Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0038924	06/19/2018
Name of Provider or Supplier	**Street Address, City, State**	
Henry County Health Center Inc	407 South White Street, Mount Pleasant, 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
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 calibration verification records and confirmed by laboratory personnel identifier #2 (refer to Laboratory Personnel Report) at approximately 12:30 pm on 06/19/2018, the laboratory failed to perform calibration verification every six months for two out of three time periods for the analytes: sodium, potassium, and chloride and three out of three time periods for the anlayte, hemoglobin A1C from 1/1 /2017 - 6/19/2018. The findings include: 1. The laboratory performed calibration

	verification for the analytes: sodium, potassium, and chloride on 6/20/2017. 2. At the time of the survey, the laboratory did not have additional calibration verification records for the analytes: sodium, potassium, and chloride from 1/1/2017 - 6/19/2018. The laboratory did not have any calibration verification records for the analyte, hemoglobin A1C.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual and confirmed by laboratory personnel, identifier #2, (refer to the Laboratory Personnel Report) on 6/19/2018 at approximately 3:30 pm, the laboratory director failed to ensure that the laboratory established and maintained a quality assessment program that included the four quality systems: general laboratory, pre analytical, analytical, and post analytical.
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 personnel records and confirmed by laboratory personnel identifier #2 (refer to Laboratory Personnel Report) at approximately 10:00 am on 06 /19/2018, 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 eight testing personnel (laboratory personnel identifier #8). The findings include: 1. The laboratory completed training records for testing personnel, identifier #8 in March 2017. 2. At the time of survey, the laboratory did not have records documenting the semiannual training for testing personnel, identifier #8.