Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0387204	12/30/2020
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
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 10: 30 am on 12/30/2020, the laboratory failed to take and document corrective action for six unacceptable PT scores from two out of six PT testing events (2020 events 1 and 3) in 2019-2020. The findings include: 1. For 2020 testing event 1, the laboratory received unacceptable PT test scores for the following: *2020 WSLH BactiReg1- blood culture anaerobic organism identification (specimen MC-4) *2020 WSLH BactiReg1- cefepime susceptibility testing (specimen MC-5) *2020 WSLH BactiReg1- ceftazidime susceptibility testing (specimen MC-5) *2020 WSLH BactiReg1- conventional agar plates- VRE identification (specimen MR-2) 2. For 2020 testing event 3, the laboratory received unacceptable PT test scores for the following: *2020 WSLH BactiReg3- conventional agar plates- VRE identification (specimen MR-12) *2020 WSLH BactiReg3- ampicillin susceptibility testing (specimen MC-23) 3. At the time of the survey, the laboratory did not have additional documentation or corrective action for the unacceptable PT test scores.
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 from March- June 2020 and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 2:45 pm on 12/30/2020, the laboratory failed to perform and document monthly maintenance on the MicroScan WalkAway instrument for two out of four months of patient testing from March- June 2020. The findings include: 1. According to the MicroScan WalkAway Maintenance Checklist form, the manufacturer requires the laboratory perform the following monthly maintenance: *Verify RENOK dispense volume *Restart computer *Clean air intake filter 2. Records indicated that the laboratory did not perform monthly maintenance in April or May 2020. 3. At the time of the survey, personnel identifier #2 confirmed that the laboratory failed to perform and document monthly maintenance on the MicroScan WalkAway as required by the manufacturer. THIS IS A REPEAT DEFICIENCY. B. Based on review of the Ortho MTS Dispenser Instructions For Use (IFU), the laboratory's Blood Bank Dispenser Maintenance log and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 1:00 pm on 12/30/2020, the laboratory failed to perform and document weekly cleaning on the blood bank saline dispensers for 71 out of 87 weeks from 04 /29/2019- 12/29/2020. The findings include: 1. The Ortho MTS Repetitive Dispenser (0.5 or 1.0 mL) IFU stated that dispensers are to be cleaned on a weekly basis. 2. Review of the Blood Bank Dispenser Maintenance log revealed that the laboratory uses both a 0.5 mL and 1.0 mL dispenser and did not perform weekly cleaning on either for the following weeks from 04/29/2019- 12/29/20: *2019: 06/24, 07/01, 07 /08, 07/29, 08/26, 09/23, 09/30, 10/07, 10/14, 10/21, 10/28, 11/4, 11/11, 11/18, 11/25, 12/02, 12/09, 12/16, 12/23, and 12/30 *2020: 01/06, 01/13, 01/20, 01/27, 02/03, 02 /10, 02/17, 02/24, 03/03, 03/10, 03/17, 03/24, 03/31, 04/07, 04/14, 04/21, 04/28, 05 /05, 05/12, 05/19, 05/26, 06/02, 06/09, 06/16, 06/23, 06/30, 07/07, 07/14, 07/28, 08 /04, 08/11, 08/18, 08/25, 09/01, 09/08, 09/15, 09/22, 09/29, 10/06, 10/13, 10/20, 10 /27, 11/03, 11/10, 11/17, 11/24, 12/01, 12/08, 12/15, 12/22, and 12/29 3. At the time of the survey, additional MTS dispenser cleaning records were not available.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of the laboratory's Blood Bank Dispenser Maintenance log and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 1:00 pm on 12/30/2020, the laboratory failed to perform and document monthly volume checks on the blood bank saline dispensers for 16 out of 20 months from May 2019- December 2020. The findings include: 1. The laboratory's Blood Bank Dispenser Maintenance log indicated that dispenser volume checks were to be performed monthly. 2. Review of the Blood Bank Dispenser Maintenance log revealed that the laboratory uses both a 0.5 mL and 1.0 mL dispenser and did not

	perform monthly volume checks on either in August 2019 or October 2019-December 2020. 3. At the time of the survey, additional MTS dispenser volume check records were not available for the months listed above.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of calibration verification records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 4: 45 pm on 12/30/2020, the laboratory failed to perform calibration verification procedures every six months for one out of four time periods from January 2019-December 2020. The findings include: 1. The laboratory performed calibration verification in January 2019, July 2019, and January 2020 for the following analytes: urine chloride, urine glucose, urine potassium, urine sodium, urine total protein, urine creatinine, urine amylase, urine microalbumin, c-reactive protein, rheumatoid factor, high-density lipoprotein, unsaturated iron-binding capacity, glycated hemoglobin, direct bilirubin, total bilirubin, alkaline phosphatase, alanine transaminase, amylase, aspartate transaminase, creatine kinase, gamma-glutamyltransferase, lactate dehydrogenase, lipase, total protein, triglycerides, creatinine, chloride, potassium, sodium, albumin, blood urea nitrogen, calcium, total cholesterol, glucose, lactic acid, lithium, magnesium, phosphorus, ammonia, carbon dioxide, ethanol, iron, and uric acid. 2. At the time of the survey, the laboratory did not have calibration verification records for the time period between January 2020 and December 2020 for the analytes listed above.
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), review of quality control (QC) records, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 3:00 pm on 12/30/2020, the laboratory failed to perform external QC for the Cardinal Health Giardia/Cryptosporidium test system as established by the laboratory for six out of 12 months from January 2020- December 2020. The findings include: 1. The laboratory's Giardia/Cryptosporidium test system IQCP stated that two levels of external QC would be performed with each new lot number and shipment of test kits and every 30 days after controls were initially run for each lot/shipment. 2. The laboratory's Giardia /Crypto QC Log listed each month of the year and indicated QC performance at the following times: January 2020 (no testing date), February 2020 (no testing date), May 2020 (no testing date), July 2020 (no testing date), October 2020 (10/04/2020), and November 2020 (11/19/2020). 3. At the time of the survey, personnel identifier #2 confirmed that the laboratory did not have QC records for March 2020, April 2020, June 2020, August 2020, September 2020, or December 2020.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's blood bank refrigerator and freezer alarm policies and procedures, blood bank system alarm check records, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 1: 00 pm on 12/30/2020, the laboratory failed to inspect and perform quarterly alarm system checks for the blood bank refrigerator for two out of four time periods and the blood bank freezer for four out of four time periods from 01/01/2020- 12/30/2020. The findings include: 1. The laboratory's "Testing of Refrigerator Alarms" and "Testing of Plasma Freezer Alarm" policies stated that the alarms on the blood storage refrigerator and plasma freezer would be checked quarterly. 2. The laboratory performed blood bank refrigerator alarm checks on 01/15/2020 and 07/22/2020. 3. The laboratory did not have refrigerator alarm check records for the time periods between 01/15/2020 and 07/22/2020 or 07/22/2020 and 12/30/2020. 4. Personnel identifier #2 confirmed that the laboratory did not perform blood bank freezer alarm checks at any time between 01/01/2020 and 12/30/2020. 5. At the time of the survey, the laboratory did not have additional blood bank refrigerator and freezer alarm system check records for the time periods listed above.

D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of personnel records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 10:00 am on 12/30/2020, the technical consultant failed to assess and document the competency of individuals performing moderate complexity testing at least annually for four out of four clinic testing personnel (personnel identifiers #12, #13, #14, and #15) in 2019.
D6055	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of personnel records, performance specification records, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 3:30 pm on 12/30/2020, the technical consultant failed to document training for the Diesse Mini-Cube and Roche Cobas e411 test systems prior to reporting patient test results for nine out of nine testing personnel (laboratory personnel identifiers #3, #4, #5, #6, #7, #8, #9, #10, and #11). The findings include: 1. The laboratory began using the Diesse Mini-Cube and Roche Cobas e411 instruments since the last survey on 09/26/2018. 2. At the time of the survey, the laboratory did not have Diesse Mini-Cube or Roche Cobas e411 test system training records for testing personnel identifiers #3, #4, #5, #6, #7, #8, #9, #10, or #11.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of personnel records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 10:00 am on 12/30/2020, the technical supervisor failed to assess and document the competency of

	individuals performing high complexity testing at least annually for nine out of nine laboratory testing personnel (personnel identifiers #3, #4, #5, #6, #7, #8, #9, #10, and #11) in 2019.