Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
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Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	29D0665234	11/09/2020
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 11/09/2020. 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.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

	This STANDARD is not met as evidenced by: Based on review of calibration verification documentation and interview with the laboratory manager, the laboratory failed to perform calibration verification for CK-MB, troponin, myoglobin, and d-dimer on the Triage for 2019 and 2020. Findings include: Review of the calibration verification documentation for the laboratory instrumentation revealed there was no documentation of the calibration verification performed every six months for the Triage CK-MB, troponin, myoglobin, and d-dimer for 2019 and 2020. The laboratory manager interviewed during the on-site inspection on 11/09/2020 at approximately 11:00 PM confirmed the findings. The laboratory performs approximately 37,857 chemistry and 32,306 hematology tests annually.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the Individualized Quality Control Plan (IQCP) for serum pregnancy and urine drug screens, there was no documentation that the quality assessment plan for the IQCP evaluated the effectiveness of the quality control plan and no risk assessments were conducted when there were changes in testing personnel. Findings include: Review of the IQCP for serum pregnancy and urine drug screens revealed that there had been no documented quality assessment of the effectiveness of the quality control plan and no risk assessments were conducted with changes in testing personnel. The laboratory manager interviewed during the on-site survey on 11/09/2020 at approximately 2:30 PM indicated that she was not aware of the IQCP for serum pregnancy and urine drug screens and therefore, the reviews had not been conducted. The laboratory performs approximately 37,857 chemistry tests annually.
D6090	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(ii) The laboratory director must ensure the results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: Based on review of CASPER Report 155D, American Proficiency Institute (API) performance summary, API website, and interview with the laboratory manager, the laboratory director failed to ensure the proficiency testing (PT) results were submitted to the PT provider within the timeframes established by the program. Findings include: 1. Review of the CASPER Report 155D and the API performance summary revealed a score of 0% for ABO, RHO, compatibility testing and antibody detection for the first event of 2019. 2. Review of the API website by the laboratory manager during the on-site survey on 11/09/2020 at approximately 1:00 PM revealed that the

	laboratory did not participate in the PT testing event. The laboratory manager confirmed the findings. The laboratory performs approximately 52 immunohematology tests annually.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure 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 CASPER Report 155D, American Proficiency Institute (API) performance summary and interview with the laboratory manager, the laboratory director failed to ensure the proficiency testing (PT) reports received are reviewed to identify any problems that require corrective action. Findings include: 1. Review of the CASPER Report 155D and the API performance summary revealed a score of 0% for ABO, RHO, compatibility testing and antibody detection for the first event of 2019. 2. There was no documentation of review of the PT performance summary to identify any problems that require corrective action. The laboratory manager confirmed the findings during the on-site survey on 11/09/2020 at approximately 1:00 PM. The laboratory performs approximately 52 immunohematology tests annually.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of CASPER Report 155D, American Proficiency Institute (API) performance summary and interview with the laboratory manager, the laboratory director failed to ensure an approved corrective action plan is followed when any PT result is found to be unacceptable. Findings include: 1. Review of the CASPER Report 155D and the API performance summary revealed a score of 0% for ABO, RHO, compatibility testing and antibody detection for the first event of 2019. There was no documentation of corrective actions taken for the unacceptable results and the failure to participate in the testing event. 2. Review of the CASPER Report 155D and the API performance summary revealed a score of 60% for CK isoenzyme for the first event of 2019 and a 60% for pO2 for the third event of 2019. There was no documentation of corrective actions taken for the unacceptable results. The laboratory manager confirmed the findings during the on-site survey on 11/09/2020 at approximately 1:00 PM. The laboratory performs approximately 52 immunohematology and 37,857 chemistry tests annually.
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 PT reports to identify any problems that require corrective action. 3. 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 identify that calibration verification studies were not conducted twice a year for the Triage d-dimer, CK-MB. troponin, and myoglobin for 2019 and 2020. 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.
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 testing personnel training and competency documentation and interview with the laboratory manager, the technical supervisor failed to ensure that high complexity testing personnel were evaluated and their performance documented at least semiannually during the first year the individual tests patient specimens. Findings include: Review of training and competency documentation of five high complexity testing personnel revealed that there was no semi-annual evaluation for one testing personnel during the first year the individual began testing patient samples. The laboratory manager interviewed during the on-site survey on 11/09/2020 at approximately 3:00 PM confirmed the finding.