

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0387204	(X3) Date Survey Completed 09/26/2018
Name of Provider or Supplier Jefferson County Health Center	Street Address, City, State 2000 S Main Street, Fairfield, 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
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> <p>This STANDARD is not met as evidenced by:</p> <p>(A) Based on review of Cepheid GeneXpert maintenance records from January-September 2018, observations made at 9:30 AM on 09/26/2018 in the microbiology and main laboratory areas, and confirmed by laboratory personnel identifier #5 (refer to Laboratory Personnel Report) at approximately 10:55 AM on 09/26/2018, the laboratory failed to perform and document daily, weekly, monthly and quarterly maintenance on the two Cepheid GeneXpert test systems for 269 out of 269 days, 39 out of 39 weeks, 9 out of 9 months and 3 out of 3 quarters. The findings include: 1. The laboratory had two GeneXpert instruments identified as serial number (S/N) 707563 (microbiology) and S/N 816563 (main laboratory). 2. Records revealed that the laboratory documented maintenance on the GeneXpert System Maintenance Log for one of the two instruments. However, the laboratory failed to identify which instrument on the log. 3. At the time of the survey, the laboratory did not have a maintenance log with instrument identification for each of the GeneXpert systems. (B) Based on review of Microsecond WalkAway maintenance records from January-September 2018 and confirmed by the laboratory personnel identifier #5 (refer to Laboratory Personnel Report) at approximately 10:15 AM on 09/26/2018, the laboratory failed to perform and document weekly and monthly maintenance on the instrument for 21 out of 36 weeks and 5 out of 9 months (February-June). The findings include: 1. According to the MicroScan WalkAway Maintenance Checklist form, the manufacturer requires the laboratory to perform the following weekly maintenance: *Clean photodiode shield; *Clean diffuser plate; *Clean reagent adapters, gaskets and bottles; *Run database optimizer; and *Clean area around</p>

computer verifying computer fans are not blocked or covered. 2. According to the MicroScan WalkAway Maintenance Checklist form, the manufacturer requires the laboratory to perform the following monthly maintenance: *Verify RENOK dispense volume; *Restart computer; and *Clean air intake filter. 4. Records revealed that the laboratory performed the weekly maintenance during the following weeks in 2018: 1/4, 1/29, 3/5, 3/12, 3/19, 4/17, 4/24, 5/16, 5/27, 6/8, 6/22, 7/10, 8/31, 9/20 and 9/25. 5. Records revealed that the laboratory performed the monthly maintenance for the following months in 2018: January, July, August and September. 6. The laboratory personnel identifier #5 confirmed that the laboratory failed to perform and document weekly and monthly maintenance on the MicroScan WalkAway as required by the manufacturer.

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 lack of Individualized Quality Control Plan (IQCP) records, review of quality control (QC) records for 2018, and confirmed by laboratory personnel identifier #5 (refer to Laboratory Personnel Report) at approximately 1:30 PM on 09/26/2018, the laboratory failed to perform a positive and negative control each day of patient testing for the following test systems: Immunocard Stat Campy Antigen and MedTox Profile V. The findings include: 1. The laboratory performed controls with each new lot of test kits and reagents for the Immunocard Stat Campy Antigen test and MedTox Profile V urine drug screen test system. 2. Laboratory personnel identifier #5 indicated that the laboratory intended to follow manufacturer's instructions for performing QC for both test systems. 3. At the time of the survey, the laboratory did not have an IQCP for the either test system.