Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D0058598	12/17/2024
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 December 16-17, 2024. 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.
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing (PT) records, the director approved laboratory policies and procedures, and interviews with the laboratory personnel and laboratory supervisor, the laboratory failed to test PT samples in the same manner as patient specimens. Findings include: 1. A review of the laboratory's PT records from March 2023 through December 2024 found that the entire panel of chemistry tests was repeated for any PT samples that had values flagged by the chemistry analyzer. 2. The laboratory director approved "Critical Results Reporting" policy indicates that results with a "repeat and alarm value" are to be repeated and confirmed. The policy does not describe repeat testing for results that are flagged by the analyzer, but are not critical values. 3. An interview with testing personnel on

	December 17, 2024 at approximately 4:00 PM indicated that all flagged analytes will be repeated even if they are not critical values. 4. These findings were confirmed by the laboratory supervisor in an interview at approximately 4:00 PM on December 17, 2024. The laboratory performs approximately 211,889 chemistry tests annually.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on a review of the American Association of Bioanalysts - Medical Laboratory Evaluation (AAB-MLE) and American Proficiency Institute (API) Proficiency Testing (PT) attestations from March 2023 through December 2024 and an interview with the laboratory supervisor, the laboratory failed to ensure that all testing personnel routinely performing patient testing were performing proficiency testing. Findings include: 1. A review of 2023 and 2024 PT attestations from AAB-MLE revealed that the proficiency testing was not rotated among the testing personnel routinely performing patient testing. a. In 2023 AAB-MLE non chem testing personnel number two on the form CMS 209 performed all three events for both blood banking and direct antiglobulin test (DAT). b. In 2024 AAB-MLE non chem testing personnel number one on the form CMS 209 performed all three events for all misc cultures, throat culture and urine culture. c. In 2023 AAB-MLE non chem testing personnel number four on the form CMS 209 performed all three events for cardiac markers. d. In 2023 AAB-MLE non chem testing personnel number nine on the form CMS 209 performed all three events for serum HCG. 2. A review of the 2023 and 2024 PT attestations from API revealed that the proficiency testing was not rotated among the testing personnel routinely performing patient testing. a. In 2023 API chem core testing personnel number two on the form CMS 209 performed all three testing events. 3. An interview with the laboratory supervisor on December 17, 2024 at approximately 2:00 PM confirmed these findings. The laboratory performs approximately 211,889 chemistry, 3,792 microbiology, five general immunology, 1,486 immunohematology and 119,616 hematology tests annually.
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 a review of the AAB-MLE and API Proficiency Testing attestations from March 2023 through December 2024 and an interview with the laboratory supervisor, the laboratory failed to ensure that the testing personnel performing the proficiency testing signed the attestation stating that the samples were performed in the same manner as patient testing. Findings include: 1. A review of API PT attestations from March 2023 through December 2024 found that in the first event in 2023 for chemistry miscellaneous the laboratory personnel performing the PT failed to sign the

	attestations. 2. A review of the March 2023 through December 2024 AAB-MLE PT documents found that the testing personnel failed to sign the attestations as detailed below. The 2023 and 2024 Chemistry testing events included the following 16 subsections: afinion glycohemoglobin, ammonia, cardiac markers, chemistry module, fecal occult blood, high-sensitivity c-reactive protein (HS-CRP), lipid profile, neonatal /direct bilirubin, provider-performed microscopy, PSA, serum alcohol/ketones, serum HCG, therapeutic drug monitoring, urinalysis module, urine drug screen and urine sediment identification. a. Testing event M1 in 2023 had 16 out of 16 subsections were missing signatures from the testing personnel on the attestations. b. Testing event M2 in 2023 had 16 out of 16 subsections missing signatures from the testing personnel on the attestations. c. Testing event M3 in 2023 had 16 out of 16 subsections missing signatures from the testing personnel on the attestations. d. Testing event M1 in 2024 had 14 out of 16 subsections were missing signatures from the testing personnel on the attestations. e. Testing event M2 in 2024 had 16 out of 16 subsections missing signatures from the testing personnel on the attestations. f. Testing event M3 in 2024 had 15 out of 16 subsections missing signatures from the testing personnel on the attestations. 3. A review of the March 2023 through December 2024 AAB-MLE PT attestations found that the testing personnel failed to sign the attestations as detailed below. The 2023 and 2024 Nonchemistry testing events included the following 12 subsections: antimicrobial susceptibility, blood bank 2, blood cell identification, coagulation module, direct antiglobulin test (DAT), hematology with 5-part diff-abbott cell-dyn, infectious mononucleosis, rapid sedimentation rate (ESR), strep a antigen detection, throat culture, misc cultures and urine culture. a. Testing event M1 in 2023 had eight out of 11 (misc cultures was added in testing event M2) subsections missing signatures from the testing personnel on the attestations. b. Testing event M2 in 2023 had 11 out of 12 subsections missing signatures from the testing personnel on the attestations. c. Testing event M3 in 2023 had 11 out of 12 subsections missing signatures from the testing personnel on the attestations. d. Testing event M1 in 2024 had six out of 12 subsections missing signatures from the testing personnel on the attestations. e. Testing event M2 in 2024 had six out of 12 subsections missing signatures from the testing personnel on the attestations. f. Testing event M3 in 2024 had eight out of 12 subsections missing signatures from the testing personnel on the attestations. 4. An interview with the laboratory supervisor on December 17, 2024 at approximately 11:00 AM confirmed these findings. The laboratory performs approximately 211,889 chemistry, 3,792 microbiology, five general immunology, 1,486 immunohematology, 119,616 hematology and 22,085 waived 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 a review of the laboratory's PT documentation from March 2023 through December 2024 and an interview with the laboratory supervisor, the laboratory failed to evaluate, take, and document corrective action for the unacceptable PT results for hematology/coagulation API PT event three in 2023 and for AAB-MLE PT urine sediment identification for the third testing event of chemistry in 2024. Findings include: 1. A review of the laboratory's PT documentation for the third API hematology/coagulation PT event of 2023 for revealed scores of 50% for PMN (CSF /body fluid). The second page of the two page corrective action checklist was not

	available at the time of survey. The PT review signed by the director indicated to "see attached form." 2. A review of the AAB-MLE PT documentation revealed scores of 50% for the third urine sediment - urinalysis event of 2024. A review of the PT documentation for this event revealed that no investigation or corrective action was completed for the unacceptable results. 3. An interview with the laboratory supervisor on December 17, 2024 at approximately 2:00 pm confirmed these findings. The laboratory performs approximately 211,889 chemistry and 119,616 hematology tests annually.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, a review of the ORTHO Confidence System package insert, a review of the blood bank quality control records, and an interview with the laboratory supervisor, the laboratory personnel failed to follow the director approved procedures. Findings include: Immunohematology: 1. The laboratory's policy titled, "Quality Control of MTS Manual Gel Test System Reagents,"Record results on the laboratory daily QC work sheet or ORTHO Confidence System Blood Bank Quality Control Record Sheet." 2. The "Blood Bank QC Log Sheet" includes a table that requires the following for each reagent used: lot number, expiration date and open date. 3. A review of the blood bank quality control records from March 2023 to December 2024 which had been documented on Blood Bank QC Log Sheet, found that the open date was not documented for any reagent in use in December 2024. 4. The new vial for Confidence Antibody (lot number CNF 369) was placed in use after lot number CNF 367 was expired on December 14, 2024. There was no open date on the QC log sheet or on the vial for lot number CNF 369. 5. A review of the blood bank controls in use compared to the blood bank quality control records from December 2024 found that Screen Cells lot number VSS 607 was currently in use, but the laboratory failed to document this lot on the Blood Bank QC Log Sheet. The Blood Bank QC Log Sheet incorrectly indicated that lot NSS 603 was the lot currently in use. Repeat testing policy: 6. The laboratory director approved "Critical Results Reporting" policy indicates that results with a "repeat and alarm value" are to be repeated and confirmed. The policy does not describe repeat testing for results that are flagged by the analyzer, but are not critical values. 7. An interview with testing personnel on December 17, 2024 at approximately 4:00 PM indicated that all flagged analytes will be repeated even if they are not critical values. 8. These findings were confirmed by the laboratory supervisor in an interview at approximately 4:00 PM on December 17, 2024. The laboratory performs approximately 211,889 chemistry, 3,792 microbiology, five general immunology, 1,486 immunohematology, 119,616 hematology and 22,085 waived 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 the lack of room temperature documentation and an interview with the laboratory supervisor, the laboratory failed to define and monitor appropriate room temperature ranges in the respiratory therapy lab where the blood gas testing instruments and reagents were housed. Findings include: 1. The laboratory failed to provide documentation that appropriate room temperatures for the NOVA Stat Profile Prime Plus per the manufacturer's instructions had been defined and monitored from March 2023 through December 2024. 2. An interview with the laboratory supervisor on December 17, 2024 at approximately 2:00 PM confirmed these findings. The laboratory performs approximately 211,889 chemistry tests annually.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on a review of the temperature logs for the main laboratory and an interview with the laboratory supervisor, the laboratory failed to document corrective action when temperatures were out of range for the room temperature, freezer and for the refrigerator temperature. Findings include: add specialties 1. A review of the temperature record log from May 2023 through December 2024, found that in November 2023 the store room freezer temperature was out of range for 21 of 30 days with no documented corrective action. The acceptable range for the freezer was documented on the temperature logs as -20 degrees Celsius. 2. A review of the temperature record log from May 2023 through December 2024, found that in March 2024 the lab room temperature was out of range for one of 31 days with no documented corrective action. The acceptable range for the room temperature was documented on the temperature logs as 20-25 degrees Celsius. 3. A review of the temperature record log from May 2023 through December 2024, found that in March 2024 the store room refrigerator temperature was out of range for five of 31 days with no documented corrective action. The acceptable range for the refrigerator temperature was documented on the temperature logs as 2-8 degrees Celsius. 4. A review of the temperature record log from May 2023 through December 2024, found that in June 2024 the Bacteriology room temperature was out of range for six of 30 days with no documented corrective action. The acceptable range for the room temperature was documented on the temperature logs as 20-25 degrees Celsius. 5. A review of the temperature record log from May 2023 through December 2024, found that in June 2024 the store room refrigerator temperature was out of range for three of 30 days with no documented corrective action. The acceptable range for the refrigerator temperature was documented on the temperature logs as 2-8 degrees Celsius. 6. A review of the temperature record log from May 2023 through December

	2024, found that in June 2024 the store room freezer temperature was out of range for 26 of 30 days with no documented corrective action. The acceptable range for the freezer was documented on the temperature logs as -20 degrees Celsius. 7. A review of the temperature record log from May 2023 through December 2024, found that in September 2024 the lab room temperature was out of range for five of 30 days with no documented corrective action. The acceptable range for the room temperature was documented on the temperature logs as 20-25 degrees Celsius. 8. A review of the temperature record log from May 2023 through December 2024, found that in September 2024 the store room freezer temperature was out of range for 21 of 30 days with no documented corrective action. The acceptable range for the freezer was documented on the temperature logs as -20 degrees Celsius. 9. A review of the temperature record log from May 2023 to December 2024, found that in September 2024 the bacteriology lab room temperature was out of range for four of 30 days with no documented corrective action. The acceptable range for the room temperature was documented on the temperature logs as 20-25 degrees Celsius. 10. An interview with the laboratory supervisor on December 17, 2024 at approximately 11:00 AM confirmed these findings. The laboratory performs approximately 211,889 chemistry, 3,792 microbiology, five general immunology, 1,486 immunohematology and 119,616 hematology 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 a review of the form CMS 209, laboratory personnel records and an interview with the laboratory supervisor, the technical consultant failed to perform and document the semi-annual competency assessments of one out of 12 testing personnel performing only moderate complexity testing during their first year of employment. Findings include: 1. A review of the laboratory personnel training documents from 2023 and 2024 found that the testing personnel number 20 on the CMS 209 did not have documented semi-annual competency in 2023. 2. An interview with the laboratory supervisor on December 16, 2024 at approximately 2:00 pm confirmed these findings. The laboratory performs approximately 211,889 chemistry tests annually.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on a review of the form CMS 209, laboratory personnel records and an

	interview with the laboratory supervisor, the technical supervisor failed to evaluate and document the competency for one of 11 testing personnel performing high complexity testing annually. Findings include: 1. A review of the laboratory personnel records from 2023 and 2024 found that testing personnel number nine on the CMS 209 did not have documented annual competency in 2023 and 2024. 2. An interview with the laboratory supervisor on December 16, 2024 at approximately 2:00 pm confirmed these findings. The laboratory performs approximately 211,889 chemistry, 3,792 microbiology, five general immunology, 1,486 immunohematology and 119,616 hematology tests annually.