Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0387204	12/15/2022
Name of Provider or Supplier	**Street Address, City, State**	
Jefferson County Health Center	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	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) 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. This STANDARD is not met as evidenced by: A. Based on review of MicroScan WalkAway maintenance records and confirmed by laboratory personnel identifier #6 (refer to the Laboratory Personnel Report) at approximately 10:15 am on 12/15/2022, the laboratory failed to perform and document all daily, weekly, and monthly maintenance as defined by the manufacturer on the MicroScan WalkAway instrument for 59 out of 91 days, 13 out of 13 weeks, and three out of three months of patient testing from 09/01/2022- 11/30/2022. The findings include: 1. The laboratory implemented and began using a new Microscan WalkAway instrument in September 2022. 2. According to the MicroScan Instrument /Computer Maintenance Checklist, the manufacturer requires the laboratory to perform the following daily maintenance: *Print QC Diagnostics Report *Print Calibration Report *Perform tasks on QC Diagnostic Report *Back up LabPro Database 3. Records indicated that the laboratory did not document all daily maintenance tasks from 09/01/2022- 09/30/2022 and 11/02/2022- 11/30/2022. 4. According to the MicroScan Instrument/Computer Maintenance Checklist, the manufacturer requires the laboratory to perform the following weekly maintenance: *Clean Photodiode Shield *Clean Diffuser Plate *Verify latest LabPro Database File is on the Backup Media 5. Records indicated that the laboratory did not document all weekly maintenance tasks from 09/01/2022- 11/30/2022. 6. According to the MicroScan Instrument/Computer Maintenance Checklist, the manufacturer requires the laboratory to perform the following monthly maintenance: *Check Renok Dispense Volume *Run Database Optimizer *Restart Computer *Clean Air Intake Filter 7. Records indicated that the laboratory did not perform all monthly

	maintenance tasks from 09/01/2022- 11/30/2022. 8. At the time of the survey, personnel identifier #6 confirmed that the laboratory failed to perform and document maintenance on the MicroScan WalkAway as required by the manufacturer. B. Based on review of the Bactec FX maintenance records and confirmed by laboratory personnel identifier #6 (refer to the Laboratory Personnel Report) at approximately 10: 50 am on 12/15/2022, the laboratory failed to perform and document the monthly air filter clean/change as defined by the manufacturer on the Bactec FX blood culture instrument for 11 out of 11 months of patient testing from 01/01/2022- 11/30/2022. C. Based on review of the microbiology Cepheid GeneXpert instrument maintenance records and confirmed by laboratory personnel identifier #6 (refer to the Laboratory Personnel Report) at approximately 11:30 am on 12/15/2022, the laboratory failed to perform and document any weekly, monthly, and quarterly maintenance as defined by the manufacturer on the microbiology Cepheid GeneXpert instrument for 14 out of 49 weeks, four out of 11 months, and four out of four quarters of patient testing from 01 /01/2022- 12/10/2022. The findings include: 1. The GeneXpert System Maintenance Log indicated that the manufacturer requires the laboratory to perform the following weekly maintenance: *Power down the GeneXpert instrument *Power down the GeneXpert computer 2. Records showed that the laboratory did not perform and document any weekly maintenance during the following weeks: 01/16/22, 01/30/22, 02/13/22, 03/13/22, 04/03/22, 04/24/22, 05/15/22, 06/19/22, 07/10/22, 07/31/22, 09/25 /22, 10/16/22, 10/23/22, and 11/13/22. 3. The Cepheid GeneXpert System Maintenance Log indicated that the manufacturer requires the laboratory to perform the following monthly maintenance: *Archive tests *Purge tests *Replace fan filters 4. Records showed that the laboratory did not perform and document any monthly maintenance during the following months in 2022: January, May, July, and October. 5. The GeneXpert System Maintenance Log indicated that the manufacturer requires the laboratory to perform the following quarterly maintenance: *Clean plunger rod and cartridge bays *Clean instrument surfaces 6. Records showed that the laboratory did not perform and document any quarterly maintenance at any time between 01/01 /2022- 12/10/2022. 7. At the time of the survey, personnel identifier #6 confirmed that the laboratory failed to perform and document maintenance on the microbiology Cepheid GeneXpert as required by the manufacturer. This is a repeat deficiency cited on 09/28/2016, 09/26/2018, and 12/30/2020.
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 the Daily Quality Control (QC) procedure and coagulation QC records and confirmed by laboratory personnel identifier #1 (Refer to the Laboratory Personnel Report) at approximately 11:30 am on 12/15/2022, the laboratory failed to document corrective action when the prothrombin time QC fell outside the established range for eight out of 59 days from 10/3/2022 - 11/30/2022. The findings include: 1. The Daily QC procedure stated, "Do not release the results of analytical procedures

	unless the results of the controls are within the determined limits of procedure." 2. For lot number 564608, expiration date 12/2/2024 of prothrombin time reagent, the laboratory established the acceptable QC range as 45.3 - 54.3 seconds for the level 3 control. 3. On 10/6/2022 at 04:18, the laboratory accepted a result of 44.8 seconds for the level 3 control. 4. On 10/08/2022 at 15:29, the laboratory accepted a result of 44.2 seconds for the level 3 control. 5. On 10/09/2022 at 00:30, the laboratory accepted a result of 43.3 seconds for the level 3 control; and at 04:32, the laboratory accepted a result of 41.6 seconds. 6. On 10/10/2022 at 05:49, the laboratory accepted a result of 44.4 seconds for the level 3 control; and at 14:45, the laboratory accepted a result of 44.4 seconds for the level 3 control. 7. On 10/11/2022 at 04:08, the laboratory accepted a result of 44.8 seconds for the level 3 control. 8. On 10/13/2022 at 04:30, the laboratory accepted a result of 44.9 seconds for the level 3 control. 9. On 10/15 /2022 at 05:30, the laboratory accepted a result of 44.4 seconds for the level 3 control. 10. On 10/29/2022 at 04:36, the laboratory accepted a result of 55.3 seconds for the level 3 control. 11. On the above dates, the laboratory performed prothrombin time testing on a total of 33 patients. 12. At the time of the survey, the laboratory did not have corrective action for the out of range level 3 prothrombin time QC results.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the MicroScan WalkAway and Cepheid GeneXpert instrument maintenance logs, previous CMS-2567 Statement of Deficiencies reports, and confirmed by laboratory personnel identifier #6 (refer to the Laboratory Personnel Report) at approximately 10:15 am on 12/15/2022, the laboratory's quality assessment policy failed to include a review of the effectiveness of corrective actions taken to resolve problems related to the performance and documentation of instrument maintenance as required by the manufacturer for the Microscan WalkAway and Cepheid GeneXpert test systems. The findings include: 1. At the time of the survey on 12/15/2022, review of instrument maintenance logs indicated the laboratory did not perform and document maintenance on the MicroScan WalkAway and Cepheid GeneXpert instruments as required by the manufacturer. Refer to D5429. 2. Review of previous CMS-2567 Statement of Deficiencies reports revealed the laboratory did not perform and document maintenance as required by the manufacturer and incurred the same deficiency for the MicroScan WalkAway test system during surveys on 09/28 /2016, 09/26/2018, and 12/30/2020 and the Cepheid GeneXpert test system on 09/26 /2018. 3. The laboratory's quality assessment policy failed to include measures to effectively resolve problems related to performance and documentation of maintenance as required by the manufacturer for the MicroScan WalkAway and Cepheid GeneXpert test systems.