Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0384308	10/25/2022
Name of Provider or Supplier	**Street Address, City, State**	
Palo Alto County Hospital	3201 First Street, Emmetsburg, IA	

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
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 review of proficiency testing records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 11:45 am on 10/24/2022, the laboratory failed to successfully participate in a proficiency testing program for the analyte, human chorionic gonadotropin (HCG), for two out of three consecutive testing events: 2022 testing events 1 and 3 (refer to D2107).
D2107	ENDOCRINOLOGY CFR(s): 493.843(f)

	Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 11: 45 am on 10/24/2022, the laboratory failed to achieve satisfactory performance for the analyte, human chorionic gonadotropin (HCG), for two out of three consecutive PT events for unsuccessful participation. The laboratory received unsatisfactory performance scores of 60% for 2022 testing event 1 and zero for 2022 testing event 3.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of chemistry quality control (QC) records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 2:20 pm on 10/24/2022, the laboratory failed to take and document corrective action when chemistry QC fell outside the laboratory's established criteria for acceptability for six out of 31 days of patient testing in May 2022. The findings include: 1. The laboratory performs chemistry testing on the Ortho Vitros 5600 instrument. 2. Review of chemistry QC records revealed that the laboratory had out of control results without corrective action on the following dates of testing and analytes: *05/03/22- c-reactive protein (level 1); 5 patient tests performed *05/04/22- prostate-specific antigen (level 1); 1 patient test performed *05/08/22- Iron (level 3); 1 patient test performed *05/17/22- prolactin (level 3); 2 patient tests performed *05/17/22- prostate-specific antigen (level 1); 1 patient test performed *05/19/22- ferritin (level 3); 1 patient test performed *05/31/22- free thyroxine (level 2); 2 patient tests performed 3. At the time of the survey, personnel identifier #1 confirmed that the laboratory did not have documented corrective action for the out of control QC results listed above.