

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D0665234	(X3) Date Survey Completed 02/01/2023
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
D5203	<p>SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232</p> <p>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.</p> <p>This STANDARD is not met as evidenced by: Based on review of patient test reports, instrument print-outs, and an interview with the laboratory manager, the laboratory failed to establish and follow policies and procedures to ensure positive identification and optimum integrity of the patient specimens from the time of collection through the completion of testing and reporting of results. Findings include: 1. Review of SARS-CoV-2 patient test reports and instrument print-outs of testing results from 1/15/2023 through 1/31/2023 revealed that two of nine positive patient specimens been tested prior to the collected and received dates documented by the laboratory in the patient test reports. 2. The SARS-CoV-2 patient test results with a corrected report date of 1/23/2023 for the patient with initials AM were reviewed. The test report revealed that the order date was 1/17/2023 8:04 PM and the "collected and rec'd" dates and times were 1/18/2023 at 9:02 AM. 3. Review of the instrument print-outs revealed that the specimen for patient AM had been tested on 1/17/2023 at 5:50 PM. 4. The SARS-CoV-2 patient test results reported on 1/20/2023 for the patient with initials FT were reviewed. The test report revealed that the order date was 1/19/2023 3:59 PM and the "collected and rec'd" dates and times were 1/20/2023 3:23 PM. 5. Review of the instrument print-outs revealed that the specimen for patient FT had been tested on 1/20/2023 at 2:58 PM. 6. The laboratory manager confirmed these findings in an interview on 2/1/2023 at approximately 1:30 PM. The laboratory manager indicated that due to stability the specimens were tested prior to the requisition being generated in the laboratory information system due to the lack of personnel in the departments ordering these</p>

tests. They indicated that the remaining information and the results entry was completed once the requisition became available. The laboratory performs 6,023 SARS-CoV-2 tests annually.

D5821

TEST REPORT
CFR(s): 493.1291(k)

When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report.

This STANDARD is not met as evidenced by:

Based on observation, review of the Allegation of Compliance (AOC) for the Statement of Deficiencies (SOD) issued 12/16/2022, review of patient test reports, and interview with the laboratory manager during the follow-up visit to assess the Allegation of Compliance for the survey completed 12/6/2022, the laboratory failed to ensure that a system was in place to promptly issue corrected reports to the authorized person ordering the test. Findings include: 1. The laboratory failed to issue the corrected Prothrombin Time (PT)/ International Normalized Ratio (INR) report for patient LW promptly. The report with the incorrect PT/INR was originally reported on 12/6/2022. The corrected results were determined on 12/20/2023 when the correct ISI value was used to determine the PT/INR. The corrected report was issued on 2/1/2023. 2. Observation of the ISI value on the Sysmex CA-600 coagulation testing instrument on 12/6/2022 revealed that an incorrect ISI value of 1.04 was being used. The correct ISI value was 1.07. One patient had been tested on 12/6/2022 using the incorrect ISI value. 3. Review of the AOC for the SOD issued 12/16/2022 revealed that the PT/INR results for patient with initials LW were originally reported as 28.6 and 2.5. Upon investigation on 12/20/2022 the laboratory found that the results were incorrectly calculated, and the correct values were 27.8 and 2.44 for PT and INR respectively. 4. When we requested a corrected report for patient LW, the laboratory submitted a copy of the report with a "CPSI addendum" that had been added to reflect these results on 2/1/2023 1400. 5. Review of the AOC for the SOD issued 12/16/2022 revealed that "once a report is archived it cannot be edited or corrected/changed. The computer system at PGH archives the reports as soon as [all the] orders are complete for an account number." 6. Review of the AOC for the SOD issued 12/16/2022 also revealed that to add verbiage as an addendum to an archived patient report, the hospital's information technology vendor, CPSI, requires the laboratory to mail a signed and notarized hard copy of the addendum to their location in Alabama, prior to issuance of the appended report. 7. The laboratory manager confirmed these findings in an interview on 2/1/2023 at approximately 2:00 PM. The laboratory performs approximately 48798 hematology tests annually.