

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0384308	(X3) Date Survey Completed 11/28/2018
Name of Provider or Supplier Palo Alto County Hospital	Street Address, City, State 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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on review of proficiency testing records and confirmed by laboratory personnel identifier #3 (refer to the Laboratory Personnel Report) at approximately 10:00 am on 11/28/2018, the laboratory failed to enroll in an approved proficiency testing program for two out of two years from January 2017- November 2018 for the subspecialty, parasitology - Trichomonas vaginalis (molecular method). The findings include: 1. The laboratory performs Trichomonas vaginalis testing on the Cepheid GeneXpert instrument. 2. At the time of the survey, the laboratory failed to enroll in an approved proficiency testing program for subspecialty, parasitology (molecular method) in 2017 and 2018 .</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p>

This STANDARD is not met as evidenced by:
Based on review of maintenance records and confirmed by laboratory personnel identifier #3 (refer to the Laboratory Personnel Report) at approximately 10:40 am on 11/28/2018, the laboratory failed to document all monthly maintenance activities on the Cepheid GeneXpert instrument for one out of one month (May 2018) in 2018. The findings include: 1. The GeneXpert Maintenance log stated the laboratory must perform the following monthly: *archive runs *delete runs *disinfect GX surfaces *disinfect cartridge bay interior *disinfect plunger rod *dust buster 2. The laboratory documented that it had performed the "dust buster" activity on 05/01/2018, but had not documented performance of the rest of the monthly maintenance activities. 3. At the time of the survey, laboratory personnel identifier #3 confirmed that the laboratory only documented performance of the "dust buster" monthly activity for the month of May 2018.

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 Individualized Quality Control Plan (IQCP) and confirmed by laboratory personnel identifier #3 (refer to the Laboratory Personnel Report) at approximately 11:10 am on 11/28/2018, the laboratory failed to include a written quality assessment plan as part of the IQCP for the following test systems: ActimProm Rupture of Membranes (ROM) and Cardinal Health Crypto Giardia Rapid Test.