Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D0665234	01/09/2020
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 generated as a result of the CLIA proficiency testing desk review, conducted off-site for your laboratory on 1/09/2020. 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.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on self-reporting by the laboratory manager on 12/20/2019 of the laboratory's failure to submit the proficiency testing (PT) results before the deadline to the

	American Proficiency Institute (API) PT program and PT desk review of CASPER Report 155D and the API PT evaluation report, the laboratory did not successfully participate in a proficiency testing program approved by CMS for each analyte or test in which the laboratory is certified under CLIA. The laboratory's failure to achieve an overall satisfactory proficiency testing event performance for two out of three testing events for the second testing event of 2018 with a score of 0% and the first testing event of 2019 with a score of 60% and a subsequent failure for the third testing event of 2019 with a score of 0%, resulted in unsuccessful proficiency testing performances for Blood Cell Identification. Findings include: The laboratory failed to maintain successful participation with the API PT program, shown by the subsequent unsuccessful performance for Blood Cell Identification, Refer to D2130.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on self-reporting by the laboratory manager on 12/20/2019 of the laboratory's failure to submit the proficiency testing (PT) results before the deadline to the American Proficiency Institute (API) PT program and PT desk review of CASPER Report 155D and the API PT evaluation report, the laboratory did not successfully participate in a proficiency testing program for Blood Cell Identification. The laboratory's failure to achieve an overall satisfactory proficiency testing event performance for two out of three testing events for the second testing event of 2018 with a score of 0% and the first testing event of 2019 with a score of 60% and a non-initial (subsequent) failure for the third testing event of 2019 with a score of 0% for the same test, resulted in unsuccessful proficiency testing performances. Findings include: Review of CASPER Report 155D and the API PT evaluation report revealed the laboratory failed to maintain successful participation with the API PT program, shown by subsequent unsuccessful performance for Blood Cell Identification. 1. An unsatisfactory score of 0% was obtained for Blood Cell Identification in the second PT event of 2018. 2. An unsatisfactory score of 60% was obtained for Blood Cell Identification in the first PT event of 2019, constituting the first unsuccessful PT performance (two out of three consecutive testing events). 3. An unsatisfactory score of 0% was obtained for Blood Cell Identification in the third PT event of 2019, constituting a subsequent unsuccessful PT performance.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on self-reporting by the laboratory manager on 12/20/2019 of the laboratory's failure to submit the proficiency testing (PT) results before the deadline to the American Proficiency Institute (API) PT program for hematology and coagulation and PT desk review of CASPER Report 155D and the API PT evaluation report, the

	Condition: Laboratories Performing Moderate Complexity Testing: Laboratory Director was not met. The laboratory director failed to provide overall management and direction in accordance with CFR 493.1407. Findings include: The laboratory director failed to ensure that the laboratory successfully participated in a PT program approved by CMS; as described in subpart 1 of this part for each specialty, subspecialty and analyte or test in which the laboratory is certified under CLIA. Refer to D6016.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on self-reporting by the laboratory manager on 12/20/2019 of the laboratory's failure to submit the proficiency testing (PT) results before the deadline to the American Proficiency Institute (API) PT program for hematology and coagulation and PT desk review of CASPER Report 155D and the API PT evaluation report, the laboratory director failed to ensure that PT samples were tested as required under Subpart H. Findings include: Review of CASPER Report 155D and the API PT evaluation report revealed the laboratory failed to achieve satisfactory performance for Blood Cell Identification in the second testing event of 2018 with a score of 0%, first testing event of 2019 with a score of 60%, and the third testing event of 2019 with a score of 0%, resulting in a subsequent unsuccessful PT performance.