blood gas analyzers for 2019 and 2020. The laboratory performs approximately 149,353 chemistry tests and 57,095 hematology 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 blood gas analysts training records submitted by the quality services director, the technical consultant failed to ensure that blood gas analysts were evaluated and their performance documented at least annually, after the first year. Findings include: Review of the training records submitted by the quality services director revealed that there was no documentation of the annual performance evaluations for two of three blood gas analysts for 2019 and 2020 and one of three blood gas analysts for 2020.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.

	1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of federal database CASPER Report 155D, American Association of Bioanalysts (AAB) proficiency testing (PT) evaluation forms, and interview with the clinical laboratory administrative director, the condition of laboratory director for laboratories performing high complexity testing was not met. The laboratory director failed to provide overall management and direction in accordance with CFR 493.1445. Findings include: The laboratory director failed to ensure that the laboratory successfully participated in a PT program approved by CMS; as described in subpart 1 of this part for each specialty, subspecialty and analyte or test in which the laboratory is certified under CLIA. Refer to D6089.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on review of CASPER Report 155D and interview with the clinical laboratory administrative director, the laboratory director failed to ensure that proficiency testing samples were tested as required. Findings include: 1. The laboratory failed to achieve satisfactory performance for Anti-HIV in the third testing event of 2019 and the second testing event of 2020 resulting in unsuccessful PT performance. 2. CASPER Report 155D reported a score of 0% for both events and the clinical laboratory administrative director confirmed the finding during the on-site inspection on 11/10 /2020 at approximately 11:00 AM.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of AAB and API proficiency testing evaluations, laboratory records, laboratory personnel records, and interview with the clinical laboratory administrative director, the laboratory director failed to ensure that the quality assessment program was maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. Findings include: 1. The quality assessment program failed to assure that the laboratory evaluated PT reports to identify any problems that require corrective action. 2. The quality assessment program failed to assure that corrective action was taken and documented for the unacceptable PT results. 3. The quality assessment program failed to assure that testing personnel training and competency assessments were conducted prior to testing personnel testing patient samples. 4. The quality assessment program failed to assure that the newly installed blood gas instrumentations' performance specifications were verified before patient

	samples were tested and the results reported. 5. The quality assessment program failed to assure that the twice yearly comparison studies between instruments that perform the same test for blood gases were completed for 2019 and 2020.
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 review of clinical laboratory personnel records and Respiratory Care training records, the laboratory director failed to ensure that prior to testing patients' specimens, all personnel receive the appropriate training and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. Findings include: 1. Review of the clinical laboratory personnel records revealed that there were no training documentation of two of two medical technologists temporarily contracted from an employment agency (travelers), who began employment approximately in June and August of 2020,. 2. Review of the clinical laboratory personnel records revealed that there was no training documentation for one of six medical technologists performing high complexity testing. The clinical laboratory administrative director confirmed the finding during the on-site inspection on 11/10 /2020 at approximately 9:30 AM. 2. Review of the Respiratory Care blood gas analysts training records submitted by the quality services director revealed that there was no training documentation for two of two blood gas analysts, one who began employment approximately in 2019 and one who began employment in 2020.