Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0384646	06/20/2018
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
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based upon review of immunohematology proficiency testing records from 2016-2018 and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 2:40 pm on 06/20/2018, the laboratory failed to identify the problem and take effective corrective action for the unsatisfactory proficiency testing score received for compatibility testing for 2016 event 2. The findings include: 1. The laboratory received a score of 80% for compatibility testing for 2016 event 2. The laboratory tested and reported sample AB-6 as "compatible" when the correct result was "Not compatible". [Note: The Wisconsin State Hygienic Laboratory referees were 100 percent consensus and the participants were 90.54 percent consensus.] 2. The laboratory documented corrected action for this event as "Retested and got a result of Compatible". The laboratory did not take any additional corrective action.
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 the Seimens Dimension chemistry analyzer calibration verification records from 2016-2018 and confirmed by laboratory personnel identifier #2 (refer to Laboratory Personnel Report) at approximately 2:10 pm on 06/20/2018, the laboratory failed to perform calibration verification every six months for four out of four time periods for the following analytes: sodium, potassium and chloride. The findings include: 1. Records revealed that the laboratory performed calibration verification in February 2016 for the analytes: sodium, potassium and chloride. 2. At the time of the survey, the laboratory did not have calibration verification records for the three analytes between February 2016 and the survey date of 06/20/2018.