Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0384646	09/15/2022
Name of Provider or Supplier	**Street Address, City, State**	
Buchanan County Health Center	1600 First Street East, Independence, 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
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). 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 9: 40 am on 09/15/2022, the laboratory failed to perform a self evaluation when the laboratory received seven ungraded PT scores from three out of five PT testing events from 01/01/2021- 09/15/2022. The findings include: 1. For 2021 testing event 3, the laboratory received ungraded PT test scores for the following: *2021 Immunology /Immunohematology 3rd event: c-reactive protein (CRP) (specimen CRP-06) and direct antiglobulin test (DAT) (specimen DAT-06) 2. For 2022 testing event 1, the laboratory received ungraded PT test scores for the following: *2022 Microbiology 1st event: gram stain (specimen GS-05) *2022 Core Chemistry 1st event: total iron-binding capacity (TIBC) (specimens CH-02, CH-04, and CH-05) 3. For 2022 testing event 2, the laboratory received ungraded PT test scores for the following: *2022 Hematology/Coagulation 2nd event: vaginal wet prep (specimen VA-02) 4. At the time of the survey, the laboratory did not have additional documentation or corrective action for the ungraded PT test scores. This is a repeat deficiency cited on 10/23/2020.
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 proficiency testing records, the Laboratory Test List & Annual Volume form, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 9:40 am on 09/15/2022, the laboratory failed to verify the accuracy of serum human chorionic gonadotropin (HCG) qualitative testing at least twice annually for two out of three time periods from 01/01 /2021 - 09/15/2022. The findings include: 1. Personnel identifier #2 confirmed that the laboratory performs serum HCG qualitative testing with the Cardinal Health HCG Combo Rapid kit test. 2. The laboratory verified the accuracy of serum HCG qualitative testing in 06/2021 with samples from the American Proficiency Institute Serum HCG verification program. 3. At the time of the survey, personnel identifier #2 confirmed that the laboratory did not have additional accuracy verification records for serum HCG qualitative testing.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of ACL Top 350 coagulation reagent verification records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 11:40 am on 09/15/2022, the laboratory failed to verify the manual calculation of the international normalized ratio (INR) and perform patient platelet-poor plasma studies for one out of one lot number of prothrombin time reagent (lot number N1209131, expiration 12/2022). The findings include: 1. The laboratory began using prothrombin time reagent lot number N1209131 (expiration 12 /2022) on 06/05/2021. 2. At the time of the survey, the laboratory did not have documentation of a manual check of the INR calculation from the instrument or patient platelet-poor plasma studies for prothrombin reagent lot number N1209131.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of function check records, review of the i-STAT operator's guide, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 5:50 pm on 09/15/2022, the laboratory failed to perform and document thermal probe function checks on the i-STAT analyzer every six months for one out of three time periods from 02/01/2021- 09/15/2021. The findings include: 1.

	The i-STAT operator's guide stated that a thermal probe check must be performed every six months. 2. Review of the laboratory's i-STAT logs indicated that the laboratory performed thermal probe checks on 02/21/2021 and 11/01/2021. 3. At the time of the survey, the laboratory did not have thermal probe function check records for the time period between 02/21/2021 and 11/01/2021 or the time period between 11 /01/2021 and 09/15/2021.
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: A. Based on review of the laboratory's policy and procedure manual, pipette function check records, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 1:50 pm on 09/15/2022, the laboratory failed to define a function check protocol for pipettes, including the frequency for performing function checks. In addition, the laboratory failed to perform and document pipette function checks for four out of five pipettes from 01/01/2020- 09/15 /2022. The findings include: 1. The laboratory performed pipette function checks in 11 /2019 for the following pipettes: Ovation variable 100-1000 uL (serial number 127904), ID Tipmaster 12.5, 25, 50 uL, Sartorius ABO-M variable 10-300 uL, and Ovation variable 10-100 uL (serial number 128157). 2. At the time of the survey, the laboratory did not have a policy for performing function checks on pipettes. In addition, the laboratory had not performed or documented function checks on the pipettes listed above from 01/01/2020- 09/15/2022. B. Based on review of the laboratory's policy and procedure manual, centrifuge function check records, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 1:50 pm on 09/15/2022, the laboratory failed to perform and document quarterly centrifuge function checks, including revolutions per minute (RPM) and timer checks, on centrifuges used in immunohematology for three out of seven time periods from 01/01/2021- 09/15/2022 and on two out of two non-immunohematology centrifuges for seven out of seven time periods from 01/01/2021-09/15/2022. The findings include: 1. The laboratory's centrifuge check policy stated that the laboratory is to perform quarterly check on all centrifuges. 2. Review of the laboratory's "Blood Bank Quarterly Centrifuge RPM & Timer Check" log indicated that the laboratory performed immunohematology centrifuge speed and timer checks on 03/14/2021, 06/29/2021, 08/17/2021, and 12/19/2021 for the following centrifuges: Sero-Fuge 2002, Ortho Workstation (serial # 51000561), and Unico Variable Speed Rotator. 3. At the time of the survey, the laboratory did not have documentation of quarterly immunohematology centrifuge speed and timer checks performed between 01/01/2022- 09/15/2022 4. The laboratory also uses the following non-immunohematology centrifuges: Sorvall ST16 (serial # 40993744) and StatSpin Express 4 (serial number 2101M51007746). 5. At the time of the survey, the laboratory did not have documentation of quarterly non-immunohematology

	centrifuge speed and timer checks performed between 01/01/2021- 09/15/2022. This is a repeat deficiency cited on 10/23/2020.
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 lack of Vitros XT 7600 calibration verification records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 3:50 pm on 09/15/2022, the laboratory failed to perform calibration verification every six months for two out of two time periods from 04/01/2021- 04/30 /2022 for the Vitros XT 7600 test system. The findings include: 1. The laboratory implemented and began using the Vitros XT 7600 for patient testing in April 2021. 2. At the time of the survey, personnel identifier #2 confirmed that the laboratory did not have calibration verification records for the time period between 04/01/2021 and 10/31 /2021 or the time period between 10/31/2021 and 04/30/2022. This is a repeat deficiency cited on 10/23/2020.
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 #2 (refer to the Laboratory Personnel Report) at approximately 5:30 pm on 09/15/2022, the laboratory failed to perform a positive and negative control each day of patient testing for the Quik Chek Complete Clostridium difficile test system. The findings include: 1. The laboratory performed controls with each new lot and shipment of test kits for the Quik Chek Complete Clostridium difficile test system. 2. Laboratory personnel identifier #2 indicated that the laboratory intended to follow the manufacturer's instructions for performing QC. 3. At the time of the survey, the laboratory did not have an IQCP for the Quik Chek Complete Clostridium difficile test system. This is a repeat deficiency cited on 10/23/2020.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: A. Based on review of the Laboratory Test List & Annual Volume form, proficiency testing records, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 5:20 pm on 09/15/2022, the laboratory failed to perform and document comparison activities for serum human chorionic gonadotropin (HCG) testing performed by two methods twice annually for two out of three time periods from 01/01/2021 - 09/15/2022. The findings include: 1. The Laboratory Test List & Annual Volume form listed serum HCG testing performed by both quantitative and qualitative methods. 2. The laboratory performed comparison activities for quantitative and qualitative serum HCG methods in 06/2021 with samples from the American Proficiency Institute Serum HCG verification program. 3. At the time of the survey, personnel identifier #2 confirmed that the laboratory did not have additional documentation of comparison activities for quantitative and qualitative serum HCG testing. B. Based on review of the Laboratory Test List & Annual Volume form, lack of comparison activity records, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 3:50 pm on 09/15/2022, the laboratory failed to document comparison activities twice annually between the Vitros XT 7600 and i-STAT analyzers for the analytes: sodium, potassium, chloride, carbon dioxide, glucose, blood urea nitrogen, creatinine, and troponin for three out of three time periods from 04/01/2021 - 09/15 /2022. The findings include: 1. The laboratory implemented and began using the Vitros XT 7600 for patient testing in April 2021. 2. The Laboratory Test List & Annual Volume form listed the laboratory as performing sodium, potassium, chloride, carbon dioxide, glucose, blood urea nitrogen, creatinine, and troponin testing on both the Vitros XT 7600 and i-STAT analyzers. 3. At the time of the survey, the laboratory did not have documentation of comparison studies performed between the Vitros XT 7600 and i-STAT analyzers from 04/01/2021 - 09/15/2022. C. Based on review of the Laboratory Test List & Annual Volume form, lack of comparison activity records, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 1:20 pm on 09/15/2022, the laboratory failed to perform and document comparison activities twice annually between the Radiometer ABL 90 and i-

	STAT analyzers for the analytes: partial pressure of oxygen (PO2), partial pressure of carbon dioxide (PCO2), and pH for three out of three time periods from 01/01/2021 - 09/15/2022. The findings include: 1. The Laboratory Test List & Annual Volume form listed the laboratory as performing PO2, PCO2, and pH testing on both the Radiometer ABL 90 and i-STAT analyzers. 2. At the time of the survey, personnel identifier #2 confirmed that the laboratory did not perform and document comparison studies between the Radiometer ABL 90 and i-STAT analyzers from 01/01/2021 - 09 /15/2022.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. 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 9: 40 am on 09/15/2022, the laboratory director failed to ensure that the laboratory followed an approved corrective action plan when it received 23 unacceptable PT scores from four out of five PT testing events from 01/01/2021- 09/15/2022. The findings include: 1. For 2021 testing event 1, the laboratory received unacceptable PT test scores for the following: *2021 Miscellaneous Chemistry 1st event- urine creatinine (specimen UC-02); urine microalbumin (Specimen UC-02); and urine total protein (specimen UC-02) *2021 Immunology/Immunohematology 1st event- direct antiglobulin test (DAT) (specimens DAT-01 and DAT-02) 2. For 2021 testing event 2, the laboratory received unacceptable PT scores for the following: *2021 Core Chemistry 2nd event- lipase (specimen CH-10); neonatal total bilirubin (specimen NB-07); and partial pressure of oxygen (PO2) (specimen BG-06) 3. For 2021 testing event 3, the laboratory received unacceptable PT scores for the following: *2021 Immunology/Immunohematology 3rd event- c-reactive protein (CRP) (specimen CRP-05) 4. For 2022 testing event 1, the laboratory received unacceptable PT test scores for the following: *2022 Miscellaneous Chemistry 1st event- urine creatinine (specimen UC-02) *2022 Core Chemistry 1st event- alanine transaminase (ALT) (specimen CH-03); chloride (specimen CH-03); aspartate aminotransferase (AST) (specimen CH-03); carbon dioxide (specimen CH-02); gamma glutamyl transferase (GGT) (specimen CH-03); lipase (specimen CH-02); and neonatal total bilirubin (specimens NB-01 and NB-02) *2022 Hematology/Coagulation 1st event- blood cell identification (specimen BCI-04) and mean corpuscular hemoglobin (MCH) (specimen XE-05) *2022 Microbiology 1st event- molecular bacti-GI (specimen GIP-05); molecular toxin- GI (specimen GIP-05); and gram stain (specimen GS-04) 5. At the time of the survey, the laboratory did not have additional documentation or corrective action for the unacceptable PT test scores listed above. This is a repeat deficiency cited on 10/23/2020.