Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0384308	10/30/2024
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
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's Cepheid Individual Quality Control Plan (IQCP) and quality control (QC) records and confirmed by interview with the general supervisor at 10:07 am on 10/30/2024, the laboratory failed to perform two levels of QC for one out of one lot number of multiplex vaginal panel (MVP) cartridges in May 2024. 1. On 5/11/2024 the laboratory performed testing on patient identifier A using reagent lot number 02305, expiration date 1/26/25 of MVP cartridges. 2. The laboratory's IQCP stated that the laboratory would perform a positive and negative control with each new lot number and/or shipment of Cepheid MVP cartridges. 3. At the time of the survey, the laboratory failed to have records documenting positive and negative QC for reagent lot number 02305, expiration date 1/26/25 of MVP cartridges.
D5503	BACTERIOLOGY CFR(s): 493.1261(a)(2) (a) The laboratory must check the following for positive and negative reactivity using control organisms: (a)(2) Each week of use for gram stains.

	This STANDARD is not met as evidenced by: Based on lack of gram stain quality control (QC) records and confirmed by interview with the general supervisor at 1:12 pm on 10/30/24, the laboratory failed to document weekly positive and negative gram stain controls for one out on one week of patient testing reviewed in May 2024. The findings include: 1. Patient identifier B had a urine culture with gram stain performed on 5/17/2024. 2. The general supervisor stated that the laboratory did not document weekly positive and negative gram stain QC, and that the laboratory performed gram stain QC with each wound culture work up. The general supervisor confirmed that there would be weeks when there would be no wound culture work ups. 3. At the time of the survey, the laboratory did not have documentation pf positive and negative gram stains controls being performed the week of 5/17/2024.