Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0385122	11/13/2019
Name of Provider or Supplier	**Street Address, City, State**	
Burgess Health Center	1600 Diamond Street, Onawa, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of proficiency testing records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 11:00 am on 11/13/2019, the laboratory failed to enroll in an approved proficiency testing program for the subspecialty, bacteriology (Clostridium difficile) in 2019. The findings include: 1. The laboratory began performing Clostridium difficile testing with the Alere C Diff Quik Chek Complete test system in November 2018. 2. At the time of the survey, the laboratory failed to enroll in an approved proficiency testing program for the subspecialty, bacteriology (Clostridium difficile) in 2019.
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 Sysmex CA-600 coagulation test system records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 3:45 pm on 11/13/2019, the laboratory failed to verify the manual calculation of the international normalized ratio (INR) for one out of one lot number of thromboplastin (549729, expiration 02/01/2021). The findings include: 1. At the time of the survey, the laboratory had in use thromboplastin lot number 549729 (expiration 02/01/2021). 2. The coagulation reagent verification records for thromboplastin lot number 549729 did not include verification of the accuracy of the INR calculation from the instrument. 3. Personnel identifier #1 confirmed that the laboratory did not verify the accuracy of the INR calculation from the instrument.
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 Siemens Dimension calibration verification records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 3:00 pm on 11/13/2019, the laboratory failed to perform and document calibration verification procedures every six months on the Siemens Dimension EXL 200 for one out of two time periods from January 2019- November 2019 for the following analytes: sodium, potassium, and chloride. The findings include: 1. The laboratory performed calibration verification on the analytes, sodium, potassium, and chloride in January 2019. 2. At the time of the survey, personnel identifier #1 confirmed that the laboratory did not have calibration verification records for the analytes, sodium, potassium, and chloride for the time period between July 2019 and November 2019.
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 #1 (refer to the Laboratory Personnel Report) at approximately 1:00 pm on 11/13/2019, the laboratory failed to perform a positive and negative control each day of patient testing for the Legionella Binax NOW Urinary Antigen Card test system. The findings include: 1. The laboratory performed controls with each new lot number and shipment of kits and monthly. 2. Laboratory personnel identifier #1 indicated that the laboratory intended to follow manufacturer's instructions for performing QC. 5. At the time of the survey, the laboratory did not have an IQCP for the Legionella Binax NOW Urinary Antigen Card test system.
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 of the laboratory's commercially prepared media quality control (QC) policy, mannitol salt QC records, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 1:30 pm on 11/13/2019, the laboratory failed to take and document corrective action when mannitol salt media QC failed to meet the laboratory's established criteria for two out of two lot numbers of media in July 2019. The findings include: 1. The laboratory's "Quality Control for Commercially Prepared Media/Microbiology" policy states: "Mannitol Salt Agar is tested with Staphylococcus aureus (ATCC 25924) produce yellow colonies, Staphylococcus epidermidis (ATCC 12229) produce red colonies and Proteus mirabilis (ATCC 12455) will have no growth." 2. The laboratory set up QC for mannitol salt lot number 550957 (no expiration date recorded) on 07/24/2019 using the following organisms: Staphylococcus aureus (ATCC 29213), Staphylococcus epidermidis (ATCC 12228) and Proteus mirabilis (ATCC 12453). 3. The laboratory documented the following QC results for lot number 550957 on 07/25 /2019: Staphylococcus aureus (ATCC 29213) produced yellow colonies, Staphylococcus epidermidis (ATCC 12228) produced red colonies and Proteus mirabilis (ATCC 12453) produced red colonies. 4. The laboratory set up QC for mannitol salt lot number 607741 (no expiration date recorded) on 07/25/2019 using

	the following organisms: Staphylococcus aureus (ATCC 29213), Staphylococcus epidermidis (ATCC 12228) and Proteus mirabilis (ATCC 12453). 5. The laboratory documented the following QC results for lot number 607741 on 07/26/2019: Staphylococcus aureus (ATCC 29213) produced yellow colonies, Staphylococcus epidermidis (ATCC 12228) produced red colonies and Proteus mirabilis (ATCC 12453) produced red colonies. 6. At the time of the survey, the laboratory did not have documentation that it used the QC organisms established in the "Quality Control for Commercially Prepared Media/Microbiology" policy. In addition, personnel identifier #1 confirmed that the laboratory did not take or document corrective action when QC failed to meet the laboratory's established criteria.
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 #1 (refer to the Laboratory Personnel Report) at approximately 8:45 am on 11/13/2019, the technical supervisor failed to assess and document the competency of individuals performing high complexity testing at least annually for one out of eight testing personnel (laboratory personnel identifier #1) in 2017 and 2018.