Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0384646	10/23/2020
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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 10: 40 am on 10/23/2020, the laboratory director failed to attest to the routine integration of PT samples into the patient workload for three out of six proficiency testing events (2020 events 1, 2 and 3) from 1/1/2019 - 10/23/2020. The findings include: 1. For 2020 event 1, the laboratory director did not sign the core chemistry, hematology /coagulation, and immunology/immunohematology PT attestation statements. 2. For 2020 event 2, the laboratory director did not sign the core chemistry, hematology /coagulation, immunology/immunohematology and microbiology PT attestation statements. 3. For 2020 event 3, the laboratory director did not sign the core chemistry and microbiology attestation statements.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the media Individual Quality Control Plan (IQCP) and blood

	culture quality control (QC) certificates and confirmed by laboratory personnel identifier #3 (refer to the Laboratory Personnel Report) at approximately 2:00 pm on 10/23/2020, the laboratory failed to retain the blood culture media QC certificates for three out of three lot numbers for blood culture media from October 2020. The findings include: 1. The IQCP plan indicated the laboratory would retain the manufacturer's QC certificates as documentation of blood culture media QC. 2. At the time of the survey, the laboratory did not retain the manufacturer's QC certificates for the following lot numbers of blood culture media: BD Bactec Plus Aerobic/F lot number 0093309, expiration date 1/31/2021; BD Bactec Lytic/10/Anaerobic/F lot number 0133703; expiration date 2/28/2021, and BD Bactec Peds Plus/F lot number 0133695, expiration date 2/28/2021.
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 #1 (refer to Laboratory Personnel Report) at approximately 10:40 am on 10/23/20, the laboratory failed to perform a self evaluation of ungraded PT scores for five out of five PT testing events (2019 events 1, 2, and 3 and 2020 events 1 and 2) from 1/1/2019 - 10/23/2020. The findings include: 1. For 2019 testing event 1, the laboratory received an ungraded PT score for urine drug screen specimen UDS-01. 2. For 2019 testing event 2, the laboratory received ungraded PT scores for urine sediment specimen US-02 and wet mount preparation specimen VKP-01. 3. For 2019 testing event 3, the laboratory received an ungraded PT score for molecular virology /respiratory panel specimen RSP-12. 4. For 2020 testing event 1, the laboratory received ungraded PT scores for molecular virology/respiratory panel specimen RSP-03 and fecal leukocyte specimen FW-01. 5. For 2020 testing event 2, the laboratory received an ungraded PT score for molecular virology/respiratory panel specimen RSP-10. 4. At the time of the survey, the laboratory did not document a self evaluation for the ungraded PT scores.
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 lack of centrifuge speed and timer check records, review of laboratory procedures and confirmed by laboratory personnel identifier #1 (refer to Laboratory Personnel Report) at approximately 1:40 pm on 10/23/2020, the laboratory failed to document annual centrifuge function checks, including revolutions per minute (RPM) and timer checks for two out of two years from 1/1/2019 - 10/23/2020. The findings include: 1. Laboratory procedures indicated that centrifuge speed and timer checks will be performed annually. 2. The laboratory documented the centrifuge speed and timer checks from 2019 and 2020 had accidentally been discarded. 3. At the time of the survey, the laboratory did not have documentation of centrifuge speed and timer checks from 2019 and 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 review of calibration verification records and confirmed by laboratory personnel identifier #3 (refer to Laboratory Personnel Report) at approximately 1:50 pm on 10/23/2020, the laboratory failed to perform calibration verification procedures every six months for one out of four time periods for the analytes sodium, potassium, chloride and glycated hemoglobin from 1/1/2019 - 10/23/2020. The findings include: 1. The laboratory performed calibration verification procedures for the analytes sodium, potassium, chloride and glycated hemoglobin on 4/19/2019, 12/12/2019 and 10/23/2020. 2. At the time of the survey, the laboratory did not have calibration verification records for the time period between 12/12/2019 and 10/23/2020. *This is a repeat deficiency from the previous survey.
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 laboratory Individualized Quality Control Plans (IQCP) and i-STAT quality control (QC) records, and confirmed by laboratory personnel identifier #1 (refer to Laboratory Personnel Report) at approximately 1:50 pm on 10/23/2020, the laboratory failed to perform two levels of QC each day of patient testing for the i-STAT test system (chem8+ and troponin cartridges) from 1/1/2019 - 10/23/2020. The findings include: 1. The laboratory followed manufacturer's instructions and performed QC with each new lot and/or shipment of chem8+ and troponin test cartridges. 2. At the time of the survey, the laboratory did not have an IQCP for the i-STAT test system allowing for less frequent QC.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 10:40 am on 10/23/20, the laboratory director failed to ensure all PT results are reviewed by the appropriate staff to evaluate the laboratory's performance and identify problems that require corrective action for four out five of proficiency testing events (2019 events 2 and 3 and 2020 events 1 and 2) from 1/1/2019 - 10/23/2020. The findings include: 1. The laboratory director and/or designee did not evaluate the PT results for 2019 events 2 and 3 and 2020 events 1 and 2. 2. The laboratory did not document corrective action for the unacceptable PT scores. Refer to D6092.
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 identifier #1 (refer to the Laboratory Personnel Report) at approximately 10:40 am on 10/23/2020, the laboratory director failed to ensure the laboratory documented corrective action when they received unacceptable PT scores for four out of five proficiency testing events (2019 events 2 and 3 and 2020 events 1 and 2) from 1/1 /2019 - 10/23/2020. The findings include: 1. For 2019 event 2, the laboratory received the following unacceptable PT scores: *60% low density lipoprotein *80% relative percent basophil *80% red blood cell distribution width *80% relative percent

	eosinophil *80% relative percent lymphocyte *80% relative percent neutrophil 2. For 2012 event 3, the laboratory received the following unacceptable PT scores: *80% myoglobin *80% low density lipoprotein *60% total iron binding capacity *50% Clostridium difficile antigen *50% Clostridium difficile toxin *80% gram stain *80% molecular virology/respiratory panel *80% manual blood cell identification *50% body fluid cell count *80% partial thromboplastin time *50% urine sediment *50% direct antiglobulin test *80% carbon dioxide (arterial blood gas) *80% pH (arterial blood gas) *80% pO2 (arterial blood gas) 3. For 2020 event 1, the laboratory received the following unacceptable PT scores: *80% D-dimer *40% myoglobin *80% low density lipoprotein *80% gram stain morphology *zero direct antiglobulin test 4. For 2020 event 2, the laboratory received the following unacceptable PT scores: *60% low density lipoprotein *80% phosphorus *80% total iron binding capacity *60% human chorionic gonadotropin (quantitative) *60% gram stain *80% gram stain morphology *20% partial thromboplastin time *20% prothrombin time *20% relative percent basophil *20% relative percent eosinophil *20% absolute immature granulocyte count *20% relative percent immature granulocyte *80% relative percent lymphocyte *80% relative percent monocyte *20% relative percent neutrophil 5. At the time of the survey, the laboratory did not have corrective action for the unacceptable PT scores.
D6127	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 semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the Laboratory Personnel Report (Form CMS-209), personnel training and competency records and confirmed by laboratory personnel identifier #1 (refer to Laboratory Personnel Report) at approximately 10:00 am on 10/23/20, the technical supervisor failed to assess the competency of individuals performing high complexity testing at least semiannually during the first year the individual tests patient specimens for one out of two testing personnel (laboratory personnel identifier #2). The findings include: 1. Laboratory personnel identifier #2 began performing patient testing on 11/14/2019. 2. At the time of the survey, the laboratory did not have a semiannually competency evaluation for laboratory personnel identifier #2.