Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D0665234	11/20/2024
Name of Provider or Supplier	**Street Address, City, State**	
Pershing General Hospital And Nursing Home Lab	855 6th St, Lovelock, 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 and change of director survey conducted at your facility on November 19-20, 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.
D2077	GENERAL IMMUNOLOGY CFR(s): 493.837(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on a review of federal database CASPER Report 0155D and American Proficiency Institute (API) proficiency testing (PT) performance summary, the laboratory failed to return PT results to API. Findings include: 1. The laboratory failed to return the results for the first event of 2023 for general immunology to API, resulting in a score of 0 for the testing event. 2. These findings are documented in the CASPER Report 0155D and the API performance summary for the first immunology PT event of 2023. 3. These findings were confirmed by the laboratory director and

	laboratory manager in an interview at approximately 3:00 PM on November 19, 2024. The laboratory performs approximately 24 general immunology waived tests annually.
D2155	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on a review of federal database CASPER Report 0155D and American Proficiency Institute (API) proficiency testing (PT) performance summary, the laboratory failed to return PT results to API. Findings include: 1. The laboratory failed to return the results for the first event of 2023 for ABO group and D (Rho) typing to API, resulting in a score of 0 for the testing event. 2. These findings are documented in the CASPER Report 0155D and the API performance summary for the first ABO group and D (Rho) typing PT event of 2023. 3. These findings were confirmed by the laboratory director and laboratory manager in an interview at approximately 3:00 PM on November 19, 2024. The laboratory performs approximately 83 immunohematology tests annually.
D2165	UNEXPECTED ANTIBODY DETECTION CFR(s): 493.861(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on a review of federal database CASPER Report 0155D and American Proficiency Institute (API) proficiency testing (PT) performance summary, the laboratory failed to return PT results to API. Findings include: 1. The laboratory failed to return the results for the first event of 2023 for unexpected antibody detection to API, resulting in a score of 0 for the testing event. 2. These findings are documented in the CASPER Report 0155D and the API performance summary for the first unexpected antibody detection PT event of 2023. 3. These findings were confirmed by the laboratory director and laboratory manager in an interview at approximately 3:00

	PM on November 19, 2024. The laboratory performs approximately 83 immunohematology tests annually.
D2174	COMPATIBILITY TESTING CFR(s): 493.863(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on a review of federal database CASPER Report 0155D and American Proficiency Institute (API) proficiency testing (PT) performance summary, the laboratory failed to return PT results to API. Findings include: 1. The laboratory failed to return the results for the first event of 2023 for compatibility testing to API, resulting in a score of 0 for the testing event. 2. These findings are documented in the CASPER Report 0155D and the API performance summary for the first compatibility testing PT event of 2023. 3. These findings were confirmed by the laboratory director and laboratory manager in an interview at approximately 3:00 PM on November 19, 2024. The laboratory performs approximately 83 immunohematology tests annually.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of the laboratory 2023 and 2024 American Proficiency Institute (API) Proficiency Testing (PT) records, and an interview with the laboratory manager and the laboratory director, the laboratory failed to ensure that the results that were not graded by the proficiency testing agency were evaluated and documented. Findings include: 1. A review of API PT evaluations and laboratory PT documentation for 2023 and 2024 revealed that the director failed to review the ungraded results for hematology/coagulation for the first PT events of 2023 and 2024. 2. A review of API PT evaluations and laboratory PT documentation for 2023 and 2024 revealed that the director failed to review the ungraded results for the first chemistry core event in 2024. 3. These findings were confirmed by the laboratory director and laboratory manager in an interview at approximately 3:00 PM on November 19, 2024. The laboratory performs approximately 26,440 hematology and 45,244 chemistry tests annually.

D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) evaluations, lack of laboratory documentation, and an interview with the laboratory director and laboratory manager, the laboratory failed to verify the accuracy of cardiac marker, D-Dimer, at least twice a year. Findings include: 1. A review of the API PT evaluations for cardiac marker, D-Dimer, revealed that the instrument was out of service on the first and third testing events in 2023. 2. The laboratory was unable to provide evidence that an additional verification of accuracy had been performed during 2023. 3. These findings were confirmed by the laboratory director and laboratory manager in an interview at approximately 3:00 PM on November 19, 2024. The laboratory performs approximately 45,244 chemistry 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 manager, the laboratory personnel failed to follow the director approved procedures. Findings include: 1. The laboratory's policy titled, "Quality Control Using ORTHO Confidence," states the required materials will be stored and used according to the manufacturer's instructions. 2. The ORTHO Confidence System package insert states to "Record results on the laboratory daily work sheet or ORTHO Confidence System Blood Bank Quality Control Record sheet." 3. A review of the blood bank quality control records from January 2023 to November 2024 which had been documented on ORTHO Confidence System Blood Bank Quality Control Record sheet, found that the following dates were not documented on the quality control record sheet, 4/18/2024, 5 /26/2024, 6/14/2024, 7/6/2024, 7/10/2024, 7/12/2024, 7/26/2024. 4. The control results for the above dates were documented on the Transfusion Service Log. No lot numbers or expiration dates were included with this documentation. 5. These findings were confirmed by the laboratory manager in an interview at approximately 12:00 PM on November 20, 2024. The laboratory performs approximately 83 immunohematology tests annually.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually

	after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on a review of the roster provided on the CMS-209 form, a review of the annual competency assessments, and an interview with the laboratory director and laboratory manager, the technical supervisor failed to ensure that Testing Personnel number three (TP3) on the CMS-209 had documented annual competency assessments for 2023 and 2024. Findings include: 1. A review of the competency assessments for the testing personnel listed on the CMS-209 form found that there were no annual competency assessments in 2023 and 2024 for TP3. 2. These findings were confirmed by the laboratory director and laboratory manager in an interview at approximately 3:00 PM on November 19, 2024. The laboratory performs approximately 79,780 tests annually.