Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0686757	01/29/2021
Name of Provider or Supplier	**Street Address, City, State**	
Ringgold County Hospital	504 N Cleveland Street, Mount Ayr, 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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the Laboratory Test List & Annual Volume form, proficiency testing (PT) records and confirmed by laboratory personnel identifier #8 (refer to the Laboratory Personnel Report) at approximately 8:15 am on 01/29/2021, the laboratory failed to verify the accuracy of testing at least twice annually for two out of two time periods from January 2020- December 2020 for the following analytes: erythrocyte sedimentation rate (ESR), 25- hydroxy vitamin D, urine sediment examination, direct antiglobulin test (DAT), and procalcitonin. The findings include: 1. The Laboratory Test List & Annual Volume form listed the following testing: ESR, 25- hydroxy vitamin D, urine sediment examination, DAT, and procalcitonin. 2. Personnel identifier #8 confirmed that the laboratory did not enroll in PT for ESR, 25- hydroxy vitamin D, urine sediment examination, DAT, and procalcitonin testing. 3. At the time of the survey, personnel identifier #8 confirmed that the laboratory did not have additional records indicating the verification of accuracy of the testing listed above from January 2020- January 2021.
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 Sysmex XS-1000i hematology analyzer maintenance records and confirmed by laboratory personnel identifier #8 (refer to the Laboratory Personnel Report) at approximately 12:45 pm on 01/29/2021, the laboratory failed to document monthly maintenance as defined by the manufacturer for 7 out of 10 months of patient testing from 01/2020- 12/2020. The findings include: 1. The Sysmex XS-1000i maintenance log indicated that the following task is to be performed and documented monthly: Perform Monthly Rinse (1,200 cycles). 2. Review of XS-1000i maintenance logs from 2020 revealed that the laboratory did not document monthly maintenance in 02/2020, 03/2020, 04/2020, 06/2020, 08/2020, 09/2020, or 11/2020. 3. At the time of the survey, personnel identifier #8 confirmed that the laboratory did not perform and document monthly maintenance as required by the manufacturer for the months listed above. B. Based on review of Sysmex CA-660 coagulation analyzer maintenance records and confirmed by laboratory personnel identifier #8 (refer to the Laboratory Personnel Report) at approximately 2:00 pm on 01/29/2021, the laboratory failed to document instrument maintenance as define by the manufacturer for four out of four quarters and one out of one year in 2020. The findings include: 1. The Sysmex CA-660 maintenance log indicated the following tasks are to be performed on a quarterly basis: * Clean diH2O Rinse Bottle w/alcohol * Perform LED Calibration * Clean filters under front of analyzer 2. Review of maintenance logs for 2020 revealed that the laboratory did not document the following quarterly maintenance: * 1st quarter 2020: clean diH2O Rinse Bottle w/alcohol and clean filters under front of analyzer * 2nd quarter 2020: perform LED calibration and clean filters under front of analyzer * 3rd quarter 2020: clean filters under front of analyzer * 4th quarter 2020: clean filters under front of analyzer 3. The Sysmex CA-660 maintenance log indicated that the following is to be performed yearly: Replace Rinse Filter/ Rinse and Prepare. 4. Review of maintenance logs for 2020 revealed that the laboratory did not document yearly maintenance in 2020. 5. At the time of the survey, personnel identifier #8 confirmed that the laboratory did not perform and document quarterly and yearly maintenance as defined by the manufacturer. C. Based on review of Dimension EXL chemistry analyzer maintenance records and confirmed by laboratory personnel identifier #8 (refer to the Laboratory Personnel Report) at approximately 9:15 am on 01/29/2021, the laboratory failed to document instrument maintenance as define by the manufacturer for 31 out of 53 weeks and 9 out of 12 months of patient testing from 01/2020- 12/2020. The findings include: 1. The laboratory uses two Siemens Dimension EXL chemistry analyzers with serial numbers DE271743 and DE271701. The laboratory documented each instrument's maintenance on separate log sheets. 2. The EXL maintenance logs indicated that the following tasks are to be performed weekly: * Clean outside of R2 probe * Clean outside of HM wash probes 3. Review of the EXL maintenance records from 2020 revealed that the laboratory did not document each instrument's weekly maintenance for the following weeks: * DE271743- 01/19, 01/26, 02/09, 03/01, 03/08, 03/15, 04/05, 04/26, 05/03, 05/17, 06 /14, 06/21, 06/28, 07/05, 07/19, 08/02, 08/16, 08/30, 09/20, 09/27, 10/11, 10/25, 11 /01, 11/08, 11/22, 11/29, 12/06, 12/20, and 12/27. * DE271701- 01/19, 01/26, 02/09, 03/01, 03/08, 03/15, 04/05, 04/26, 05/03, 05/17, 5/31, 06/14, 06/21, 06/28, 07/05, 07 /19, 08/02, 08/16, 08/30, 09/20, 09/27, 10/11, 10/25, 11/01, 11/08, 11/22, 11/29, 12 /06, 12/13, 12/20, and 12/27. 4. The EXL maintenance logs indicated that the following tasks are to be performed monthly: * Replace IMT pump tubing * Clean IMT System * Replace/clean air filters * Stylette HM wash probes * Replace HM pump heads * Clean R2 drains * Clean R Drain 5. Review of the EXL maintenance records from 2020 revealed that the laboratory did not document all of the monthly maintenance tasks for each instrument in the following months: * DE271743- 01 /2020, 03/2020, 04/2020, 05/2020, 07/2020, 10/2020, and 12/2020. * DE271701- 01

	/2020, 03/2020, 04/2020, 05/2020, 07/2020, 09/2020, 11/2020, and 12/2020. 6. At the time of the survey, personnel identifier #8 confirmed that the laboratory did not perform and document weekly and monthly maintenance as defined by the manufacturer.
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 Sysmex CA-660 calibration records, lack of calibration verification records and confirmed by laboratory personnel identifier #8 (refer to the Laboratory Personnel Report) at approximately 2:00 pm on 01/29/2021, the laboratory failed to perform and document calibration verification every six months on the Sysmex CA-660 test system for the analyte, D-dimer, for three out of four times from 06/01/2019- 12/31/2020. The findings include: 1. The laboratory performed calibrations on each new lot of Innovance D-dimer reagent using 6 levels of calibrator in 06/2019, 04/2020, and 12/2020. 2. At the time of the survey, the laboratory did not have additional calibration or calibration verification records for the time periods of 12 /2019 and 06/2020.
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, and confirmed by laboratory personnel identifier #8 (refer to the Laboratory Personnel Report) at approximately 12:20 pm on 01/29/2021, the laboratory failed to perform two levels of QC each day of patient testing for the BD Affirm test system. The findings include: 1. The laboratory installed and began using the BD Affirm test system in November 2018. 2. The laboratory performed QC with each new lot and shipment of test kits. 3. Laboratory personnel identifier #8 indicated that the laboratory intended to follow manufacturer's instructions for performing QC. 4. At the time of the survey, the laboratory did not have an IQCP for the BD Affirm test system.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of patient test records, quality control (QC) records, Vidas 3 instrument printouts, and confirmed by laboratory personnel identifier #8 at approximately 4:00 pm on 01/29/2021, the laboratory failed to perform two levels of QC each day of patient testing for one out of one day of patient testing (06/02/2020) in June 2020. The findings include: 1. Patient A had procalcitonin testing performed on 06/02/2020. 2. According to the Vidas 3 instrument printout for Patient A, testing completed at 7:17 pm on 06/02/2020. 3. The Vidas 3 instrument QC printout indicated that the last controls performed prior to testing on Patient A were performed and completed at 6:50 am on 06/01/2020. 4. At the time of the survey, personnel identifier #8 confirmed that the laboratory did not have additional QC records for 06/02/2020.
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: A. Based on review of the laboratory's blood bank policies, blood bank system alarm check records, and confirmed by laboratory personnel identifier #8 (refer to the Laboratory Personnel Report) at approximately 1:00 pm on 01/29/2021, the laboratory failed to inspect and perform quarterly alarm system checks for the blood bank refrigerator and freezer for seven out of eight time periods from 01/01/2019- 12/31 /2020. The findings include: 1. The laboratory's "Blood Bank Quality Control" policy

	stated that the alarms on the blood bank refrigerator and freezer would be checked quarterly. 2. The laboratory had an outside biomedical engineering company perform a blood bank freezer alarm check on 07/29/2020 and a blood bank refrigerator alarm check on 08/06/2020. 3. At the time of the survey, personnel identifier #8 confirmed that the laboratory did not have any additional blood bank refrigerator or freezer alarm system check records from 01/01/2019- 12/31/2020. B. Based on review of the laboratory's blood bank policies, blood bank temperature records and charts, and confirmed by laboratory personnel identifier #8 (refer to the Laboratory Personnel Report) at approximately 1:00 pm on 01/29/2021, the laboratory failed to document the high and low activation temperatures and nurse response notes as part of the alarm system inspection for one out of one time period from 07/01/2020 to 08/31/2020. The findings include: 1. The laboratory's "Blood Bank Quality Control" policy stated that the blood bank refrigerator and freezer alarm systems would be checked on a quarterly basis. It also stated that the high and low activation temperatures would be documented as well as information regarding response from the nurse's station. 2. The laboratory's "Alarm Record" policy stated that the results of the alarm checks would be noted on the Blood Bank Refrigerator/Freezer Log. 3. The laboratory had an outside biomedical engineering company perform a blood bank freezer alarm check on 07/29/2020 and a blood bank refrigerator alarm check on 08/06/2020. 4. Review of the biomedical engineering work order reports showed no records of high and low activation temperatures or nurse response notes for either the refrigerator or freezer alarm checks. 3. Review of the recording chart wheels from the dates listed above also did not indicate at what temperature the high and low alarm activation occurred nor at what time the nursing station responded to the alarm. 4. At the time of the survey, personnel identifier #8 confirmed that the laboratory did not have blood bank alarm check records documented on the Blood Bank Refrigerator/Freezer Log for the dates listed above.