

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D0665234	(X3) Date Survey Completed 12/06/2022
Name of Provider or Supplier Pershing General Hospital And Nursing Home Lab	Street Address, City, State 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 12/6/2022. 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.
D3000	<p>FACILITY ADMINISTRATION CFR(s): 493.1100</p> <p>Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.</p> <p>This CONDITION is not met as evidenced by: Based on review of Division records, a sample survey of patient test results from October 1, 2022 to December 6, 2022, log of reported SARS-CoV-2 positive results, and interview with the laboratory manager, the Condition: Facility Administration was not met. The laboratory failed to report SARS-CoV-2 (COVID-19) test results as required. Findings include: 1. 1. Division records revealed that the laboratory had begun performing SARS-CoV-2 testing on 12/17/2020 using Abbott ID Now SARS-CoV-2 PCR testing and BinaxNOW COVID-19 antigen testing. 2. The SARS-CoV-2 patient test result log was reviewed from October 2022 through December 6, 2022. 3. The log of reported SARS-CoV-2 results from 12/1/2022 to 12/8/2022 submitted by</p>

the laboratory manager revealed that positive test results were not reported as required for patient with initials TD tested on 11/25/2022, patient with initials EH tested on 12/1/2022, and patient with initials LM tested on 12/2/2022. 4. The laboratory was unable to provide documentation that the positive test result was reported as required for patient with initials GB tested on 10/6/2022. 5. In an interview with the laboratory manager at approximately 5:15 PM on 12/6/2022, she confirmed these findings and stated that she was unable to access a comprehensive report of SARS-CoV-2 results that had been reported as required. The laboratory performs 6,023 SARS-CoV-2 tests annually.

D5211

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:
Based on review of the American Proficiency Institute Proficiency Testing (PT) evaluation, the laboratory's PT documentation and an interview with the laboratory manager, the laboratory failed to ensure that corrective action was documented for the unacceptable result for antibody screening in the second PT event in 2022. Findings include: 1. American Proficiency Institute (API) Proficiency Testing (PT) documentation from 2021 through 2022 was reviewed. Sample SER-06 had an unacceptable result, causing an overall score of 80% in antibody screening for the second event in 2022 in Immunohematology 2. Review of the laboratory's PT documentation revealed that no evaluation and corrective action was documented for sample SER-06. 3. The laboratory director signed his approval of the corrective action, prior to the laboratory manager completing the investigation and corrective action for unacceptable sample SER-06. 4. The laboratory manager confirmed that she had not yet completed the investigation for the unacceptable antibody screening result during the interview on 12/6/2022 at approximately 10:30 AM. The laboratory performs approximately 79 immunohematology 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, review of the immunohematology (blood banking) quality control forms for 8/28/2022, and an interview with the laboratory manager, the laboratory failed to ensure that laboratory reagents were not used after their expiration date. Findings include: 1. Review of the immunohematology (blood banking) Quality Control forms from August 2022 to December 2022 revealed that expired reagents were used to perform quality control (QC) on 8/28/2022. Anti-AB (lot ABB 704A) expired on 8/25/2022 and the enhancement media (lot AEP 026A) expired on 8/18/2022. 2. During the on-site survey on 12/6/2022, observation of reagents stored in the laboratory's refrigerator revealed two boxes of PSA calibrators (lot 1ED006) with an expiration date of 11/1/2022, which were available for use. 3. The laboratory manager

confirmed these findings during the interview on 12/6/2022 at approximately 4:45 PM. The laboratory performs approximately 43952 chemistry tests and 79 immunohematology tests annually.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on observation, review of verification documentation and laboratory policies, and an interview with the laboratory manager, the laboratory failed to follow their written policies to verify the Sysmex CA-600 coagulation testing instrument was programmed with the correct ISI value provided by the manufacturer for the lot of Innovin reagent currently in use. The laboratory failed to perform the reagent roll-over studies for the current lot of Innovin. Findings include: 1. Observation of the ISI value on the Sysmex CA-600 coagulation testing instrument on 12/6/2022 revealed that Innovin lot number 549779 with an ISI value of 1.04 was being used in INR calculations by the CA-600. 2. Observation of the Innovin vial which had been opened and put into use on 12/6/2022 showed that it was lot number 549795 with an ISI value of 1.07. 3. Review of the laboratory policy for reagent lot roll-over studies on the Sysmex CA-600 stated that verification of the reference range and method correlation were to be performed when changing reagent lots. 4. In an interview with the laboratory manager at approximately 5:00 PM on 12/6/2022, she stated that she had not performed the appropriate reagent lot roll-over studies as described in the approved laboratory policy for operation of the CA-600. 5. One patient sample had been tested for PT/INR after the reagent change on 12/6/2022. The laboratory performs approximately 48798 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 Form CMS-209, laboratory personnel records, and an interview with the laboratory manager, the technical consultant failed to perform and document the semi-annual competency assessments of one out of seven testing personnel performing moderate complexity testing during their first year of employment. Findings include: 1. The technical consultant failed to ensure that semi-annual competency assessments were performed and documented for testing personnel, designated as #5 on Form CMS-209, during their first year of employment. 2. Review of personnel records showed that this person, designated as #5 on Form CMS-209, was employed by the laboratory to perform moderate complexity testing from approximately May 2020 through January 2022. 2. The laboratory manager confirmed these findings during the survey on 12/6/2022 at approximately 9:30 AM. The

laboratory performs approximately 271 microbiology, 43,952 chemistry, and 48798 hematology tests annually.

D6064

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(a)

Each individual performing moderate complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required.

This STANDARD is not met as evidenced by:

Based on review of Division personnel certification documents, Form CMS-209, personnel training records, observation, and an interview with the laboratory manager, the laboratory failed to ensure that personnel possessed an appropriate State of Nevada personnel certificate for all specialties of moderate complexity testing performed in the laboratory. Findings include: 1. Review of State of Nevada personnel certificates belonging to the eight employees listed on the Form CMS-209 revealed that testing personnel, designated as #8 on Form CMS-209, who began employment with the laboratory in approximately September of 2021, had a State of Nevada General Supervisor of Licensed Laboratory certificate with a specialty only in Chemistry. 2. Review of training records for testing personnel, designated as #8 on Form CMS-209, revealed that there was training documented for hematology Coulter DxH 520 and AcT 5diff analyzers, the Sysmex CA-600 coagulation analyzer, and the microbiology tests, wet mount and KOH examinations. These tests are outside of the chemistry specialty. 3. Testing personnel, designated as #8 on Form CMS-209, was observed to be performing coagulation testing on the Sysmex CA-600, on 12/6/2022 at approximately 4:30 PM. Coagulation testing falls under the specialty of hematology. 4. In an interview on 12/6/2022 at approximately 5:15 PM, the laboratory manager confirmed these findings. The laboratory performs approximately 48798 hematology tests and 271 microbiology tests annually.

D6101

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(11)

The laboratory director must employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart.

This STANDARD is not met as evidenced by:

Based on review of Form CMS-209, Division records of personnel certification, Form CMS-116, and an interview with the laboratory manager, the laboratory director failed to employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to accurately perform tests and report test results. Findings include: 1. Form CMS-209 listed a total of seven testing personnel, designated as #2 through #8 on the Form CMS-209, for the period of 2021 through 2022. Review of Division personnel certification records showed that five testing personnel were qualified to perform both moderate and high complexity testing in all specialties tested in the laboratory. A sixth person was limited to performing moderate and high complexity testing in chemistry. The seventh person was limited to performing moderate complexity testing from May 2020 through January 2022, and waived testing after her State of Nevada personnel certificate changed to Laboratory

Assistant.. 2. At the time of the survey on 12/6/2022, the laboratory testing personnel was comprised of one full-time laboratory manager who is qualified to perform both moderate and high complexity testing, one full time traveler who is limited to performing moderate and high complexity testing in chemistry only, one pro re nata (PRN) person who is qualified to perform moderate and high complexity testing, and one laboratory assistant who can only perform waived testing. 3. The PRN testing personnel, designated as #4 on Form CMS-209, completed initial training and competency on 2/19/2021, but has not been evaluated for competency after that date. The laboratory manager indicated during an interview on 12/6/2021 at approximately 9:30 AM that this person is rarely available to cover a shift in the laboratory. 4. The Form CMS-116 indicates that the laboratory hours of operation are 24 hours per day, seven days a week. 5. There are insufficient testing personnel to cover moderate and high complexity testing in all specialties tested in the laboratory during the hours of operation. 6. The Laboratory manager confirmed the current number of staff in an interview on 12/6/2022 at approximately 9:30 AM. The laboratory performs approximately 93,109 moderate and high complexity tests per year.

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 records, the Form CMS-209, and an interview with the laboratory manager, the technical supervisor failed to evaluate and document the competency of one out of six testing personnel performing high complexity testing at least semiannually during the first year the individual tests patient specimens. Findings include: 1. Review of the personnel records showed that the technical supervisor failed to ensure that the semi-annual competency assessments were performed and documented for testing personnel, designated as #4 on Form CMS-209, during their first year of employment. 2. Review of personnel records showed that testing personnel, designated as #4 on Form CMS-209, began employment with the laboratory in approximately January of 2021. 3. The laboratory manager confirmed the findings during the survey on 12/6/2022 at approximately 9:30 AM. The laboratory performs approximately 93,109 laboratory tests annually.

D6168

TESTING PERSONNEL
 CFR(s): 493.1487

The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.

This CONDITION is not met as evidenced by:
 Based on review of Division personnel certification documents, immunohematology (blood banking) test records, laboratory test reports, and an interview with the laboratory manager, the Condition: Laboratories performing high complexity testing; testing personnel was not met. The laboratory failed to ensure that high complexity testing personnel was qualified (refer to D6170) and trained to perform

	<p>immunohematology testing (refer to D6174) and that quality controls were documented (refer to D6177).</p>
<p>D6170</p>	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(a)</p> <p>Each individual performing high complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required.</p> <p>This STANDARD is not met as evidenced by: Based on review of Form CMS-209, Division personnel certification documents, immunohematology test records, laboratory test reports, and an interview with the laboratory manager, the laboratory failed to ensure that personnel possessed an appropriate Nevada State personnel certificate for all specialties of high complexity testing performed in the laboratory. Findings include: 1. A review of Division personnel certificates and the personnel records of the seven testing personnel employed by the laboratory revealed that testing personnel, designated as #8 on Form CMS-209, who began employment with the laboratory in approximately September of 2021, had a State of Nevada General Supervisor of Licensed laboratory certificate with a specialty in Chemistry only. 2. Review of immunohematology test records and laboratory test results revealed that this unqualified testing personnel, designated as #8 on Form CMS-209, had performed patient ABO and Rh typing and antibody screening on 9/2/2022 and 11/12/2022. These tests are classified as immunohematology and are outside of the chemistry specialty. 3. In an interview on 12/6/2022 at approximately 5:00 PM, the laboratory manager confirmed these findings. The laboratory performs approximately 79 immunohematology tests annually.</p>
<p>D6174</p>	<p>TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(a)</p> <p>Each individual performs only those high complexity tests that are authorized by the laboratory director and require a degree of skill commensurate with the individual's education, training or experience, and technical abilities.</p> <p>This STANDARD is not met as evidenced by: Based on review of training records, immunohematology test records, laboratory test reports, and interview with the laboratory manager, the laboratory director failed to ensure that testing personnel performed only those high complexity tests for which the personnel had received appropriate training. Findings include: 1. Review of training records for testing personnel, designated as #8 on form CMS-209, revealed that there was no documentation of training for immunohematology (blood banking). 2. Review of immunohematology test records and laboratory test reports revealed that testing personnel, designated as #8 on form CMS-209, performed patient ABO and Rh typing and antibody screening on 9/2/2022 and 11/12/2022, without documented training and competency assessments. 3. The laboratory manager confirmed the findings during the interview on 12/6/2022 at approximately 5:00 PM. The laboratory performs approximately 79 immunohematology tests annually.</p>
<p>D6177</p>	<p>TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3)</p>

Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

This STANDARD is not met as evidenced by:

Based on review of immunohematology patient test records and quality control records, and interview with the laboratory manager the laboratory failed to ensure that all immunohematology quality controls were documented on each day of patient testing. Findings include: 1. Review of immunohematology patient test records revealed that testing personnel, designated as #8 on form CMS-209, had performed patient ABO and Rh typing and antibody screening on 9/2/2022 and 11/12/2022. 2. Review of immunohematology (blood banking) quality control records for 2022 revealed that that testing personnel, designated as #8 on form CMS-209, had not documented any quality control results for 9/2/2022 and 11/12/2022. 3. The laboratory manager confirmed the findings during the interview on 12/6/2022 at approximately 5:00 PM. The laboratory performs approximately 79 immunohematology tests annually