Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	29D0665234	09/18/2018
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 survey conducted at your facility on September 18, 2018. 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.
D2127	HEMATOLOGY CFR(s): 493.851(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) Performance Summary and interview with the laboratory manager, the laboratory failed to return proficiency testing (PT) results to API within the time frame specified by the program in the second testing event of 2018 for hematology resulting in unsatisfactory performance. Findings include: 1. Review of the Performance Summary from API showed the laboratory scored 0% for hematology for failure to participate in the second testing event of 2018. 2. The laboratory manager indicated during the on-site survey on 9/18 /18 at approximately 3:00 PM that the PT test results were not submitted to API before the deadline. The laboratory performs approximately 32,306 hematology tests annually.
D2153	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(a) Failure to attain a score of at least 100 percent of acceptable responses for each

	analyte or test in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of the federal database CASPER Report 155D, American Proficiency Institute (API) Performance Summary, and interview with the laboratory manager, the laboratory failed to score at least 100 percent for ABO Group typing resulting in unsatisfactory analyte performance for the first event of 2018. Findings include: 1. Review of the federal database CASPER Report 155D and the Performance Summary from API showed the laboratory scored 80% for ABO Group typing for the first event of 2018. 2. The laboratory manager confirmed the finding during the on-site survey on 9/18/18 at approximately 3:00 PM. The laboratory performs approximately 23 ABO & Rh Group typing 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 review of the federal database CASPER Report 155D, American Proficiency Institute (API) Performance Summary, and interview with the laboratory manager, the laboratory failed to score at least 100 percent for Compatibility Testing resulting in unsatisfactory analyte performance for the first event of 2018. Findings include: 1. Review of the federal database CASPER Report 155D and the Performance Summary from API showed the laboratory scored 80% for Compatibility Testing for the first event of 2018. 2. The laboratory manager confirmed the finding during the on-site survey on 9/18/18 at approximately 3:00 PM. The laboratory performs approximately 14 Compatibility Tests annually.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of the API Comparitive Evaluation for the first event of 2018 and interview with the laboratory manager, the laboratory failed to verify the accuracy of Blood Cell Identification results which were not graded. Findings include: 1. Review of the API Comparitive Evaluation for the first event of 2018 for hematology revealed that the ungraded Blood Cell Identification results were not evaluated and the Data Summary sheet was not reviewed to verify the accuracy of the results. 2. The laboratory manager interviewed during the on-site survey on 9-18-18 at approximately 3:00 PM indicated that proficiency test results that were not graded were not evaluated for accuracy. The laboratory performs approximately 32,306 hematology results annually.

D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: Based on review the Wellness Tuesdays information sheet and interview with the laboratory manager, the laboratory failed to have a written request for patient testing from an authorized person. Findings include: The laboratory manager interviewed during the on-site survey on 9/18/18 at approximately 4:30 PM indicated that patient specimens were tested on Wellness Tuesdays on the third Tuesday of each month without orders from a person authorized under State law to order tests or receive test results. The patients came in for testing and ordered the tests themselves. The test menu included: Comprehensive Metabolic Panel, Lipid Panel, Complete Blood Count, Hemoglobin A1c, Thyroid Stimulating Hormone (TSH), and Prostate Specific Antigen (PSA). The laboratory performs approximately 37,857 chemistry and 32,306 hematology tests annually.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual, manufacturer's instructions, and interview with the laboratory manager, the laboratory failed to perform quality control tests with two control materials of different concentrations each day patient specimens are assayed for the Triage d-dimer test. Findings include: 1. The laboratory's procedure manual and the Triage manufacturer's d-dimer instructions stated that external quality controls are tested with each new lot number of devices and every 30 days thereafter if the same lot number is in use. There was no Individualized Quality Control Plan (IQCP) established and approved for the Triage d-dimer test to validate the laboratory's quality control procedure. 2. The laboratory manager interviewed during the on-site survey on 9/18/18 from 10:00 AM to 5:30 PM confirmed that quality controls for the Triage d-dimer test were not performed each day patient specimens were tested and no IQCP was established and approved for this test. The laboratory performs approximately 32,306 hematology tests annually.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document

	all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual, review of laboratory records and interview with the laboratory manager, the laboratory failed to perform quarterly blood bank refrigerator alarm checks as specified by internal policy. Findings include: 1. Review of the laboratory procedure for blood bank refrigerator alarm checks stated that alarm checks were to be conducted quarterly. 2. Records reviewed showed that alarm checks were not conducted in 2018 and one due in November 2017 was not conducted. 3. The laboratory manager interviewed during the on-site inspection on 9 /18/18 confirmed the findings at approximately 11:30 AM.
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 correlation records and interview with the laboratory manager, the laboratory failed to perform comparison studies for the d-dimer test performed on the Sysmex CA 600 coagulation analyzer and the Triage meter and the white blood cell differential performed manually and on the AcT 5 Diff hematology analyzer. Findings include: 1. Review of the instrument correlation records revealed that twice a year comparison studies for the d-dimer tested on the Sysmex CA 600 and the Triage meter were not conducted for 2016, 2017, and 2018. 2. Review of the correlation records for the AcT 5 Diff hematology analyzer and the manual white blood cell differential revealed that there were no records for the twice a year comparison studies for 2018. 3. The laboratory manager confirmed the findings during the on-site survey on 9/18/18 at approximately 1:00 PM. The laboratory performs approximately 32,306 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 review of laboratory personnel training and competency records and interview with the laboratory manager, the technical consultant failed to evaluate and document training and compentency of the specialty medical technician performing moderate complexity tests at least semiannually during the first year the individual began testing patient specimens. Findings include: 1. The training and competency records reviewed for the specialty medical technician did not have his semi-annual competency assessment during the first year he began testing patient specimens. His

	initial assessment was performed in April 2015 and his next competency assessment was performed in October 2016. 2. The laboratory manager confirmed the finding during the on-site survey on 9/18/18 at approximately 3:30 PM.
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 API proficiency test evaluations, procedure manual, laboratory records, laboratory personnel records, and interview with the laboratory manager, 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 submitted proficiency test (PT) results to API prior to the deadline. 2. The quality assessment program failed to assure that the laboratory evaluated ungraded PT results for accuracy to identify any problems that require corrective action. 3. The quality assessment program failed to identify that quality controls were not performed each day patient specimens were tested for d-dimer on the Triage or to identify that the Individualized Quality Control Plan had not been established and approved for the Triage d-dimer test to allow for quality control testing as specified in the laboratory procedure or manufacturer's instructions. 4. The quality assessment program failed to identify that the blood bank refrigerator alarm checks were not being conducted quarterly as stated in the laboratory procedure manual. 5. The quality assessment program failed to identify that comparison studies were not conducted twice a year for the d-dimer test performed on the Sysmex CA 600 coagulation analyzer and the Triage meter and the white blood cell differential performed on the AcT 5 Diff and by manual method. 6. The quality assessment program failed to identify that testing personnel training and competency assessments were not conducted as required by regulation: semiannually the first year of testing patient specimens and annually thereafter.
D6127	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 semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of laboratory personnel training and competency records and interview with the laboratory manager, the technical supervisor failed to evaluate and document the competency assessments at least semiannually during the first year the laboratory manager began testing patient specimens. Findings include: 1. The training and competency records reviewed for the laboratory manager performing high complexity tests did not have her semi-annual competency assessment during the first year she began testing patient specimens. Her initial assessment was performed in October 2017 and no other competency assessments were performed. 2. The

	laboratory manager confirmed the finding during the on-site survey on 9/18/18 at approximately 4:00 PM.